FACILITATING ORGANIZATIONAL CHANGE: THE USE OF ACTIVITY THEORY AS A FRAMEWORK FOR SOCIAL CONSTRUCTION OF STRATEGIC KNOWLEDGE

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To my father

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Larissa V. Malopinsky

FACILITATING ORGANIZATIONAL CHANGE: THE USE OF ACTIVITY THEORY AS A FRAMEWORK FOR SOCIAL CONSTRUCTION OF STRATEGIC KNOWLEDGE

This action research study draws on the interpretive approach to organizational learning as a socially constructed organizational reality. It is grounded in the philosophy of strategy as a social practice that views strategizing as interactions of multiple organizational actors. As middle managers become increasingly involved in change, their strategic thinking capabilities and leadership competencies become more critical. However, management education remains largely detached from organizational strategy making process. Organizational literature offers limited empirical data on the dynamics of strategizing process, strategic discourse, and effectiveness of strategic tools used for guiding strategizing activities.

In this study, I explore the potential of Activity Theory for facilitating collaborative strategizing activities and advancing managers' strategic knowledge and decision-making capabilities. A strategic tool based on Activity Theory principles – an activity-based tool – was designed and evaluated in the context of a strategic episode at a global pharmaceutical company. In contrast to conventional approaches to evaluating the effectiveness of strategic tools that concentrate primarily on the outcomes of a strategizing action, I examine the application of activity-based tool in the context of social interactions of organizational members who collaboratively construct new business processes thus progressively building their strategizing expertise. Strategic learning in this context manifests itself not only through specific outcomes of a strategizing action, but, most importantly, in the very process of collaborative analysis of organizational issues and negotiation of strategic decisions for addressing those issues. The

study's focus is on several, equally important aspects of strategizing process: analysis and redesign of current business processes, strategic discourse of collaborating organizational members, and strategic learning outcomes. The effectiveness of the activity-based tool is evaluated in relation to these aspects using mixed methods of data collection and analysis.

This dissertation research contributes to advancing our understanding of the application of Activity Theory in organizational strategic development and provides organizational strategists and human resource development professionals with a systematic approach to engaging managers in strategizing practice.

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CHAPTER ONE: INTRODUCTION

"There is nothing more difficult to take in hand, more perilous to conduct, or more uncertain in its success, than to take the lead in the introduction of a new order of things."

Nicolo Machiavelli

The study reported here is an extension of a larger performance consulting project that was carried out in 2003-2005 in the corporation where I worked in the capacity of an external consultant. I worked closely with the organizational training group assisting pharmaceutical manufacturing divisions in their implementation of new operational requirements for the drug production process and the new documentation standards.

This introductory chapter begins with an overview of the main concepts used in this manuscript in order to assist the reader in navigating through the theoretical constructs and the technical vocabulary of the study. Next, I present the research study's goals and propositions, research questions, and the potential theoretical and practical value. Finally, I discuss the organizational context in which this dissertation study took place and clarify my consulting and research roles.

This dissertation presents an array of complex theoretical concepts that are new to social scientists. Discussion of neither organizational context and actions nor the results of the study is possible without referencing technical concepts embedded in the surveys responses, design documents, and managerial discourse that constitute the main data collected for this study. I make every effort to simplify and to explain these complex concepts through providing terminology organizers at the beginning of the chapters and reiterating certain key notions throughout the manuscript. This repetition is unavoidable, and even desirable, as the same

themes and ideas are analyzed and discussed from different perspectives and appear in different parts of this document.

Key Concepts

This section defines the key terms related to Activity Theory and organizational strategy derived from formal definitions established in the research and professional literature (e.g., Engeström, 1987; Jarzabkowski, 2003; Luhmann, 1996; Stenfors and Tanner, 2007; Whittington, 1996) and adapted or conceptualized specifically for this dissertation study.

Activity Theory. A psychological meta-theory, or a framework, that views human activities as complex, socially situated phenomena grounded in historical and cultural contexts. Activity Theory emphasizes the notion of human interaction with environment through various mediating artifacts (e.g., language, physical tools), which may enable or constrain human activities. Activity Theory is primarily used by both theoretical and applied psychology and learning sciences.

Activity system. A unit of analysis in Activity Theory that is defined as the structured interactions of a subject (one or more individuals) with long-term and/or continuously renewed objects (tasks, problem domains) through the mediation of tools (e.g., methods, technologies) and rules (e.g., standards, prescriptions), which are used by the subject to transform an object into an outcome.

Activity triangle. The visual representation of an activity system in the form of a mediational triangular model.

Activity-based strategic tool. An activity triangle that has its components modified to match the language and business context of the organization that participated in this study. Designed for guiding strategizing activities of middle managers who participated in the study.

Organizational strategy. An elaborate and systematic program of organizational development designed to achieve a particular goal or a set of goals. Strategy may apply to many aspects of organizational life: business strategy, manufacturing strategy, marketing strategy. In this study, the definition of strategy is limited to the program of changes developed by the vice-president of one of the manufacturing divisions of a pharmaceutical company. This program focused on the following main objectives:

- incorporating new methods and technologies into the manufacturing process to improve performance (e.g., more systematic use of statistical analysis of manufacturing data),
- changing current documentation practices (e.g., organizing historical records of product development that may help to address current manufacturing issues), and
- ensuring consistent execution of manufacturing operations through the alignment of process performance criteria and providing the same level of quality control at all plants that produce the same drug.

Change agenda. A comprehensive plan containing new directions for an organization necessitated by external and/or internal forces. In this study, a change agenda is a 40-page document that includes

- the organizational mission and vision,
- changes directed at several areas of business management: human resource management, project management, data management, documentation management, and quality control,
- the expected outcomes of the change efforts,
- the estimated timeline for implementing change-related activities, and

- the criteria for evaluating the results of these activities.

Strategizing process. An organization's emergent actions that define its strategy and decisions regarding the allocation of its resources to pursue this strategy. The strategizing process involves

- reflection on current organizational systems and their components as well as interactions between the system components,
- identification of the strengths and weaknesses of the current business systems and their potential impact on organizational performance; and
- formulation and justification of system changes required for improving organizational performance.

The strategizing process may employ various strategic tools and result in specific outcomes, such as strategic plans or redefined mission and vision statements.

Strategic episode. A formally-scheduled, time-limited sequence of strategizing actions (a workshop, a meeting) during which employees "suspend" structures, hierarchies, and communication currently established by the organization to create an opportunity for reflection, the exchange of ideas, and the definition of new ways of doing business. In this study, a strategic episode is a 60-minute workshop exercise during which middle managers were engaged in collaborative strategizing using an activity-based strategic tool.

Strategic tool. Generic name for any model, technique, framework, method, or approach used to facilitate the strategizing process in organizations. Strategic tools may be based on methods or theories emanating from any discipline of school of thought.

Social construction of strategic knowledge. Collaborative development of new concepts and the negotiation of meanings during the strategizing process. A 5-stage framework of

collaborative construction of strategic knowledge was conceptualized and applied in this study in order to analyze the conversations of strategizing managers.

Strategic competency. A combination of knowledge and skills enabling the effective connection of organizational knowledge assets, individual professional expertise and experience, and leadership, problem-solving and decision-making abilities for the purposes of advancing organizational performance and creating a competitive advantage.

Strategic design. In this study, 'strategic design' refers to the output of the strategizing activity, which represents the activity-based tool mapped onto a specific organizational event, such as the technical evaluation of pharmaceutical manufacturing operations or the analysis of a deviation from a standard operating procedure. Once the events are deconstructed and graphically presented as meditational triangular models, they can be approached for systematic analysis as activity systems.

Strategic discourse. A mode of organizing strategic knowledge, ideas, or experiences through the means of written and spoken language. In this study, the term 'strategic discourse' defines the conversations that took place among the managers who were engaged in collaborative strategizing using an activity-based strategic tool.

Conceptual Framework

Problem Statement

The recent trend in strategic management and organizational performance research has been to emphasize the role organizational knowledge plays in creating the competitive advantages of firms (Argote & Ingram, 2000; Saint-Onge & Wallace, 2003; Teece, Pisano, & Shuen, 1997). Leveraging knowledge has been increasingly viewed by organizations as a method for creating value, enhancing organizational performance, and achieving a competitive edge. The

theoretical argument is made that if organizational resources are the basis for a competitive advantage, they cannot be shared by many competitors, and they should be difficult for competing firms to replicate (Johnson, Melin & Whittington, 2003; Hendry & Seidl, 2003).

In today's competitive world, organizations may no longer consider organizational learning as a static property managed as any other physical assets. Strategy scholars argue that organizational learning must be viewed as a dynamic process of formal and informal knowledge exchange focused on solving specific organizational problems, thus creating necessary linkages between business strategy and individual and organizational performance (Johnson & Huff, 1997; Watson, 2001; Whittington, 1996). The empirical research supports this theoretical argument by demonstrating that the competitive position of an organization and its survival largely depends on its knowledge assets (Baum & Ingram, 1998; Crossan & Berdrow, 2003; Darr, Argote, & Epple, 1995; McAdam & Leonard, 1999).

Organizational learning capabilities become especially critical at times of change when firms require employees to acquire strategic knowledge that would empower them to participate actively in organizational renewal initiatives (Jarzabkowski, 2003; Johnson, Melin & Whittington, 2003). Research literature estimates that more than half of all change initiatives fail, and the causes of failure are often attributed to the inability of an organization to align learning processes with its change initiatives (Argote & Ingram, 2000; Carrol & Hatakenaka, 2001; Hammer & Champy, 1995). The researchers argue that high organizational performance and participation of all organizational members in large-scale change can be achieved only when leadership recognizes the importance of employee involvement in the strategic decision-making process.

Although strategic and change management capabilities are being increasingly recognized by organizations as critical competencies for middle-level management (Leonard & Goff, 2003; Sidorova & Sarker, 2000), managerial learning practices remain largely detached from organizational strategy, which is still viewed as a transfer of information from executives to line management (Johnson, Melin & Whittington, 2003; Kalman, 2001; Mintzberg, Ahlstrand, & Lampel, 1998). Top-down methods of communicating strategic directions significantly limit the development of an organizational vision shared by all employees (Conger & Toegel, 2002). Researchers warn top managers that using an authoritarian approach to implementing new business processes may lead to the fragmentation of the change efforts and result in a lack of employees' commitment to the strategic decisions (Leonard & Goff, 2003).

Scholars advocating the concept of strategy as social practice (Christensen & Overdorf, 2000; Dudik, 2000; Jarzabkowski, 2004; Johnson, 2004; Hendry, 2000; Luhmann, 1986, 1996; Pettigrew, 2001; Whittington, 2003) argue that organizations must not only view their employees as contributors to the strategizing process, but must also provide the conditions and necessary context for systematic exchange of strategic ideas among ordinary organizational members. However, the researchers admit that little is known about how such a strategizing process can be organized, how its outcomes can be returned into an organizational system for implementation, and what approaches and tools can make the strategizing process more effective (Hendry & Seidl, 2003; Jarzabkowski, 2005; Mezias, Grinyer, & Guth, 2001).

Strategic tools, such as Balanced Scorecard, Force-Field Analysis, or SWOT (Strengths-Weaknesses-Opportunities-Threats) Analysis, have generated much interest in organizations in the past decades as potential ways of supporting the strategizing process. However, while dozens of such tools are available, mainstream organizational and human performance technology

literature does not provide sufficient evidence of how they benefit organizations and their members. The role of strategic tools in organizational change processes remains to be explored (Stenfors & Tanner, 2007). Although criteria and procedures for evaluating effectiveness of strategic tools have been widely debated by researchers and practitioners (e.g., Borenstein, 1998; Olphert and Wilson, 2004; Rosenhead and Mingers, 2001), the evaluation remains limited to the assessment of the outcomes of use of a tool (Stenfors and Tanner, 2007). Little is known about the actual process of using a tool or how the process is linked to change in organizational and individual performance. This situation may be explained by the complexity and uniqueness of the contexts in which strategic tools are used, as well as by various organizational issues, such as confidentiality constraints. Therefore, user testimonials are often presented as an alternative to empirical studies for demonstrating positive outcomes following the use of a tool. Although they provide some insights on the role of tools in the strategizing process, subjective perceptions alone do not constitute sufficient evidence of the actual value of strategic tools as related to organizational performance improvement (Davis and Kottemann, 1994). Even those rare quantitative studies which have been able to demonstrate linkages between the use of strategic tools and increased productivity or economic gains (e.g., Clemen and Kwitt, 2001; Dorgan, Dowdy and Rippin, 2006) do not describe with any exactness the way in which the tools are used to create value or when they are less beneficial to organizations.

Despite my efforts, I was not able to find studies that examined the impact of strategic tools on managerial learning. As asserted earlier, the involvement of organizational practitioners in strategizing is vital for successful implementation of organizational change efforts, and strategic tools have a potential for making participation of managers more effective as they provide necessary structure for collaboration, the exchange of ideas, and the construction of new

meanings. Therefore, there is a great need for exploring the mechanisms of applying strategic tools for assisting managers in the development of change propositions and for examining the impact of those tools' use on managerial learning.

This dissertation study attempts to address this need by studying a strategic tool designed on the principles of Activity Theory. Activity Theory has never been used as a framework guiding the strategizing process; therefore, this study simultaneously tests the applicability of the tool's design in the context of a strategizing activity performed by middle managers and evaluates the managerial learning that resulted from this experience.

Study Focus and Rationale

As mentioned earlier, this dissertation study originated with a consulting project I performed for one of the manufacturing divisions of a large pharmaceutical company, and it focuses on only one aspect of the project: a strategizing episode of middle managers who used the Activity Theory based strategic tool – called the *activity-based strategic tool* throughout this manuscript - to support their interactions. After conducting an analysis of the issues surrounding slow implementation of the change program developed by organizational leaders, I recommended bringing middle managers into the strategizing process. The results of the analysis are discussed in the Description of the Consulting Project section of this dissertation. The activity-based tool was developed and pilot-tested before being used at the workshop for middle managers, which was intended to assist them with

- identifying and analyzing problems that slowed down implementation of the change program, and
- developing approaches for more effective execution of tasks.

The rationale for using the tool for guiding the strategizing process was that the process would provide conceptual and visual support that managers needed for the systematic, structured analysis of the current problems and for the exchange of expertise and ideas with their peers from different functional units and management levels.

The selection of Activity Theory as a framework for facilitating the strategizing process was not arbitrary. Despite the lack of formal inquiry into the use of Activity Theory in change management and strategic planning, it has been effectively utilized in the past several years as a framework for conducting analyses of organizational structures and processes (Mwanza, 2001; Jarzabkowski, 2003a; Justice, 2005); it has also been applied in academic learning environments to analyze the dynamics of social interactions of individuals participating in collaborative learning activities (Ardichvili, 2003; Barab, Barnett, Yamagata-Lynch, Squire, & Keating, 2002; Barab, Evans, & Baek, 2003; Brown & Cole, 2002; Diamondstone, 2002; Engeström, 1999a, 2001; Hansson, 2002; Johnson, 2003; Lim & Hang, 2003; Squire, 2004).

In contrast to conventional approaches to evaluating the effectiveness of strategic tools that focus primarily on the outcomes of a tool's use, this study looks at the tool from two equally important perspectives. First, it examines the social interactions of managers who use the activity-based tool to analyze current business systems, define problems, and design solutions - the process conceptualized in this study as *strategizing*. Social learning is embedded in the strategizing process as managers progressively build their strategic expertise through exchange of experiences and negotiation of ideas expressed through discourse and strategic design artifacts. Second, it looks at the learning outcomes of the strategizing process demonstrated through survey-based test responses, manager testimonials, and the integration of strategic ideas

into real business plans. In order for an activity-based strategic tool to be considered an effective technique for supporting managerial strategizing, one must determine:

- whether the activity-based tool allowed managers to interact such that they could contribute their knowledge and expertise to organizational strategic development, and,
- whether the use of the tool helped managers advance their own strategic knowledge and skills.

Research Questions

The following main research questions are addressed in this study:

- How was the activity-based strategic tool used in the strategizing process of middle managers?
- What was the impact of the strategizing experience on managerial learning?

The questions below address the specific aspects of the main research questions by focusing on the context of the strategizing process, managerial interactions, and learning outcomes of participating managers:

- How did the use of the activity-based strategic tool contribute to the identification, analysis, and resolution of organizational issues?
- What was the evidence of the social construction of strategic knowledge during the strategic episode that utilized the activity-based strategic tool?
- How did the use of the activity-based strategic tool contribute to the advancement of managerial strategic competencies?
- What was the evidence of transfer of learning from the strategic episode to the workplace context?

The study uses the concept of 'strategic episode' (Luhmann, 1995) to refer to the 60-minute strategizing activity, which was a part of the formally scheduled 4-hour workshop designed for middle managers.

Through the above research questions, the study examines both the process and the outcomes of the strategizing episode in which the activity-based strategic tool was used

- to reflect on the current organizational systems and their components as well as interactions between the system components,
- to identify the strengths and weaknesses of the current business systems and their potential impact on organizational performance, and
- to formulate and to rationalize system changes required for improving organizational performance.

Each research question focuses on a specific aspect of a strategic episode. Thus, the question of the role of the activity-based strategic tool in the identification, analysis, and resolution of organizational issues is addressed through the analysis of the design documents produced by managers during their collaborative analysis and redesign of current business systems. The question concerning the evidence of the social construction of strategic knowledge is addressed through an examination of the managers' discussions of system analysis and redesign. Finally, the question of the potential impact of the activity-based strategic tool on the advancement of managerial strategic competencies is addressed through

- the analysis and comparison of the test results obtained before and after the strategizing episode,
- the analysis of the managerial reflection on the collaborative strategizing experience, and

- the analysis of change plans submitted after the strategizing episode.

Significance of the Study

From a theoretical standpoint, this study seeks to advance our understanding of the application of Activity Theory in organizational strategizing practice and to develop a theoretically justified design approach for guiding collaborative learning processes in organizations enacting systemic transformations. It examines the socially defined modes of acting within the context of a strategic episode, as well as the implications of the social construction of strategic knowledge for managerial learning (Turner, 1994; Whittington, 2001). On the practical level, this study attempts to provide organizational strategists and performance specialists with a new tool for systematic guidance of strategizing activities in the context of training events.

Although this study does not claim generalization across various organizational contexts, the results may provide insights into approaches for facilitating learning events for middle managers in organizations undergoing a change process.

CHAPTER TWO: ORGANIZATIONAL CONTEXT

In this chapter, I will characterize the organization whose members participated in the dissertation study, describe the consulting project's scope, methodology, and results, and discuss my consulting role. I will then explain the relationship between the consulting project and the dissertation research.

As in the previous chapter, I would like to begin with a brief overview of the specific terms used by the organization being studied in order to assist the reader in navigating through the discussion of organizational structures and activities related to this study.

Key Organizational Terms

Manufacturing site/facility. A manufacturing plant consisting of one or more buildings where analogous pharmaceutical products are made (e.g., several biochemical drugs in a liquid form).

Manufacturing network. A cluster of manufacturing sites located in different geographical areas that produce analogous pharmaceutical products.

Functional unit. A manufacturing division responsible for specific aspects of the drug manufacturing process. Several functional units are mentioned in this manuscript:

- Engineering – responsible for the facilities and equipment used in manufacturing pharmaceuticals,
- Operations – responsible for the execution of manufacturing steps,
- MTS – responsible for the technical and scientific control of the operations carried out at the plant,
- Quality – responsible for the quality control of the final product,
- IT – responsible for the computer support of manufacturing operations, and
- Statistics – responsible for the statistical analysis of operational data and for the data trends monitoring.

Business system. In the context of this study, a complex network of components and their relationships based on one of the four critical manufacturing events explained below: Acceptance from Development, Deviation Management, Process Validation, and Technology Transfer.

Acceptance from Development. Also called an *initial process transfer*, a critical event in the product lifecycle focused on the adaptation of the drug-making process from the method of production in the laboratory to a method suitable for large-scale plant-based manufacturing.

Development is the company's division that concentrates its efforts on product development all the way from the new drug concept to its transfer to the manufacturing environment. The development division establishes the drug production process on a small-scale in the laboratory environment and assists manufacturing colleagues in adapting this process to a large-scale operations using commercial equipment.

Deviation management. A series of activities focused on the investigation of errors and deviations from and violations of standard operating procedures in the drug manufacturing process. For example, if during the manufacturing of a product, the monitoring computers indicate a temperature increase that exceeds that allowed by industry and internal standards, the process must be stopped and the cause for this increase investigated to ensure that the quality of the product is not compromised.

Process validation. A pilot testing of a new drug manufacturing process that is always conducted before the product is considered for commercial production. The manufacturing process is considered validated (approved) if the outputs of the testing are acceptable according to the standards established by the company and the regulating agency.

Technology transfer. A series of activities focused on transferring the drug manufacturing process established at one plant to, or replicating it at, another location. For example, when the US-based manufacturing facilities of the organization reached their maximum capacity to make a specific drug, the decision was made to build another plant to serve the needs of the overseas market. The drug manufacturing process needed to be 'copied' to ensure that the new plant followed the same standards and used the same technical documents.

World-Class Commercialization (WCC). A framework developed by organizational strategists representing seven stages in the pharmaceutical product lifecycle, from its

development and testing in the laboratory environment to its large-scale manufacturing and the transference of the manufacturing process to new plants. Every stage in the lifecycle is controlled by technical evaluations called 'manufacturability reviews' that assess the organization's readiness to proceed to the next WCC stage. For example, before the manufacturing plant begins to produce the drug on a large scale, a manufacturability review is conducted to ensure that all the necessary components are in place (e.g., equipment is tested and ready, process documentation is available and approved) and all requirements are addressed (e.g., operational personnel received safety training).

Process Control & Capability Cycle (PCCC). A conceptual model that defines essential business activities and their sequence and documentation deliverables within each WCC stage. The PCCC model is used by the employees as a reference source for performance expectations. For example, process validation activities (pilot production of the first batch of the drug to assess the process accuracy from scientific and technical standpoints) may be carried out only after manufacturing equipment is 'qualified', that is, tested and approved for commercial drug production. A validation plan must be prepared before carrying out process validation activities.

Technical documentation. A generic name used for describing various types of documents that provide management requirements for the drug manufacturing process. The most frequently used titles in this manuscript include:

- *Development History Report* – a summary of product development on a small, laboratory-based scale. Includes test studies, lessons learned, recommendations for large-scale manufacturing.
- *Process Flow Document* – a main document guiding daily manufacturing operations. Ensures consistency among operations conducted at different plants

that produce the same drug. Includes criteria for correct manufacturing (e.g., temperature, humidity and time limits), requirements for equipment and for the quality of the process outputs at every manufacturing step.

- *Validation Plan* – a plan to assess the readiness of the plant to produce a specific medicinal product on a large scale (as opposed to in the laboratory).
- *Technology Transfer Plan* – a plan for managing activities focused on the drug manufacturing process established at one plant being transferred to or replicated at another plant.
- *Deviation Investigation Report* – a document summarizing the results of an investigation of the process errors or deviations that resulted in producing the unacceptable quality drug.

Technical evaluation. A generic name used for various types of product and process quality evaluations. For example, the Annual Product Review (APR) is conducted by the company immediately after the technology transfer and every year thereafter to ensure that all documents guiding manufacturing operations are in place, all manufacturing steps are performed in accordance with the standard operating procedures, and all the equipment is qualified to be used for producing safe pharmaceutical products. Quarterly Process and Product Assessments (QPPAs) are the 'progress checks' that are conducted four times a year, and their results serve as input for APR.

Client Organization

The client organization, the Manufacturing Technology and Science (MTS)[1], is a manufacturing division of a global Fortune 500 U.S.-headquartered pharmaceutical corporation,

[1] MTS is a fictitious name. All names and titles used in this document are pseudonyms created to maintain confidentiality in accordance with Confidentiality and Non-Use Agreement between the author and the company.

Medex[1]. Medex is among the top 10 firms in its industry sector, and markets its products to over 140 countries. The corporation's main activities include research, development, and manufacturing of products regulated by the U.S. Food and Drug Administration (FDA), the Drug Enforcement Administration (DEA), the Occupational Safety and Health Administration (OSHA), and other domestic, international, and foreign[2] regulating agencies. The research is conducted in more than 60 countries. Currently, Medex employs about 44,000 people worldwide; approximately 30% of its employees are engaged in the company's global operations at its corporate headquarters, 20% in other U.S. sites, and about 50% in other countries. Approximately 25% of Medex employees work in the manufacturing sector. The manufacturing sector is divided into four networks based on the characteristics of the pharmaceutical products, and the MTS organization has representatives in every network. The fourteen manufacturing sites affiliated with specific networks are located both in the US and overseas (Europe, South America, and the Pacific region).

The role of the MTS organization in the larger manufacturing context is developing a program for supporting Medex Manufacturing from scientific and technical perspectives. MTS is responsible for

- the new manufacturing processes that are transferred from the laboratory environment to a large-scale manufacturing facilities (Acceptance from Development),
- managing the transfer of a manufacturing process from one plant to another, and
- monitoring processes already established at the sites.

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[1] Medex is a fictitious name. All names and titles used in this document are pseudonyms created to maintain confidentiality in accordance with Confidentiality and Non-Use Agreement between the author and the company.
[2] For the company's operations conducted beyond the U.S. borders.

Some employees jokingly call MTS the 'technical police' as it ensures that all manufacturing processes at all the plants are run in accordance with the company's and industry's standards and are properly documented. When a problem occurs during a drug's production, it is MTS that leads an investigation and ensures that all scientific and technical requirements are met during the problem analysis and resolution.

MTS is comprised of approximately 800 employees, including scientific advisors, research scientists, technical supervisors, and process technology managers working closely with the Development division and other functional units of Manufacturing, including: Operations, Engineering, and Quality Control.

The MTS employees are organized in site-based and global groups. The site-based groups focus primarily on day-to-day production support and "fire fighting" of manufacturing problems, while the global MTS group assumes leadership and support functions for all site-based MTS groups.

The main reason for creating MTS in 2002 was the need for systematic technical and scientific control over the manufacturing processes carried out at the sites. From late 2001 through early 2002, in response to increased industry requirements and competitive market demands, Medex Manufacturing embarked on a large-scale change that would ultimately affect the most fundamental aspects of its manufacturing processes, such as quality control or technical documentation management. The change was largely necessitated by increasing FDA scrutiny of the Medex manufacturing operations. In 2001-2002, a number of citations were issued to the company by FDA inspectors regarding unacceptable project management and documentation practices. The MTS organization was charged with the task of building a strong scientific and

technical support infrastructure for manufacturing operations to be able to address the FDA concerns and eliminate process deficiencies.

Change Program

In early 2003, MTS proposed a 2-year organizational development program – a change agenda – that introduced new requirements for manufacturing process management, documentation practices and product quality control. The emphasis was made on fostering managerial practices that are science-driven, well-documented and proactive in dealing with technical and scientific errors. A change agenda program was summarized into a 40-page document organized into four sections based on the following critical business areas:

- *People:* capability, capacity, and development; training and performance improvement; organizational structure
- *Processes*: project management; capacity planning and time entry; technical governance; validation; statistics
- *Products*: technical evaluation documentation; documentation management
- *Technology*: technology advancement and development; process analytical technology; data management

For each of the four critical business areas, the agenda presents key messages and descriptions of needs and issues to be resolved, and it provides an implementation plan defining the end state, supporting activities, expected outcomes, organizational impact, metrics, and estimated timelines. The example in Table 1 below contains a portion of the change agenda document related to changes in the use of statistics in manufacturing processes that were expected to be implemented during a 3-year period.

Table 1

Fragment of the MTS Change Agenda (Process Management: Statistics)

The end in mind	We will have an aligned strategy that implements dedicated, on-site statistical support for every manufacturing process, with statisticians playing pivotal roles in the support of all process monitoring, process improvement and optimization initiatives. The statisticians will drive deeper process understanding through the use of experimental design, and variability reduction through the use of statistical tools. All manufacturing personnel will have basic statistical skills that become part of the language, mindset, and expectation in all manufacturing, enabling consistently improving interpretation of data and science-based decision making.
Scope and timeline	<u>Complete in 2003</u>: - Global vision for statistics established and shared with MTS leadership - MTS Statistics group formed - All US-based manufacturing sites have dedicated, on-site statistical support - Launched initiative to grow manufacturing statistical support in Europe, including annual visits <u>Complete in 2004-2005</u>: - Establish global statistical training strategy in manufacturing - Develop (or streamline existing) courses and implement new curricula - Identify statistical leaders for each network to assure: (1) best practices, technical excellence, shared learning within the network; (2) technical and career development of statisticians within the network; (3) engagement with network leadership toward influencing issues and supporting key technical projects within the network
Deliverables	- Support key projects [list of projects provided] - Support initiatives to build statistical capability, e.g., in-process monitoring in Plant 101 - Hire contractors to provide basic statistical support to sites and third parties - Visit European sites to engage leadership and share the vision - Deliver on statistical training commitments at the sites - Complete global statistical training strategy for MTS - Support product reviews as they are instituted at the networks and sites - Continue to educate and influence management and technical leadership to create appropriate expectations around use of statistics - Increase the utilization of statistical experimental design

	- Continue to establish linkages between statisticians and leading scientists; increase collaboration and interactions between statisticians at all levels - Plan MTS Statistics forum
Areas of impact	- MTS Commercialization Technology Center - MTS Technical Services - Engineering - Chemistry Manufacturing & Control Project Management - Quality Control/Quality Control Laboratories - Site Leadership
Expected outcomes	There will be direct impact at every level as MTS Statistics continues to work to embed statistical concepts within MTS with partners and leadership to create a statistically oriented culture. Staff will need to understand the statistician's role (more than a data analyst) and how statistical thinking can be applied broadly at all levels of the business
Benefits	- Implementation of statistical concepts improves study design, data collection, and experimental effort, leading to faster, more efficient process improvements, deeper process understanding, and reducing experimental rework - Better interpretation and decision-making with data at all levels—from operator to senior management - The understanding and application of statistical tools leads to a reduction in process, laboratory, and business variation - The application of advanced statistical tools and capabilities provides greater process insights and improves productivity
Key messages	- Implementing statistical concepts drives data and science into decision-making and is essential to science and technology in manufacturing - Basic statistical tools (control charting, capability indices, exploratory data analysis and experimental design) are essential elements of achieving excellence in manufacturing - Statistics is not a tool to justify data generated from incapable, out-of-control processes - The training of manufacturing personnel in statistical tools is essential to creating appropriate expectations around the use of statistical tools in manufacturing
Requirements	MTS functional leadership will be required to: - Engage statisticians and utilize statistical support provided - Create and regularly communicate appropriate expectations regarding: - Presentation & Review of Data

	- Interpretation of Data - Efficient, systematic use of experimental resources - Shared learning with respect to the above - Reward appropriate use of statistical tools and statistical thinking behaviors
Issues to be resolved	- Collaborative effort to improve organization, consistency, roles, and responsibilities between manufacturing units and statistics - Resources to aid statisticians in data extraction and simple analysis (data analyst role) in order that their time can be focused on process improvements in manufacturing

The change agenda is an evolving document that is updated annually; it focuses on organizational needs and issues to be resolved during the current year.

Once the change agenda was formulated, the MTS leadership began communicating its content through staff meetings, video broadcasts, and Intranet publications.

I would like to pause here briefly to discuss two conceptual frameworks that served as the guides for all activities defined by the change agenda: World-Class Commercialization (WCC) and Process Control & Capability Cycle (PCCC). Presentation of these frameworks is critical as they are actively used by strategizing managers as the reference points in the context of this study. Both frameworks were developed at the same time as the change agenda to communicate the MTS vision regarding the production of high-quality medicines all the way from the drug's development to the delivery to the patient. The figures below provide the simplified versions of the original graphical representations of these frameworks. It should be noted here that both frameworks were presented as 'ideal' models to do business, something that the MTS employees should use as guiding tools while working on specific projects defined by the change agenda. The following excerpt from the change agenda describes the WCC framework:

> Our vision is implemented in the World-Class Commercialization, a staged framework that provides a common language and reliable processes and deliverables for the lifecycle

of a molecule; from development through technical transfer and post-launch stewardship. Both Development and Manufacturing therefore must play active roles in order to achieve WCC – the desired sate.

The WCC conceptual framework (Figure 1) is focused on the process aspect of the MTS vision and represents (a) the stages in the product lifecycle, from drug development to the transfer of manufacturing processes to new sites and (b) the division of responsibilities for specific stages between the Development and Manufacturing organizations. As we see from the illustration, representatives of both organizations work together in the Technology Transfer Team to prepare the product to be moved from the laboratory environment to the plant. Every stage in the lifecycle is controlled by manufacturability reviews, the comprehensive technical evaluations of the organization's readiness to proceed to the next WCC step.

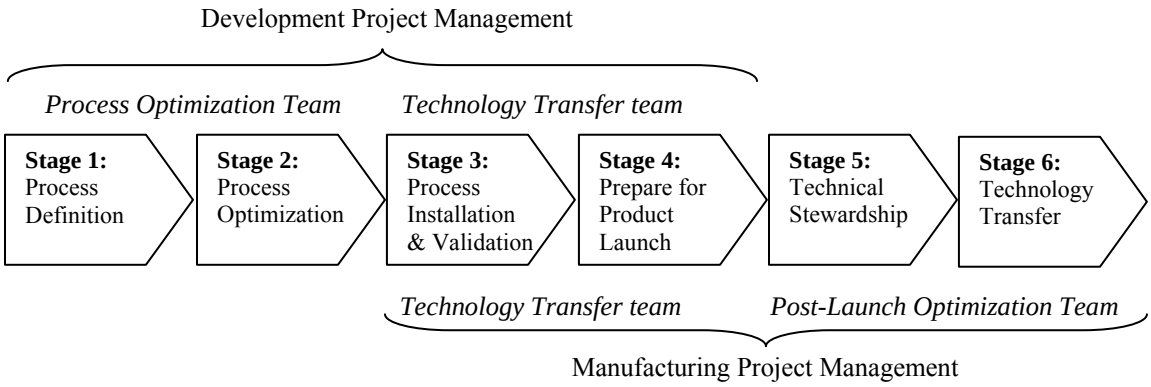


Figure 1. WCC framework

The Process Control and Capability Cycle (Figure 2) defines essential deliverables that are expected to be produced during each product's lifecycle.

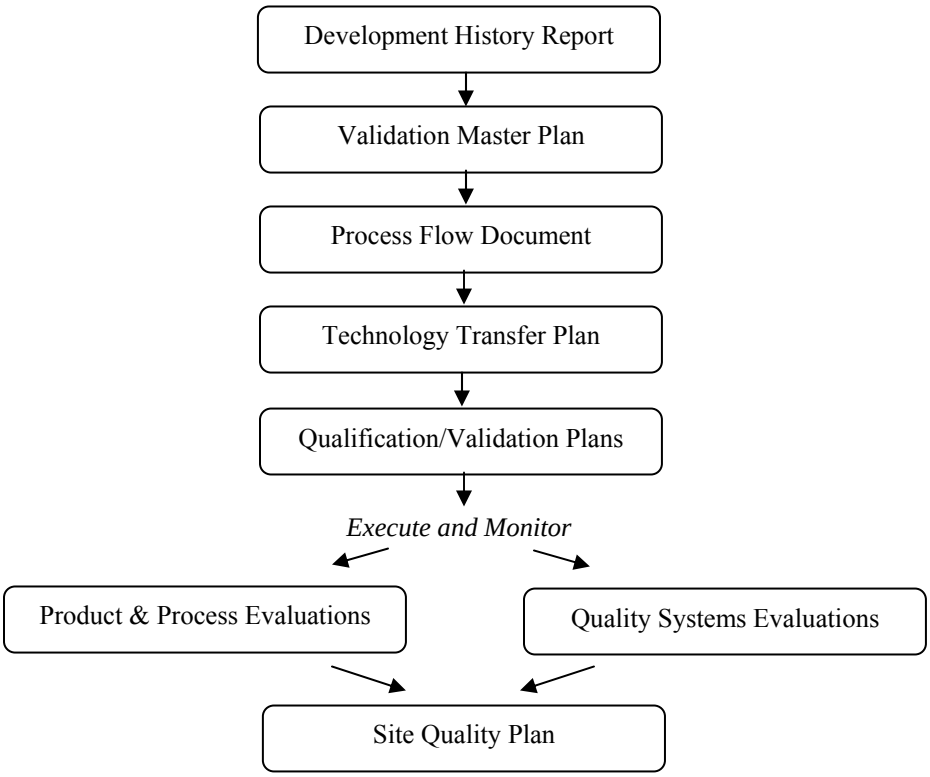


Figure 2. PCCC framework

The change agenda describes the PCCC framework as following:

> *"The process control and capability cycle (PCCC) represents a set of shared deliverables, standards, and expectations within development and manufacturing. The PCCC graphically depicts the flow of deliverables associated with the activities essential to the success of WCC, across the entire lifecycle of a molecule. Collectively, the elements of the PCCC comprise a system in which we establish references, share expectations, define and use common business practices, and evaluate results against internal and external standards."* (MTS Change Agenda, version 0.4, May, 2004)

During the period of two years preceding this dissertation study, MTS leadership sponsored several site-based and network-based initiatives focused on implementing new requirements for manufacturing processes. However, the 2004 version of the change agenda contained a record of multiple issues across all four categories that had to be resolved

immediately in order to avoid further negative repercussions. For example, many plants still did not have a Process Flow Document (PFD), essential guidance that provides the criteria for valid manufacturing operations and the justification for those criteria. The PFD is the baseline comparator for deviation investigations, internal process assessments and external audits, such as FDA inspections. The program for integrating statistics discussed earlier in this section was also not fully implemented at every site. Many products, especially old ones, did not have Development History Reports, extensive summaries of the drug development and testing over years and lessons learned that manufacturing employees are expected to review and reference every time a problem is being analyzed or any process optimization is considered. The networks still did not have shared databases of raw data and technical documents that they were expected to analyze to identify negative trends (e.g., a consistent temperature rise that nears the limit allowed by the standard) that need to be investigated in a timely manner.

The MTS executives came to a decision to call for a global conference where the line managers could communicate their needs and problems and develop a more effective approach to the change agenda implementation. Among the key components proposed for the conference was a workshop for managers that would 'set the tone' for the conference by delivering key change agenda messages and expectations. Analysis of managerial learning and communication needs related to the change agenda implementation was recommended to be conducted prior to the conference to inform the design of the workshop.

As I had been working with the MTS since its establishment in 2002 and had developed considerable knowledge of its structure and business practices, I was invited as an external consultant to lead the analysis of the line managers' needs, design a workshop, and evaluate its effectiveness. Therefore, this dissertation research is grounded in the larger context of the

consulting project, and my role was one of an action researcher who was actively involved in shaping and examining the research contexts while working closely with the practitioners to address specific organizational goals (Ellis & Kiely, 2000; Friedman, 2001). The data and the findings of the consulting project were used for informing my research agenda.

Project Chronology

The three phases of the research project essentially coincided with the phases of the consulting project and, therefore, are presented here concurrently, as parts of one project.

The project began with an analysis of the learning needs of the managers who were struggling with the change agenda implementation. The results of the analysis reported to the MTS executives revealed the necessity for departure from a traditional information transmission approach to strategic education based on formal instructor-focused presentations and lectures. A collaborative workshop with the use of a new strategic tool developed using the Activity Theory framework was designed and a pilot tested successfully with several MTS representatives. The results of the pilot demonstrated strong potential for the activity-based strategic tool to be used not only in the context of the planned workshop, but to be examined in its capacity to facilitate collaborative strategic knowledge construction and to advance managerial strategic learning. A research agenda was formulated that focused on collecting and analyzing the data (e.g., managerial discourse, design sketches, observation records, change implementation plans) additional to that gathered for analysis under the scope of the consulting project (e.g., pre- and post-workshop surveys). Once the workshop was delivered, I conducted an evaluation of employee satisfaction with the strategizing experience and submitted the evaluation to the client along with recommendations for future learning and communication initiatives based on the

input from the workshop participants. My consulting mission was officially over, and I concentrated on analysis and interpretation of the research study findings.

Table 2 provides the timeline of the consulting project activities and specifies the data collected during each phase. The data collected only for research purposes, as well as research-only related activities, are marked by (*).

Table 2

Consulting project timeline and activities

Phase	Timeline	Activities	Data Collected & Analyzed
Phase 1: Analysis	November 2003 – December 2003	- Collecting & organizing strategic documentation - Conducting document analysis - Designing surveys and interview/ focus group questionnaires	- Change agenda-related documents - Interview/focus group outputs - Survey outputs
	Stage 2: January 2004 – February 2004	- Collecting and analyzing data through surveys, interviews and focus groups	
	Stage 3: March 2004	- Preparing client report and recommendations for a workshop	
Phase 2: Intervention	Stage 1: April 2004 – May 2004	- Designing workshop process and guidance documentation - Piloting workshop activities - Requesting permission to conduct dissertation research* - Developing research agenda*	- Pilot outputs (design sketch, answer sheets)* - Workshop output documents (design sketches, answer sheets)* - Observation notes* - Audio records of managerial conversations*
	Stage 2: June 2004	- Delivering workshop - Collecting observation notes and workshop output documents	
Phase 3: Evaluation	Stage 1: July 2004	- Designing follow-up survey	- Survey results - Interview/focus group records* - Change implementation plans*
	Stage 2: August 2004 –	- Collecting and analyzing follow-up survey data	

September 2004	- Preparing client report and recommendations for further communication and training initiatives - Designing follow-up interview and focus group questionnaires* - Collecting change implementation plans*
Stage 3: October 2004 - December 2004	- Conducting follow-up interviews and focus groups* - Analyzing interviews and focus groups records* - Conducting document analysis of change implementation plans*

In the paragraphs below, I describe each phase of the project, elaborating particularly on the first phase. Although the first analytical phase preceded the official beginning of the research project, its results defined the design and methodological choices of the consequent research steps.

Phase 1: Analysis

The MTS request for analysis was grounded in the need for information regarding the challenges that its managers experienced when trying to implement the change agenda requirements. The leadership wanted to know which topics and requirements of the change agenda were unclear to the middle managers and how training and communication specialists could help. Phase 1 took about four months, from November 2003 to March 2004. I typically worked 2-3 days a week at the MTS location for 4-6 hours a day, either analyzing the MTS strategic documentation (Appendix A) to develop an in-depth understanding of the topics included in the change agenda, or conducting semi-structured interviews and focus groups with MTS executives and members of the strategic planning group (Appendix C).

The interview results revealed several issues that needed to be immediately addressed:

- *Limited understanding of the change agenda requirements resulting in their inconsistent implementation.* MTS leaders were concerned that some of the change agenda requirements, such as Process Flow Documents (PFDs), were either not implemented at all at certain plants, or their implementation was not aligned among the plants, resulting in a lack of a consistent approach to managing the manufacturing process. The interviewees offered their view on the issue:

  "I feel as though the training on PFDs was given at the sites, it was not detailed enough to be useful. The main objective seemed to be to tell people why they need a PFD rather than what the expectations were and give actual examples to spark discussions. The minimum expectations document was helpful, but it is difficult to instill a new practice without follow up and helping each site on an individual basis." (Manager, MTS Strategic Planning Group)

- *Change leadership and expertise*. The strategic planning group emphasized the need for advancing critical change management competencies, such as ill-structured problem-solving, scientific and technical governance, and strategic planning, as they believed part of the problem with the change agenda implementation could be attributed to the managers' struggle to prioritize critical tasks and think strategically when approaching business challenges:

  "Our behaviors at the sites reflect a mind set of "the inspection went ok so we're ok" and "yes, this is the policy or procedure, but this is a critical business need" and "what is the minimum we have to do to not be shut down"- - behaviors that generated the inspections of 2001-2003. These behaviors do not match the rhetoric of our change agenda posters and presentations to the agency and staff. I wonder, what's the appropriate forum or context to explore root causes for this discrepancy?" (Senior Research Advisor, MTS Strategic Planning Group)

- *Definition of roles and responsibilities*. The interviewees emphasized unclear definition of roles and responsibilities at the plants assigned to MTS employees and their colleagues from partner organizations: Quality, Engineering and Operations. The manufacturing processes that required MTS involvement are very

complex and used the expertise of several functional units partnering with MTS. The assessment of the situations at the site shared at the interviews indicated lack of ownership of the processes and contributing roles that needed to be assigned to the functional units. This resulted in uncertainty regarding the level of involvement in process management, delays with producing technical documents and their multiple review loops. Similar concern was about the unclear definition of the role of the global MTS group and MTS teams working at the plants:

"We clearly lack communication network or forums that would bridge the sites and corporate areas and the functions within the sites in a fashion where good discussion happens on the change topics. Communication affects the way we complete the tasks. Change requires communication, time for reflection and then time for more discussion... I think, more discussion should be at the site level about who is responsible for what, what kind of help they need, who can provide that help – we are talking about common goals here." (Manager, MTS Strategic Planning Group)

"We need drafting and alignment of processes shared across sites. Parameters are different across sites and are often not aligned with regulatory commitments. Let's take validation. Definition of validation criteria and management of validation is an integrated process. We need to focus on getting the process integrated, not just the document. The focus is in the wrong place. We need to help improve Quality's technical abilities so that they can support the change agenda instead of being a barrier." (Senior Research Advisor, MTS Strategic Planning Group)

The interview results were supported by the outputs of the survey administered to the MTS middle managers (Appendix B) to obtain their perspective on the challenges and training and communication needs related to implementing the MTS change agenda. The survey participants were eighty-six middle managers representing the MTS organization and partnering divisions in four manufacturing networks who were invited to attend the MTS global conference in June 2004, which focused on change implementation topics and to participate in the workshop that opened that conference. Appendix D provides a summary of the participants' demographic

information. Managers received the request to respond to the 153-item survey through the MTS listserv and direct e-mail notifications explaining the goals of the survey and importance of the study for MTS development. The text of the soliciting e-mail is provided in Appendix E. The survey response rate was 100%. The scope, length and content of the survey, as was indicated earlier, was largely determined by the MTS Communications group who requested specific information to help them plan training and informational events more effectively. Although the survey is provided in its entirety in Appendix B, a large segment of it remains beyond the scope of the research project as it addresses specific organizational needs. Examination of the responses to the questions related to the challenges surrounding implementation of change revealed the following:

- *Role distribution*. Managers echoed observations of the strategic planning group regarding misalignment of responsibilities between different functional units:

  "How do we ensure that we align Quality control and Quality assurance around some elements and business processes introduced by MTS? How do we establish the ownership between Engineering, MTS and Quality for given topics? I believe, this is one of our major challenges today." (Manager, Quality)

- *Establishing priorities for change implementation*. The majority of managers responding to the survey indicated that they experienced difficulty prioritizing and adapting strategic information for daily use due to the large volume of the required changes and shortage of local resources:

  "Following the change agenda requirements is a very difficult process because we are asked for so much in a single document/process – we need to benchmark our competitors to determine what we need to do rather than what we can." (Consultant, MTS)

  "Overall volume of change concerns me – too much is going on, prioritization could help as well as integration with Quality and operational change. I am worried that we do not have sufficient resources in our area to embrace all of the

initiatives and integrate them into our working environment." (Manager, Engineering)

- *Conflict between the requirements of the change agenda and constraints of the current work environment*. One of the major obstacles named by the survey respondents was a mismatch between new requirements and the workplace realities:

  "Balancing MTS change agenda with local site constraints is difficult. For example, MTS desires a given standard for how we understand and manage our processes. This standard is sometimes incompatible with site capital constraints." (Manager, MTS)

  "I don't have answers, only the questions at this point. How to best balance the competing priorities between Central MTS and sites in a plant-centric environment? How to simplify our work processes to achieve amazing increases in productivity? How do we maintain the discipline to finish the remediation work that we are only half way through before moving on to the next phase of the change agenda? How do we comply with the new requirements if we have 25-year old equipment that cannot be qualified?" (Team Leader, MTS)

- *Involvement of line managers in the strategizing process.* Yet another critical issue identified during the analysis phase was sporadic, if any, involvement of line management in strategic planning and decision-making. Lack of opportunity for representatives of various management tiers to contribute to change agenda planning and share ownership over strategic decisions with top leadership may have contributed to managerial resistance and the growing number of conflicting priorities:

  "The individuals that are at the point of implementing the change agenda need more access and involvement in change. This could be done on a network level, using the network leaders and specific change agenda leaders from corporate area along with senior management facilitating and engaging site staff into the change agenda (not after it's already decided). I think that the change agenda needs to be more a collaboration and integrated activity than just a presentation of models." (Manager, MTS)

"I believe the message of the MTS change agenda often gets lost when compared to the site objectives. More time needs to be spent by Corporate resources in understanding and supporting the issues and resources at the site vs. governance of the site from afar. In other words: "Get your hands dirty in the change activities vs. managing us in doing them!" I don't need more presentations on PCC's, PFD's or iVMP's, I need help at the site level in making them happen! Corporate people need to know what's happening at the sites and let us manage the process, too." (Manager, DPN)

- *Organizational learning practices.* The survey analysis revealed that most of the learning activities related to the strategic change agenda were conducted utilizing an information-transmission approach in the form of traditional lecture or presentation. The employees also did not have many opportunities to exchange their knowledge and experiences with partners from other manufacturing divisions:

  "When receiving training, I would like to have an opportunity to discuss the topics of process and cleaning validation with people from other areas like Quality Control and Process Engineering who are as much involved in this as we are. So far, it has not happen." (Senior Project Associate, MTS)

  "Content knowledge does not always translate into good teaching. We need to move from the philosophy to action and work together to give our people a sense of ownership and accountability. We've seen enough PowerPoint slides, let's get together at the same table: MTS, Quality, engineers and talk about how we may accomplish a specific task." (Research Advisor, MTS)

The results of the interviews and survey were used for formulating the design and methodological goals of Phase 2: Change Experiment. The conclusion was made that the presentational format of the strategic content, usually practiced by MTS, was no longer effective. A proposal was developed to depart from the didactic model, and to bring managers to the discussion of strategic changes, giving them an opportunity to exchange knowledge and practices in the context of analyzing and redesigning current business systems. The Activity Theory triangular model was proposed to be adapted to guide the collaborative strategizing activity

during the workshop because the available research (a) confirmed the effectiveness of this model in collaborative learning environments, and (b) demonstrated its potential for analysis and design of organizational systems.

MTS leadership requested a focus of the workshop to be on several business systems that were defined as critical in the organizational change process: Acceptance from Development, Process Validation, Technology Transfer, and Deviation Management. The detailed description of these business systems is provided in the *Organizational Context* section of the introductory chapter. At this point, I proceeded with the design of the workshop and development of evaluation instruments for assessing its effectiveness.

Phase 2: Intervention

During the next two months, I was engaged in designing a three-and-a-half hour, facilitated workshop focused on addressing the issues reported in Phase 1. The Annual Product Review system was recommended as the context for the pilot workshop activities as it represented a very new process not ready yet to be discussed with a large audience.

The workshop was designed for managers from four manufacturing networks who were planning to attend the change agenda implementation conference in June 2004. The workshop was designed as a sequence of three activities. The first activity engaged participants in the analysis and design of the processes related to four business systems, identification of strong linkages and contradictions between the system components, and indentification of necessary system changes. This exercise utilized an activity-based strategic tool designed using the Activity Theory framework.

In the second activity, managers were expected to identify the course of action for implementing the changes proposed in the previous exercise using a force-field analysis

approach. The third activity invited managers to examine the Medex-specific issues presented in brief business scenarios. Managers were expected to collaboratively analyze the issues, propose solutions, and evaluate them from technical, scientific, business, and regulatory compliance perspectives. The detailed description of the workshop structure and process is provided in Chapter 3: Methodology and in Appendix F, which contains the workshop Facilitator's Guide.

The workshop was piloted with a group of three managers from different functional units (MTS, Engineering and Quality) and two representatives of the strategic planning group. During the pilot, an activity-based strategic tool was tested to ensure that its design was understandable for the intended audience and could be used for its intended purpose. A detailed description of the pilot study procedures and outcomes is provided in Chapter 3: Methodology. The pilot results demonstrated the potential of the activity-based strategic tool to be used for guiding the strategizing process and prompting managers to collaboratively identify system issues and address them through system redesign. Observations from the pilot brought me to a decision to develop a research agenda for studying the strategizing context and the use of the tool from the social learning perspective. At this point, my role in Medex was split between being a consultant preparing to deliver a workshop and a scholar approaching the same events from the research perspective.

The workshop was delivered on the first day of the MTS conference, on June 15, 2004. The detailed description of the workshop context and activities is provided in Chapter 3: Methodology. The workshop was intended to 'set the stage' by introducing major strategic issues that were further elaborated at the conference meetings. As I mentioned in the previous section, all the data collected during the workshop, including design sketches, records of managerial discourse, activity sheets, and observation notes, were used solely for research purposes; the

MTS organization only required a report of the participants' feedback on the workshop and their recommendations for further training and communication events collected through the follow-up survey.

Phase 3: Evaluation

The final phase of the project was split between completing my consulting requirements and continuing the research work. A 74-item follow-up survey was administered to the workshop participants (Appendix H) in order to provide feedback on the workshop, and test the participants' knowledge of strategic concepts by requesting them to answer sets of questions repeated from the pre-workshop survey.

Once I analyzed the managers' feedback and reported it to the MTS Communications group, along with recommendations for further improvement of managerial training practices, my consulting duties ended. Since the managers' feedback on the workshop is intertwined with the discussion of their experience during a strategizing episode, presentation and discussion of their comments can be found in Chapter 4: Results and Discussion.

From that moment, I continued working on the project only as a researcher, collecting more data and analyzing it for the development of interpretations and conclusions. Additional data collected after the workshop included interviews and focus groups with the managers who attended the workshop. The purpose of these interviews was to discuss the collaborative strategizing experience and its learning outcomes. Another set of data was provided to me by the MTS Communication group approximately three months after the workshop. It included four change implementation plans submitted from each manufacturing network and written by managers who attended the workshop. Collecting this data was not planned by my research agenda; therefore, its analysis was limited in a number of ways. For example, I did not have an

opportunity to find out which workshop groups the authors of the plans were affiliated with; in fact, the only information available was that the authors of those plans did participate in the workshop. Despite this and other limitations of the data discussed in the Methodology section, I felt that the plans could be included in the study. They provided additional evidence on how the strategic concepts that managers learned during the workshop were transferred into the workplace.

Clarification of Consulting and Research Roles

The limitation discussed above was quite natural as I was balancing the roles of a consultant and a researcher, which both have time and data access constraints, especially when working with a large corporation that has a high level of security, bureaucracy, and little interest in supporting an outsider's individual research.

One of the major challenges of an action researcher is to distinguish the research and consulting roles while working for a specific organization and to define the scope and limitations of the research and consulting projects. As a consultant, I was working closely with the MTS Communications Group, which was ultimately responsible for conducting the analysis and delivering the workshop. My responsibilities included:

- designing the needs analysis survey,
- conducting interviews with the members of the strategic planning group,
- analyzing the survey and interviews' results and summarizing them into a report for the MTS executives,
- designing of the workshop for managers,
- designing the follow-up survey, and

- summarizing the results of the workshop and follow-up survey into a final report for the MTS Communications group that contained recommendations for further managerial training and communication initiatives related to the change agenda implementation.

As I mentioned above, the research project officially started after I reported the results of the needs analysis to the MTS executives, and designed and piloted the workshop. The need analysis outputs and the results of the workshop pilot indicated that the conceptual framework used in the project and the design choices made for the workshop could potentially be effectively applied, not just in the situation of the organization for which I was working, but in similar situations that involve the challenges of change implementation. A research agenda was then formulated that focused on the following aspect of the strategizing workshop: examining the use by middle managers of the activity-based strategic tool for analyzing and redesigning current business systems, and evaluating the managerial learning that resulted from this experience. The request to use all the data collected under the scope of the consulting project was submitted to Medex; additional permission was obtained to conduct interviews and focus groups with the workshop participants (see Appendices Q and R).

While the consulting and research projects overlapped in terms of timeline and data collection approach, the foci of data analysis for the two projects were different. The expectations for consulting reports were limited to identifying the communication and learning needs of the MTS managers as related to the change agenda before the workshop, and evaluating the managers' satisfaction with the workshop activities. Examination of the activity-based tool in the strategizing context as well as the impact of its use on managerial learning was outside the scope of my consulting duties.

Although the ultimate goal of both projects was to assist the MTS managers in their strategy learning and change efforts, the research agenda advanced to examining the collaborative strategizing process that used an activity-based strategic tool and to exploring the social construction of strategic learning that took place during that process. This was done through the examination of the dynamics and design outputs of strategizing actions where managers used the tool to construct current business systems, to discuss the dynamics of their components, identify contradictions, and generate change propositions. Evaluation of strategic learning was extended beyond the testing of managerial satisfaction. It involved inquiry into the discourse of strategizing managers and evaluation of the advancement of managerial conversations through the phases of social construction of knowledge. The research study also examined the transfer of strategizing concepts into the workplace when managers developed real plans for tackling the issues that were preventing them from moving forward with implementation of the change agenda.

My role as a researcher was limited in a number of ways. For example, the content, scope, and design of the surveys administered pre- and post-workshop were largely determined by the MTS Communications group. These instruments served very specific organizational purposes: to find out what strategic topics were unclear to managers, what training and communication activities were more or less effective, and how the organization could address managers' informational and learning needs to help them overcome the challenges of completing the change agenda requirements. Therefore, a large number of the survey items were not directly applicable to this study's goals, and their analysis is not presented in this manuscript. An additional example of the limitations on this study is that the consulting project was not concerned with examining the differences between the needs of the domestic and foreign

managerial groups; therefore, the analysis of the cultural impact on the strategizing dynamics was limited to the analysis of anecdotal evidence provided during debriefing interviews. This limitation became especially obvious when the research findings revealed the relationships between the cross-cultural dynamics and managerial performance during strategizing. The time allowed for the strategizing episode during the workshop is yet another limitation imposed by the client organization, though I consider such limitations natural for action inquiry, since the role of an action researcher always includes negotiations between specific organizational needs and the needs of an individual researcher. These limitations can be addressed by consequent studies designed with the focus on specific issues found by this exploratory work.

CHAPTER THREE: THEORETICAL FOUNDATIONS AND RELEVANT RESEARCH

In this section, the theoretical frameworks guiding this study's inquiry and relevant studies are discussed. The existing literature on organizational strategy evolution is reviewed, and the emerging views of strategy as social practice are discussed. Next, Activity Theory is introduced as an analytical and design framework applied in organizational contexts in order to understand and improve various aspects of organizational performance. The chapter further summarizes the trends in organizational learning practices and approaches used by organizations, and focuses specifically on the use of Activity Theory in learning contexts. Finally, organizational research trends relevant to the inquiry approach utilized in this study are discussed.

Motivation

I would like to begin presentation of the theories underlying this study with a brief discussion of the rationale behind considering the Activity Theory framework for guiding the

managerial strategizing process and explain my reasons for designing strategic episode as a collaborative activity.

As a MTS consultant, I observed that the employees, despite their recognition of the necessity to change, and despite their honest efforts to comply with the new requirements, often felt overwhelmed by the amount of strategic information presented to them and by the lack of guidance on practical implementation of change. As one of the employees put it: "Will we ever be able to manage this gestalt and achieve what we need?!" referring to the challenges of prioritizing multiple requirements of the change agenda, which they had to follow in addition to their daily tasks. Employee support regarding the change agenda-related projects was essentially lacking. With the exception of presentations, video broadcasts, and MTS intranet site postings of strategic documents, MTS employees were not provided with any form of training or on-the-job support; rather, they were expected to determine independently how to incorporate new requirements into their already busy schedules.

The results of the needs analysis confirmed my observations: the MTS employees were experiencing difficulties interpreting the complex language of the change agenda and were concerned with the overwhelming number of repetitive and abstract strategic messages:

> *"We need a way to simplify our message and energize our employees. While we are in a complex business where interactions and interdependencies are critical, we can't continue to show slide after slide of bubble charts and flow diagrams. We need to use the KISS principle and then highlight the accomplishments at each site. Providing a consistent vision is important, but repeating the same message is non-value adding and demotivates areas that understand, but are struggling with a crushing work load."* (Team Leader, MTS)
>
> *"Our leadership seems incapable of communicating their vision in a way understandable for masses."* (Consultant, MTS)
>
> *"We currently make our message too complex. Having a 30+ page change agenda is telling in our ability to tell our story. The Corporation is able to convey it's priorities in 5 high level bullets, why can't MTS do the same? We may already have this but it is lost in*

> *a maze of other communications. There is no doubt that our leaders have a vision for MTS, the real question is how we can present that vision in a way that is simple, straightforward, motivating and compelling to those battling multiple priorities."* (Senior Project Associate, MTS)

The needs analysis also revealed the employee request for more than "show and tell" approach to developing in-depth understanding of new directions for their organization. Many survey respondents expressed concerns with the lack of regular employees' involvement in strategic development process:

> *"When introducing new concepts/approaches or requirements, the opportunity for face to face discussions and exchange of ideas, concerns and best practices is invaluable. Self study alone or formal presentations with limited discussions is not sufficient when significant change is being implemented. We need to stop spinning our wheels!"* (Manager, MTS)

> *"If the agenda had more real examples, it would be better. Get to ask the person on the ground questions regarding the topic, get direct learning from him and then use it to share with others."* (Project Associate, MTS)

My informal observations and results of the analysis raised questions about the meaning and value of the strategy for all members of an organization, not just for its top management group. The approach used by organizational strategists was lacking connection with those "ordinary strategic practitioners" (Whittington, 1996) who were charged with bringing changes into their daily routines. What role do middle managers play in defining strategic goals and outcomes? What is the impact of their contributions, or lack of thereof, on implementation of the organizational change agenda? Will the involvement of middle managers in the strategizing process help align leadership expectations with the realities of employees' daily work? Why are strategic propositions so difficult to implement? What competencies and types of support are necessary for successful implementation of strategy?

Similar questions have been addressed in recent organizational strategy literature that views strategy as a form of social practice in organizations (Hendry & Seidl, 2003; Ikävalko, 2005; Jarzabkowski, Balogun, & Seidl, 2007; Johnson et al., 2003; Whittington, 2003, 2004). From this perspective, strategy is concerned with the strategic competence of a middle-rank manager, a practitioner; and the strategic development process is viewed as the interaction of motivated practitioners as opposed to the top management-dominated constructs of an organization's future (Whittington, 1996; 2002).

The questions that I formulated about managerial agency in organizational strategizing processes prompted me to examine the available research on strategic learning and managerial competencies necessary for effective enactment of strategy. Although a number of studies emphasize the critical importance of organizational learning in the strategy making process (e.g., Hodgkinson & Johnson, 1994; Huff, 1990; Pettigrew & Whipp, 1991), the specifics of the strategizing process, the use of strategic tools, the interactions between various managerial levels during strategizing, and the connection to the macro-strategic process remain largely unexplored (Regnér, 2005). The context of my consulting project, therefore, presented a unique opportunity to implement and examine a new approach to strategizing that involves middle managers who used an activity-based strategic tool to help each other learn complex strategic concepts and uncover barriers to change implementation.

In the paragraphs below, I present theoretical frameworks and available research works that are relevant to this dissertation study.

Organizational Change and Managerial Competencies

Over the past decades, there has been an increased interest in developing an understanding of how organizations evolve over time and respond to the need for change

(Pettigrew, Woodman, & Cameron, 2001). Today's organizations are experiencing massive pressure to improve performance and constantly innovate in highly unstable economic, political, and social environments. In order to survive and stay competitive, organizations and their members must react quickly to rapidly changing markets, globalization, and emerging innovative technologies (Doppler & Lauterburg, 2001; Malopinsky & Osman, 2006).

Historically, research on change and innovation put emphasis on an organization's ability to adapt to external changes and to sustain process and product innovation (Hamel & Prahalad, 1994; Mintzberg, 1990; Whittington, 2001). The researchers argue that mere responding to changes in the external environment or innovating in terms of products and services is no longer sufficient, and organizations must proactively address future challenges by initiating strategic innovation or business concept innovation that will transform their processes, thus allowing them to sustain their competitive advantage (Baker, 2002; Hamel, 1996). Transformational, or strategic, change has become a critical topic for today's organizations, especially in the developed world, where corporations are reaching the limits of incremental process improvement through cost-cutting and efficiency programs (Baker, 2002; Hamel, 2000). Hammer and Champy, in their seminal work, introduced the concept of radical reengineering that is required for organizations to achieve maximum efficiency and effectiveness (Hammer & Champy, 1994). However, the results of the early transformational studies in organizations revealed that management has often been a barrier to implementation of change initiatives.

The research suggests that successful strategic change in organizations necessitates transformation of managerial strategies and practices (Hendry & Seidl, 2003; Jarzabkowski 2003a; Mantere & Sillince, 2006; Mezias et al., 2001). The ability to change and innovate becomes an organization's competitive advantage in today's business world. Thinking

strategically and developing capabilities for managing change within the specific organizational context is nowadays considered a critical competency for both middle- and senior-level management. Organizations increasingly demand that their leadership depart from autocratic management methods, consider teamwork and employee participation in strategic decision-making, and find balance between the organizational demands and the needs and interests of regular workers (Hargadon & Sutton, 2000). The organizational research literature confirms that a balanced approach, taking into consideration both organizational and individual needs, is likely to be the most effective in implementing change (Beer & Nohria, 2000; Senge et al. 1999).

Organizational Strategy

Evolution

Thompson and Strickland (1993) define organizational strategy as "the pattern of organizational moves and managerial approaches used to achieve organizational objectives and to pursue the organization's mission" (p.3). Brown & Eisenhardt (1998), when defining strategy, emphasize the competitive attributes of strategy, stating that the quintessence of strategy is choosing to perform activities differently than an organization's rivals do. Ultimately, organizational strategy is concerned with understanding the directions an organization is taking and the means it uses to achieve its destination.

Whittington (2001) identifies four historical approaches related to strategic processes and outcomes. The *classical approach* is concerned with analysis and planning a right strategy for positioning the firm on the market (Ansoff, 1965; Chandler, 1962). This approach assumes rational strategic decisions made by an organization's leaders and utilization of organizational structures for strategy implementation, but it does not take into account the participation of any other organizational members in the strategy-making process, and it does not question the

potential irrationality of top managers in their strategic decision-making (Ikävalko, 2005). The *evolutionary approach* in strategic development builds its argument on the biological principles of survival (Nelson & Winter, 1992; Xaivier, Swaminthan, & Will, 1998) where the strategy is constrained to keeping transaction costs low and being flexible in a constantly changing market. The *processual approach* challenges the strategic planning of top managers, considering it a ritual rather than an activity that takes into consideration all driving and constraining forces within and outside an organization (Weick, 2001). The *systemic approach* views strategy as embedded into the socioeconomic context of a firm (Ringer & Robinson, 1996). Although the classical and evolutionary approaches are currently under criticism from the advocates of the dynamic view of strategy and managerial agency in strategic development, Whittington (2001) suggests that elements of each approach may have their place in shaping organizational strategy, depending on the context of a strategy-making initiative. Whittington's taxonomy may be better understood in the context of historical analysis of strategic development trends in organizations.

The early concepts of organizational strategy evolved in the industrial-organization (IO)-based strategy perspective (Porter, 1981) and the resource-based view (RBV) (Barney, 1986, 1991; Dierickx & Cool, 1989; Rumelt, 1984) that established the dependency of organizational strategy on industry structures and resource factors (Regnér, 2005). They were based on the implicit premise that strategy can be designed by top executives upon careful analysis of internal and external factors impacting a firm's competitive position (Ansoff, 1965; Chandler, 1962). The strategy formulation process was de-contextualized and detached from daily situated activities (Jørgensen & Sørensen, 2003), and the emphasis was typically made on strategic content as opposed to strategic process (Skinner, 1969). The dominance of content-based views in strategy research reduced the role of organizational members to "simplistic figures represented by a few

demographic variables that may be questionably linked to firm performance" (Jarzabkowski, 2004, p.2), and did not permit the analysis of their role in strategy creation. The strategy developed by the organization's top management group was given ontological primacy, and it was assumed to transmit its values to the rest of organizational members who were passive recipients of leadership's strategic message.

The strategy-as-process school of research made a significant departure from the content-based theories by introducing a dynamic view of strategy and the concept of managerial agency in the strategic development of a firm (Burgelman, 1983; 1991; 1996; Johnson, 1987; Mintzberg, 1978, 1990; Mintzberg et al., 1998; Pettigrew, 1987; Quinn, 1988). Mintzberg's school claims that strategy integrates the ideas and actions from multiple organizational members. It emphasizes a unique position of the organizational learning processes as strategic assets (Dierickx & Cool, 1989; Helfat, 2000; Markides, 1999; Teece, Pisano, & Shuen, 1997). However, strategy process scholars have yet to provide a fine-grained analysis of the micro-level processes in strategy development or demonstrate the managerial impact on macro-level strategic change (Johnson & Huff, 1997; Regnér, 2005).

These shortcomings have been addressed, to some extent, in the past few years by the strategy-as-practice school of thought that views strategy as a situated, socially-constructed activity involving interaction and collaboration of multiple organizational actors (Whittington, 2003; Wilson & Jarzabkowski, 2004).

Strategy as Social Practice

The practice view of strategy claims that the process of strategizing is embedded in the daily activities and knowledge of practitioners who execute organizational strategy through their

daily routines (Christensen & Overdorf, 2000; Dudik, 2000; Hendry, 2000; Jarzabkowski, 2004; Johnson, 2004; Pettigrew, 2001; Whittington, 2003).

The emergent school of strategy-as-practice advocates managerial agency in strategic development. It argues that strategy formation is a social activity that is not restricted to organizational strategists; bottom-up and middle-out possibilities for strategy-making also exist. According to practice perspective, people, such as middle managers or regular employees, who might not be designated formally as "strategists" can and must engage in collective, systematic, and iterative revisiting of the existing processes and technologies (Hendry & Seidl, 2003; Mantere, 2005).

The unit of analysis in practice research is a social interaction episode among practitioners focused on constructing and exchanging strategic knowledge (Luhmann, 1996; Wilson & Jarzabkowski, 2004). The emphasis is made on the situated, relational nature of the interaction, meaning that the strategy-making activity is grounded in the specific organizational context that simultaneously impacts and is impacted by this activity (Brown & Duguid, 1991; Contu & Willmott, 2003; Lave & Wenger, 1991).

Another critical attribute of situated activity is the use of mediating tools. Suchman (1987), in her seminal work on situated activity, brought attention to the significance of the artifacts inherently associated with actions and actors and used for mediating purposes. Practice researchers argue that, meaningless in isolation, the mediating artifacts become critical technical and social tools facilitating the strategy-making process in particular contexts (Blackler, Crump, & McDonald, 2000; Eden & Ackerman, 1998; Stenfors & Tanner, 2007). The notion of artifact use for communicating and negotiating strategic ideas became a cornerstone of this dissertation

study, focusing my thinking on exploring the potential application of Activity Theory in the strategizing process.

This paradigm shift in strategy research has significant implications for organizations: in today's fluid resource markets, sustainable advantage lies in micro assets that are hard to imitate (Johnson, Melin & Whittington, 2003). But we need to develop more specific understanding of how exactly organizational actors negotiate strategic decisions, of which conceptual tools they use in strategy-making process, of how they influence and are influenced by organizational rules and norms, and of how the outcomes of their activities impact organizational process transformation.

Although interest in the interactions and discursive practices of strategizing managers has gained considerable momentum in the past two years, there is still very limited empirical data availability that would demonstrate the methods of strategic negotiations between organizational actors and the tools they use (Balogun, & Seidl, 2007; Jarzabkowski, Laine & Vaara, 2007; Paroutis & Pettigrew, 2007; Regner, 2005). This dissertation study attempts to contribute to these strategy-as-practice efforts.

Organizational Learning and Strategic Change

Strategy is explicitly concerned with the creation of intentional, often radical, change through determining processes, technologies, and resource allocation (Hendry & Seidl, 2003) and with providing necessary direction for an organization to face the uncertainties of the business environment at times of organizational restructuring (Spender, 1989). Strategic knowledge is characterized as an active process of knowing that is (a) mediated through tools and technologies, (b) situated in or specific to particular contexts, and (c) constructed through the constant process of negotiating the concepts and redefining practices (Blackler, 1995).

Knowledge-Based View of Strategy

Senge (1990), in his seminal work on learning organizations, emphasized integration of organizational strategy and learning; he viewed learning as a collective inquiry focused on developing a shared vision, a common language, shared mental models and systems thinking – all attributes of strategic knowledge – that result in change in organizational actions. Nonaka & Takeuchi (1995) also proposed that organizational knowledge is essentially strategic as it is associated with the continuous process of organizational innovation. They argue that integration of learning and organizational practice not only facilitates knowledge development but also results in enhancement of organizational capacity for change and growth. These authors further propose that creating a shared context in which individuals can interact with each other is the essential key for transforming individual and collective knowledge into competitive organizational assets.

Organizational Learning as Social Construction of Knowledge

Viewing strategy as a form of social practice suggests that the learning process is embedded in the context of strategy development; that is, the organizational members are engaged in collaborative learning through strategic decision making when they negotiate new processes with their peers (Hendry, 2000; Johnson & Huff, 1997; Mezias et al., 2001; Watson, 2001; Whittington, 2001). Luhmann (1996) refers to such collaborative activities as a "creation of strategic episodes", a concept derived from the theory of change.

Collaborative construction of strategy in the form of a learning activity provides an opportunity for all parties involved in managing the complex organizational operations to negotiate new meanings of organizational structures and processes and engage in the discourses of strategic problems concerned with change (Engeström, 1999a; Luhmann, 1996).

For the purposes of this dissertation, learning is conceptualized as the process of participating in a collaborative activity (Lave & Wenger, 1991; Vygotsky, 1978; Wertsch, 1997) and it is viewed not as memorization of facts, but as a transformational action, that is, a construction of knowledge through social experiences and development of shared understanding (Schwen, Kalman, & Evans 2006). The teacher's role departs from being a content provider to being a facilitator of learning activities focused on negotiating goals, practices, and concepts with peers (Barab et al., 2002; Duffy & Cunningham, 1996; Jonassen, 1991). Such pedagogical practice is grounded in functional representations that extend a learner's understanding of the phenomena and establish the context for meaningful learning reflection (Barab et al., 1999; 2002; Hannafin, Hall, Land, & Hill, 1994).

In the past decade, several frameworks and models of social knowledge construction have been introduced in the educational research literature (Engeström, 1999b; Garrison, Anderson, & Archer, 2001; Gunawardena, Lowe, & Anderson, 1997; Nonaka & Takeuchi, 1995). The researchers theorize that the knowledge construction process is not linear and evolves through specific phases, or cycles, that involve constant knowledge transactions between actors through information exploration and comparison, cognitive dissonance, negotiations of meaning, and co-construction of new concepts and models. Thus, Gunawardena, *et al.* (1997) present the social construction of knowledge in a 5-phase model, where the initial sharing and comparing of information occurs in everyday transaction through observations, questions, and identification of problems. These operations may lead to the discovery of inconsistencies between the existing knowledge frameworks that actors possess and new information, or dissonance between cognitive schemata possessed by different actors. This inconsistency necessitates negotiations of meaning and collaborative construction of new concepts that are continuously tested and

modified through personal experience and formal data experimentation, and ultimately result in formulation of agreement and metacognitive statements illustrating new knowledge construction and application in particular contexts.

The Practical Inquiry Model (Garrison *et al*., 2001) conceptualizes social knowledge construction as the process that encompasses four phases of critical thinking and cognitive presence: from the initiation phase, one of goal and problem formation, to the exploration phase, when learners move between individual and social reflection on the issues being examined. The integration phase allows learners to construct shared meanings or problem solutions based on the negotiations that took place in the previous phase. Finally, learners progress to the resolution phase, when the new constructs are evaluated. This cycle represents knowledge as a problematic field and makes an explicit provision for sequences of analyzing and debating an issue in a systematic way.

The framework of social construction of knowledge, which is particularly close to the context of the collaborative design activity of this dissertation study, was presented by Engeström (1987) as an expansive learning cycle. Engeström describes a process of "construction and resolution of successively evolving tensions or contradictions in a complex system that includes the object or objects, the mediating artefacts, and the perspectives of the participants" (p.384). The concept of an expansive learning cycle is grounded in collectively organized, artifact-mediated activity systems (Cole & Engeström, 1993; Leontiev, 1978) that continuously evolve through historical cycles in situation-specific contexts. The notion of different perspectives is essential: construction of new knowledge happens as a dialogical process in which individual perspectives meet, collide, and negotiate new meanings (Engeström, 1995; Holland & Reeves, 1996). This conceptual conflict in social interactions drives reflection

on individual perspectives and assumptions and stimulates collective inquiry (Bakhtin, 1981). Engeström (1999b) discusses the expansive learning cycle as an innovative learning process where the initial abstraction is gradually transformed into "a concrete system of multiple, constantly developing manifestations" (p. 382). In the context of this dissertation study, this statement would clearly describe the process of ascending from the abstract concepts formulated by the organizational change agenda to concrete representations of the emerging business processes constructed by organizational actors through dialectical exchanges of knowledge and experience.

The expansive learning cycle views innovation as a stepwise construction of new collaborative practices. It is described as a sequence of epistemic actions that starts from questioning the accepted practice and applying historical analysis of the situation with the goal of exploring underlying principles and rationales. The newly found explanatory relationship is modeled through construction of a simplified representation that suggests a potential solution to the problematic situation. This representation is examined and implemented through concrete practical applications, and the whole process is evaluated with the purpose of consolidating its outcomes into a new practice (Figure 3).

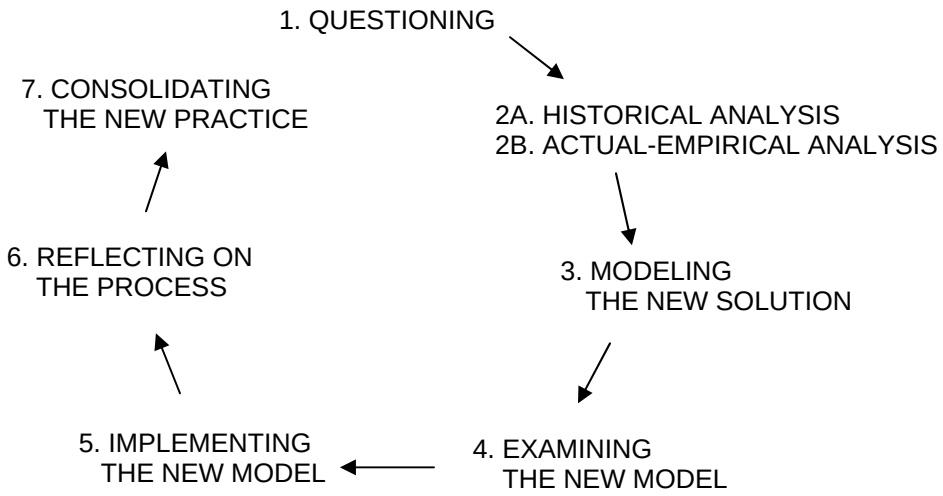


Figure 3. Sequence of actions in an expansive learning cycle (Adapted from Engeström, 1999b, p.384).

It should be noted here that initially, when the expansive learning framework was conceptualized, it was mainly applied to large-scale transformations spanning several years, and the action phases were analyzed from an historical perspective (Engeström, 1991, 1993b). Later, the research introduced miniature cycles of innovative learning, which lasted briefly, focused on teams rather than on entire organizations, and were regarded as potentially expansive (Engeström, 1999b).

A small-scale, innovative learning cycle shares its properties with the strategic episode discussed earlier; both constitute social interaction among practitioners focused on knowledge construction (Hendry & Seidl, 2003; Luhmann, 1996; Wilson & Jarzabkowski, 2004).

This dissertation study uses the expansive learning cycle as a framework for analyzing a small-scale innovative learning process that takes several hours and emphasizes the local discursive knowledge construction of the shared meanings undertaken by several teams. It guides the interpretation of the strategy-formulating discourse and observed interactions between strategizing managers.

Activity Theory

In this study, Activity Theory is used by collaborating managers as a framework for making strategic decisions. Activity Theory eliminates the traditional dichotomy of learning versus doing (Barab et al., 2002; Engeström, 1999; Garrison, 1995) through engaging organizational members in learning about new processes while constructing those processes.

Historical Overview

Activity Theory is rooted in the socio-cultural school of psychology that emerged in Russia between the 1920s and the 1940s (Leontiev, 1974; 1978, 1981; Rubinstein, 1914, 1984; Vygotsky, 1978). Activity theorists built their original conceptual framework on the works of Marx and Engels (Engels, 1972; Marx, 1973; Marx & Engels, 1984) that claimed the primacy of practice in shaping human consciousness. Russian psychologist Sergei Rubinstein should be credited for formulating the initial concept of human action as a unit of psychological analysis, which eventually grew into what we know today as a Vygotskian school of cultural-historical psychology. Vygotsky and his colleagues formulated a set of completely new theoretical concepts of artifact-mediated and object-oriented action that departed from the traditional psychological orientations dominated by psychoanalysis and behaviorism (Kaptelinin, Kuutti, & Bannon, 1995). The main idea was that the human mind's development can only be understood within the context of goal-oriented and socially-determined interaction of individuals with their environment through cultural means, tools, and signs.

The tripartite model of human interaction with environment (Figure 4), also known as the mediational model, was initially proposed by Vygotsky (1978), and was later introduced in the context of a hierarchical model of human activity developed by Leontiev (1978).

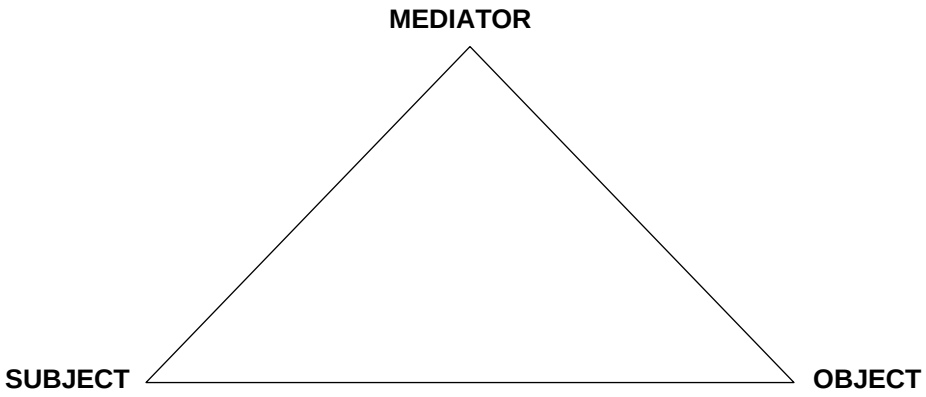


Figure 4. Mediational model
(Adapted from Vygotsky, 1978, p.40)

The model was further elaborated by Engeström (1987, 1993) who integrated social and cultural aspects into the model of human activity thus suggesting a possibility of analyzing the activity as a complex system of interrelated processes (Figure 5).

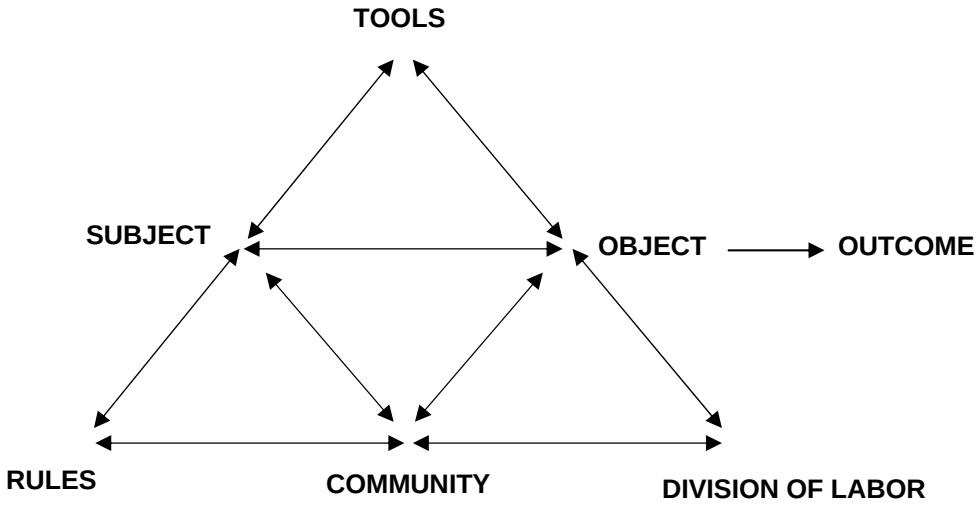


Figure 5. The structure of the activity system
(Adapted from Engeström, 1987, p.78)

Although historically grounded in the pure psychological research domain, in the past decade Activity Theory has been of interest to the organizational researchers attempting to extend the application of this theoretical framework in their analysis of business problems and understanding work dynamics (Ardichvili, 2003; Bannon & Bødker, 1997; Engeström, 2000; Hannson, 2002; Hutchins & Klausen, 1998; Seppänen, 2002).

Activity Theory conceptualizes psychological and cognitive development as a process of social interactions within particular contexts and creates interdependencies between individual and social levels (Vygotsky, 1978; Wertsch, 1985, 1998). Those interactions form an interpretative basis from which individuals derive meanings of specific actions comprising a shared activity (Engeström, Engeström, & Kerosuo, 2003). The activity evolves around dynamic relations of the primary actors (*subjects* of activity) and problem zones at which the activity is directed (*objects* of activity) thus forming an *activity system*, a complex web of interactions that take place in a specific situated context and are mediated by various physical and conceptual tools and artifacts, such as language or technologies. The *community* aspect of the model refers to multiple individuals or groups who share the same object, or problem space, and evolve as a separate entity distinct from other communities. The *rules* aspect is represented by various norms, requirements, and standards that explicitly or implicitly regulate the actions within the activity system. The *division of labor* addresses distribution of tasks and responsibilities among the members of the activity system's community, as well as identifies their power relationships.

Principles of Activity Theory

Many scholars argue that Activity Theory is not a "theory" in the strict interpretation of the term, but rather a conceptual framework offering a set of principles that can be used for generating more specific theories (Kaptelinin & Nardi, 1997; Kuuti, 1996). Those principles

include the hierarchical structure of activity, internalization/ externalization, tool mediation, object-orientedness, and continuous development and change.

The activity theorists distinguish among three levels of analysis utilized by Activity Theory: *activities*, which are directed towards achieving specific objectives or resolving problems, *actions*, which individuals conduct toward their goals, and routine *operations* contingent upon the conditions in which the specific action is performed. All these levels of the hierarchical activity scheme are related. Thus, activities are comprised of conscious actions that are performed through automatic operations with the purpose of achieving a top-level goal, or the object of a whole activity (Leontiev, 1978).

Activity Theory recognizes the transformation of external activities into internal ones, thus providing an opportunity to identify the optimal interaction approaches and simulate potential interactions with environment without manipulating real objects (Kaptelinin & Nardi, 2006). Internalization allows projecting future interactions and relationships and identifying potential contradictions, thus making the future actions more efficient. Externalization, or transformation of internal activities into external ones, is often necessary when people need to compare their understanding, or internal depictions, of the specific processes with the ones of their peers. This principle is especially relevant in the context of this dissertation study: organizational members were able to externalize their existing conceptual models related to specific business processes, negotiate their ideas with peers, engage in the process of internalization of new strategic concepts, and consider alternative business solutions through the collaborative design process.

As the notion of human interaction with environment is the central one in Activity Theory, the mediation principle plays a critical role in this approach (Bannon & Bødker, 1997).

Tools in Activity Theory should be understood in a broad sense: both technical ones that are intended to manipulate physical objects and psychological ones used to influence people (Vygotsky, 1978). Mediating tools hold a dichotomic functionality of enabling certain changes and interactions but, at the same time, are constrained by their own limitations regarding the influence they may exert on the object. Tools evolve during the development of an activity, and they carry the cultural and social knowledge and experiences of the people who invented and modified them in order to solve certain problems. Thus, in an organizational context such tools may include various documents and technologies, such as a call-tracking system, a database of frequently asked questions (Mwanza, 2001), or protocols of treatment and standard operating procedures (Larkin, 2001) used to facilitate and support business process. Data management systems, performance assessment tools, templates, schedules – all these artifacts are tools used by multiple organizational actors engaged in collective activity focused on achieving a specific business objective.

Bannon and Bødker (1997) point at the controversy surrounding Activity Theory's principle of object-orientedness: grounded in Marxist materialism, the theory assumes the objective, physical reality-determining subjective phenomena, and at the same time recognizes the socially-determined phenomena as objective properties. The practical implication of this principle is that the object, or objective, of the activity can be not only a physical artifact but also a specific problem, a concept, or a process that needs to be resolved, revised, or adapted. Thus, in Mwanza's case (2001) of using Activity Theory for guiding the computer systems design process, the activity was directed toward achieving better customer support, an objective that included certain social and cultural properties.

As suggested by Ilenkov (1977), an activity can be understood only through the analysis of its historical transformations. Activity Theory uses dialectical logic to examine practices in the context of development and change through tensions caused by certain environmental conditions. As a research methodology, Activity Theory is not concerned with the laboratory experiment providing a reality snapshot, but rather with systematic exploration of the developmental changes of the activity system's object. The historical aspect of Activity Theory is critical for the analysis of organizational systems as it allows a historical comparison between the past, present, and projected future of an organization, and provides a necessary methodological lens for understanding initial processes and relationships within an organization, change motives and resistance to change, transformation, and stagnation (Engeström, 1999). Thus, in the context of this study, it was important to delve into existing processes and organizational structures, as well as existing strategizing practices, in order to identify the areas of most strategic importance. These areas revealed themselves also as tension points within the organization and as points of confusion among the organizational members. Tensions, or internal contradictions, as Ilenkov argued (1977), constitute the principle of self-organization of an activity system and are considered the enablers of its continuing development.

Contradictions

For activity theorists, the architecture of the system and mere presence of all components is not sufficient for analyzing the complexity of the phenomenon. What is sought is the analysis of the alignments and tensions between the system components as they interact within the system and contribute to the interactions between different systems. Engeström (1993a) refers to such interactions as contradictions building upon the ideas of internal contradictions as the driving force of continuous transformation of activity systems initially conceptualized by Ilenkov (1977;

1982) and Leontiev (1981). Barab and his colleagues (Barab et al., 1999; Barab, Barnett, & Squire, 2002; Barab, Schatz, & Scheckler, 2004), in their empirical studies that involved Activity Theory as an analytical tool for studying the complex dynamics of learning environments, emphasized the importance of identifying those core struggles and developing an understanding of their contribution to a system's functioning and evolution. Referring to the work of Wenger (1998), researchers discuss the interplay of a system's dualities that becomes the driving force for innovation and change. Engeström (1999) suggests four levels of contradictions that may occur in an activity system.

Primary Contradictions

Primary contradictions are those that occur within a component of a system, when a certain element of the system contradicts itself. A good organizational example could be a certain rule or a requirement that initially was meant to improve a business process but eventually became obsolete. For example, at the time of this study, the old Medex quality policies, which, speaking in Activity Theory terms, belong to the *Tools* category, were still in effect though they did not adequately address many of the critical processes implemented and new equipment installed in the years since they were established.

Secondary Contradictions

The policies discussed above not only contradicted themselves but also exerted a negative impact on other organizational aspects thus causing secondary contradictions. A good illustration is the conflict of the old policies with the newly developed quality standards. During a certain time, Medex manufacturing operated under both old policies and new standards, which created ambiguity and confusion among employees. Secondary contradictions occur between different elements of an activity system when either existing elements change their intrinsic or extrinsic

value, or a new element enters the activity system from outside thus bringing new goals and requiring relationships that do not yet exist in the system. Secondary contradictions can take place when a new technology or certain tools are being integrated into the system. Thus, new standards were an example of such tools causing the conflict with the policies.

Tertiary Contradictions

A tertiary contradiction may appear when a new objective is introduced into the activity, typically more advanced technologically or culturally different. A formal process directed towards implementation of the new objective may take place, but the system experiences resistance on various levels (Engeström, 1999). Contradictions of the tertiary type are characteristic of the radical change that occurs at the introduction of new business processes into an existing system. Such change often causes confusion and all types of tensions in a system. The change might arouse the parochial self-interest of employees concerned with the potential negative implications for their position; the change initiative's goals might be misunderstood or misinterpreted; existing organizational structures might be unable to adopt a more advanced model expediently (Malopinsky & Osman, 2006). A Medex-specific example of a tertiary contradiction is a requirement for conducting Annual Product Reviews (APRs). APR process is a more advanced and effective way to perform a regular evaluation of the product and process quality that superseded complex and in many ways redundant reviews that were conducted separately on a product and on a process. Although APRs were demonstrably more advantageous than the old quality evaluation methods, they created multiple tensions in the organization: employees responsible for managing APR process were not supported with the methods that would help with transition from the old quality reviews to APRs. The requirements for the scope and format of APR were not defined creating confusion and anxiety among managers who had to

figure out how to organize this process. Many plants had neither time nor resources to undertake such transition and continued to perform quality reviews in the old way. This demonstrated inconsistency among the methods used by the plants producing the same drugs – a big issue in the eyes of the regulatory agencies auditing those plants.

Quaternary Contradictions

Activity systems do not exist in isolation, but rather interact in a complex network of other systems that impact the system's internal processes, causing quaternary contradictions between the central activity and the neighboring activities (Engeström, 1993a, 1993b). Thus in complex organizations, such as the one focused upon in this study, different functional areas can have some conflicting goals and interests despite the fact that their main objective can be the same. For instance, in the case of a process failure, a business division requires resolution of an issue quickly to insure that the manufacturing process continues without interruption and meets market demands, while a science division views the situation as the context for detailed investigation of the issue to prevent it from happening in the future. Both systems have the same major goal of delivering a good quality product to customers, but the contradiction between them is obvious.

Activity theorists suggest that contradictions within and between the activity systems are "the principle of self-movement and the form in which the development is cast" (Ilenkov, 1977, p.230), meaning that through their resolution organizations constantly evolve and change. Identifying contradictions is critical not only for more effective facilitation of activity system dynamics but also for understanding how those tensions contribute to the system change (Barab et al., 2004). In this study, I attempt to analyze the process of identifying contradictions by

managers involved in strategizing activities and discuss how those contradictions drive and constrain their strategic design process.

Use of Activity Theory in the Strategizing Process

This study borrows Luhmann's concept of the "strategic episode" (Luhmann, 1986, 1996) for discussing the collaborative strategizing process of middle managers. Strategic episodes are organizational learning activities through which organizations are able to suspend their normal routine structures and practices and create an opportunity for their members to reflect on business process and contemplate change (Luhmann, 1986, 1996; Hendry & Seidl, 2003). During such activities, strategic planning moves out of the strategy departments or specially created strategic planning groups and is performed by ordinary organizational actors, such as line managers.

Strategic episodes are mechanisms of knowledge exchange in which incremental changes are reflexively monitored, and managers are involved not only in identifying situations where the existing process needs to be changed, but in creating concrete points of realignment of the organizational processes following the new strategy (Hendry & Seidl, 2003). During a strategic episode, managers purposefully ignore the constraints of the current organizational structures and engage in brainstorming of new possibilities for their practices with the goal of improving organizational performance.

The importance of strategic episodes as mechanisms for change has long been recognized in both the academic and practitioner literatures on strategic change (Johnson, 1987; Mezias et al., 2001; Weber, 1998). Using strategic episodes as a routine element of organizational life is essential to the long-term survival of an organization and an integral part of its structure (Hendry & Seidl, 2003). Activity Theory enhances the outcomes of strategic episodes as it allows the

participants not only to exchange ideas and concerns related to the proposed change, but also to *translate* those ideas and concerns through activation of multiple elements of the activity systems that do not always surface during exchanges between organizational members. Utilization of activity-based methodology during strategic episodes also allows the inscription of collaborative decisions in technical artifacts, such as new policies, process methodologies and concept maps depicting new ways to do business. In the context of strategic change, both strategic episodes and activity-based exchanges would focus on specific process steps or organizational structures that should be revisited, and these approaches would share the following questions: Who participates and how are the participants determined? What techniques are used for facilitating communication of the strategic content? What factors of the system enable or restrict the continuous process of innovation; in other words, what tensions, or internal contradictions exist among the components of the system?

The use of Activity Theory for the design of learning activities for organizational leaders involved in negotiations of the change agenda was especially relevant in this study. Strategy research recognizes that the interdependences of various organizational components involved in the change challenges organizational members to exchange knowledge about them, and a new approach is needed to facilitate learning about the complex interrelationships of human and technical "actors". In our context, the challenge becomes even more prominent as the organizational leaders are usually separated in time and space since the organization is comprised of multiple business networks located both in the U. S. and overseas. Translation of the new strategy was also challenged by the fact that the organization in focus did not have an extensive experience of collaborative learning and sharing of information. The strategic message

would be communicated using the classical top-down methods and would be left open to interpretations within the contexts of local business units.

The activity-based approach to share the change agenda during the strategic episodes has only recently emerged and is now being applied to questions of competitive advantage and sustainability (Ambrosini & Bowman, 2002; Eden and Ackermann, 2000; Hendry & Seidl, 2003; Johnson & Johnson, 2002). The benefit of the activity-based view of strategy is extending existing traditions of strategy research, demonstrating the linkages and intersections of the organizational strategy research with other related research fields, such as social constructivism and situated cognition, and offering practical, actionable guidance to performance consultants and organizational learning strategists. A continuous process of integrating strategy into organizational learning and practice, rather than treating strategy as a well-defined set of measurements, makes the application of socio-technical approaches the winning base of competitive advantage demanded by contemporary business environments (Brown & Eisenhardt, 1998; Johnson & Huff, 1997).

CHAPTER FOUR: METHODOLOGY

This chapter begins with the discussion of the inquiry approach followed by the discussion of the research design. Then I present the pilot study during which an activity-based strategic tool was conceptualized and tested along with the analytical strategy selected for the main study. The pilot study results are followed by the description of the main study context, data collection methods and analytical procedures. The chapter continues with an overview of the steps made to ensure the quality and rigor of this research and concludes with the discussion of the ethical aspects of the study.

Two primary questions define this study's inquiry:

- How was the activity-based strategic tool used in the strategizing process of middle managers?
- What was the impact of the strategizing experience on managerial learning?

The secondary questions below address the specific aspects of the primary research questions:

- How did the use of the activity-based strategic tool affect identification, analysis, and resolution of organizational issues?
- What was the evidence of the social construction of strategic knowledge during the strategic episode that utilized the activity-based strategic tool?
- How did the use of the activity-based strategic tool contribute to the advancement of managerial strategic competencies?
- What was the evidence of transfer of learning from the strategic episode to the workplace context?

Research Design

Inquiry Approach

Before presenting the methodology employed in this dissertation study, I would like to clarify my epistemological position and offer a rationale for methodological choice. While acknowledging the influence of constructivist learning strategies on the design of the intervention under analysis (a strategic episode), this study is epistemologically and methodologically grounded in the postpositivist domain (Dewey, 1929/1988, 1938/1991; Elgin, 1996; Popper, 1959, 1963, 1979; Rescher, 2001). In postpositivist design, it is the problem under investigation that determines the methodologies needed for its resolution, and social science

researchers may use pluralistic approaches and mixed methods to derive knowledge about the problem (Cherryholmes, 1992; Patton, 1990). The mixed methods approach allows researchers to address the issues of method limitation and to balance the inevitable biases inherent in any single method.

Drawing substantially on Dewey and Popper, Phillips and Burbules (2000) discuss postpositivist research as "competent inquiry" that requires both exacting rigor and an adequate accounting of the complexity of the issue under investigation. Rigorous inquiry leading to formulation of "warranted assertions" (Dewey, 1938/1991, p.16) is essential for progressive resolution of complex social problems and allows a researcher to speak to the potential for generalizable results based on the strong connection between the study design and underlying theory. Although the particular design and context of this research project would only permit the establishment of the relationship between the research strategy and the outcomes of the case under analysis, its theory-driven methodology and rigorous implementation can lay foundation for further confirmatory research and find its application in similar organizational contexts.

Action Research Framework

The overarching framework of this study is the 3-phase action research consistent with the research process defined by Susman (Susman, 1983; Susman & Evered, 1978) that originated in the *diagnostic and therapeutic* domains conceptualized by Blum (1955). According to Blum, action research first involves the analysis of an organizational situation conducted collaboratively by researchers and practitioners, the members of the organization under analysis. During this stage, the problems regarding specific organizational situations are identified, and hypotheses are formulated concerning the organizational interventions and their potential impact on identified issues. Once the analysis is completed, a change experiment is conducted when

researchers introduce new processes and then evaluate their impact on organizational performance.

The action inquiry method has received increasing attention in the past decade as an approach for bridging the gap between academic research and organizational practice (Ellis & Kiely, 2000; Friedman, 2001). This postpositivist social inquiry approach resides within the domain of critical theory built on the Marxian proposition of a human being's ability to drive societal change and become emancipated (Bourdieu, 1998; Horkheimer, 1982). In the context of ongoing change that today's organizations experience at an "accelerated pace" (Ellis & Kiely, 2000, p.83), action research is viewed as a dynamic and flexible research approach that captures well the complexity of the changing environment (Baskerville & Wood-Harper, 1996). Argyris (1997) refers to organizational action research as a methodology where the researchers try to directly improve the participating organizations and, at the same time, generate scientific knowledge. The goal of action inquiry is to create appropriate conditions for solving particular organizational problems and to inform new organizational designs, thus advancing the change process (Robson, 2002). Baskerville and Wood-Harper (1996) suggest that the ideal action research domain must possess the following key characteristics: (a) the researcher is actively involved with expected benefit for both researcher and organization, (b) the action research is a process linking theory and practice, and (c) the knowledge obtained during the action research project can be immediately applied. This study is consistent with the above criteria. I worked closely with the organization's leadership and applied the input provided by middle managers in designing a management training intervention, a workshop activity that engaged managers in the strategizing process. Activity Theory framework provided the theoretical foundation for the design of this event, the content of which was defined by managers themselves and was focused

on the immediate practical issues experienced by the organization at that time. The outputs of the strategizing experience were applied in planning specific change actions that followed the strategizing event.

A challenging aspect of action research is the conflict between the necessity to employ a certain research framework and the fact the any research framework would be restrictive, thus preventing an action researcher from gaining a richer understanding of the phenomena being studied (Argyris, 1997). The level of scientific discipline in planning, conducting, and documenting action research is important not only from the methodological perspective but also from the learning that results from the intervention conducted by action researchers (Argyris & Schön, 1989). In this study, several measures were taken to address the issue of rigor and validity of action research:

1. Established theoretical models and frameworks are used for guiding the research activities.
2. Operational description of the steps conducted by the action researcher is provided.
3. Linkages between the strategic episode and the change implementation plans are explored.
4. Alternative factors contributing to the organization's changes reported after the training intervention are discussed.

Embedded Case Study

In this study, the embedded single-case study (Yin, 2003) is used as a research strategy. Yin defines a case study as an "empirical inquiry that investigates a contemporary phenomenon within its real-life context, benefits from the prior development of theoretical propositions to

guide data collection and analysis, and relies on multiple sources of evidence, with data needing to converge in a triangulating fashion" (p.13).

According to Yin, a selection of a single-case design is justifiable when the study represents the critical case in testing some theoretical propositions, which is true in the context of this study. This exploratory research is testing whether and to what extent Activity Theory can be used by a corporate organization seeking to support its managers during a time of change. Although Activity Theory has been introduced as a potentially effective analytical tool (e.g., Mwanza, 2001; Marken, 2005), the question of practical application of Activity Theory in both corporate and academic learning environments remains largely unexplored. Moreover, neither the theory nor the strategic tool it inspired were ever applied in the context of organizational strategic development and redesign of the business systems. This case study is charting a new path of Activity Theory application in the organizational context that may be explored further by future studies.

Within the single case study, several subunits of analysis may be incorporated, resulting in a more complex, or embedded, research design (Figure 6).

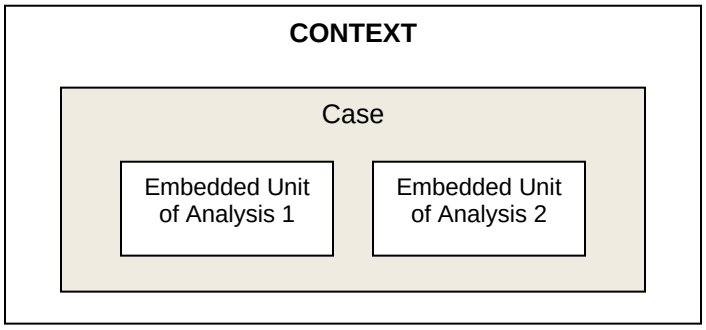


Figure 6. Embedded Single-Case Study Design
(Adapted from Yin, 2003, p.40)

These subunits can provide opportunities for extensive analysis of any specific phenomenon in operational detail and enhance the insights into a single case. However, Yin emphasizes the importance of the appropriate balance between the subunit of analysis and the holistic aspects of the case in order to avoid unjustifiable shift in the original inquiry orientation.

In this study, the subunits were four business systems selected for analysis and redesign at the workshop due to their criticality for the MTS change program: Acceptance from Development, Process Validation, Technology Transfer, and Deviation Management. The embedded case study design allowed me to extensively examine the strategic designs and managerial discourse at a subunit level, make a comparison across the subunits, and return to the larger unit of analysis – the MTS change program – in order to generate interpretations and conclusions about the common issues and trends in the particular organizational context.

Data Collection Methods

Mixed methods of data collection were utilized in this study (Creswell, 2003). The advantage of the mixed method approach is related to its diversity of data collected and the opportunity to triangulate the data thus counterbalancing qualitative and quantitative limitations and achieving a more complete understanding of the phenomena being studied (Green, Caracelli, & Graham, 1989; Tashakorri & Teddlie, 1998). This method is found to be particularly relevant for studying complex social environments and addressing the research questions having practical implications (Creswell, 2003).

In this study, both qualitative and quantitative types of data were collected with the purpose of capturing the strategic knowledge of middle managers, identifying the strong linkages between the organizational components involved in strategic events, and determining the

contradictions within and between organizational components that created barriers to strategy implementation.

A concurrent triangulation approach (Figure 7) was used to collect both quantitative and qualitative data through document analysis, interviews, and surveys in order to confirm and cross-validate the issues related to strategy implementation (Creswell, 2003; Green et al., 1989).

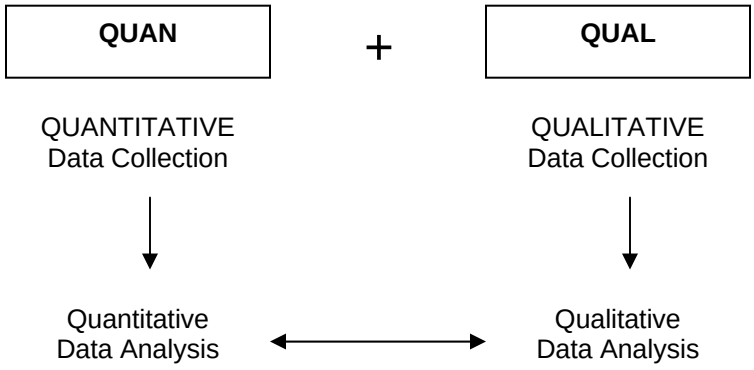


Figure 7. Concurrent triangulation research
(Adapted from Creswell, 2003, p.214)

A concurrent triangulation approach is characterized by using two different methods with the purpose of confirming, cross-validating, or corroborating findings within a single study (Greene et al., 1989; Morgan, 1998). It assumes a collection of types of data during one phase of the study, which requires a shorter data collection period than in any of the sequential methods, and the results are integrated during the interpretation phase (Creswell, 2003).

In this study, the data obtained through the survey questionnaire were analyzed using statistical techniques while the documents, interviews, and focus groups were analyzed qualitatively. This approach is consistent with what Tashakkori and Teddlie (1998) describe as a multilevel design. The reason for selecting the concurrent triangulation approach was to analyze the situation from different perspectives and counterbalance the weaknesses and limitations of each method. The surveys were designed to obtain information from the line managers regarding

their knowledge of the strategic content and the challenges they experienced when implementing change proposed by the organization's executives and the strategic planning group. The qualitative data that included the semi-structured interviews with the top management team were intended to provide the executive perspective on the issues surrounding the strategic change agenda implementation and compare the executive point of view with the issues specified in the surveys. It is important to note that both types of data were collected concurrently, and the themes that emerged in both areas were compared in the data analysis stages preceding and following the workshop.

Research Project Timeline

As indicated in Chapter Two: Organizational Context, this dissertation study which focuses on managerial strategic learning was embedded in the corporate consulting project that took fourteen months to complete (see Table 2). In addition to the data collected during the strategic episode, which was a brief, three-and-a-half hour event, this study utilizes the data obtained for the consulting project several months prior and after this event. The complexity of the project demands additional clarification of the timeline, consulting and research activities and associated deliverables in order to assist the readers as they walk through the discussion of the study methodology and findings. The diagram below presents the timeline of the project and indicates the project phases ad specific activities and deliverables associated with each phase (Figure 8).

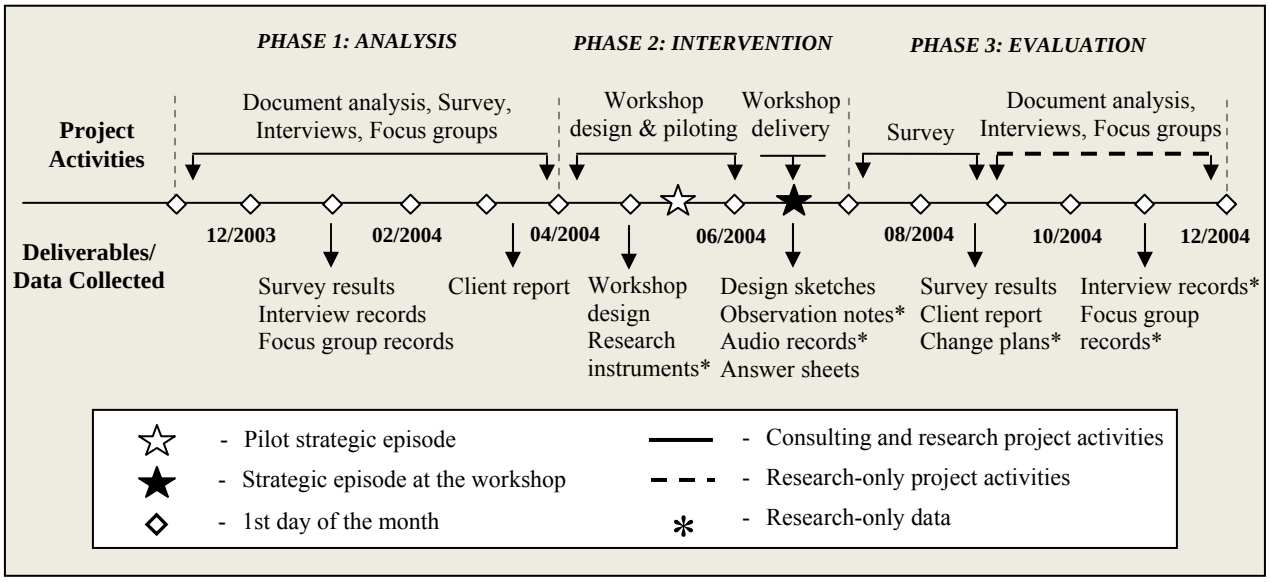


Figure 8. Project Timeline and Deliverables

Pilot Study

In May 2004, a pilot design activity was conducted with the group of managers (N=5) representing different functional units (N=3) and the strategic planning group (N=2).

The pilot study was concerned with: (a) development of the activity-based design tool to be used during a strategic episode; (b) defining procedures for examining strategic design results; and (c) defining the units of analysis of strategic interactions and developing a coding scheme for strategic discourse analysis.

During the pilot design session, which lasted two hours, observation notes were made to capture the dynamics of the teamwork. All design sketches were documented, and interactions of the pilot participants were audio recorded to collect the evidence supporting their design decisions.

Mwanza's methodology (Mwanza, 2001) was used for guiding design process and structuring analysis of the design outcomes. This methodology is concerned with

- modeling the situation being examined through interpreting the various components of the activity triangle through the series of open-ended questions (8-step model) discussed in the previous section, and
- analyzing the situation's Activity System through breaking it down into smaller manageable units of sub-activity triangles and answering the questions generated for each of the sub-activity triangles.

This methodology has been described in literature as an approach for analyzing problematic areas in organizational systems. An advanced approach was used in this dissertation study: the third phase - redesign of the analyzed system conducted by middle managers - was implemented utilizing an activity-based design tool.

Development of Activity-based Strategic Tool

The pilot version of the design tool was constructed through adaptation of Engeström's (1987) graphical representation of activity system and Mwanza's (2001) 8-step model applied to one of the strategic domains, Annual Product Review (APR).

First, the elements of the activity triangle were graphically outlined (Figure 9) and the participants were engaged in their interpretation using the APR context.

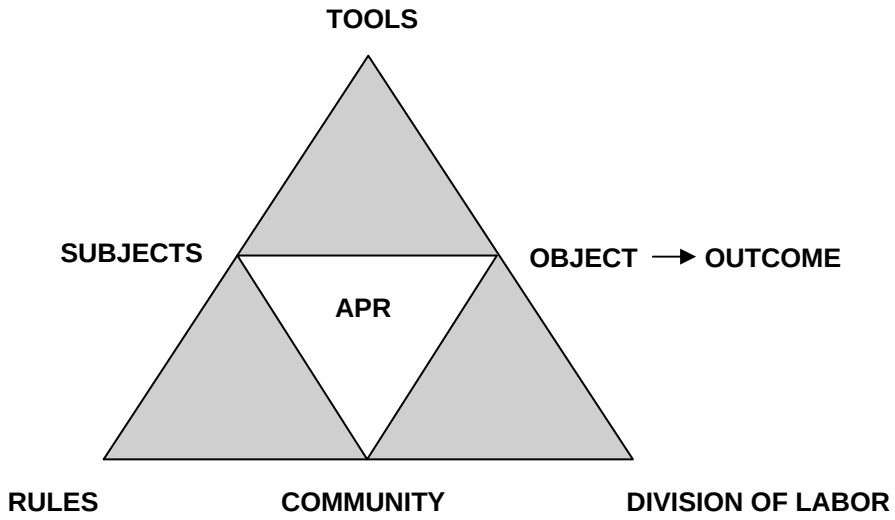


Figure 9. Activity-based Design Tool V.1
(Adapted from Engeström, 1987 p.78)

Managers were asked to respond to a set of open-ended questions associated with each element of the activity triangle. The reason for doing this was to ensure the match between the interpretations of the system's elements suggested by the pilot participants and their understanding of the APR process where these elements are enacted. The questions were generated based on the 8-step model questions generated in Mwanza's study (2001):

1. *Activity* of interest: What sort of activity is in focus?
2. *Subjects* in the activity: Who is involved in carrying out this activity?
3. *Object* of activity: Why is this activity taking place?
4. *Tools* mediating the activity: By what means are the subjects carrying out this activity?
5. *Rules* and regulations mediating the activity: Are there any organizational norms, rules or regulations governing the performance of this activity?

6. *Division of labor* mediating the activity: Who is responsible for what while carrying out this activity, and how are the roles organized?
7. *Community* in which activity is conducted: What is the environment in which this activity is carried out?
8. Activity *Outcome*: What is the desired outcome from carrying out this activity?

The participants were engaged in the exchange of ideas assisting each other in generating the interpretations relevant to the APR domain. My role was to support the participants in the process of applying abstract concepts in the specific business context by providing the questions listed above and prompting the participants with open-ended questions. The goal was to let the model emerge through the negotiations between the pilot participants.

The initial phase of the pilot test revealed the necessity of modifying the design tool. The participants struggled with several aspects of the model; therefore, certain modifications had to be made before they could proceed with modeling the APR system.

The first level of modifications was concerned with the language used for identifying the elements included in the Activity Theory triangle. The words "subjects", "object", or "division of labor" were either abstract and confusing to the pilot participants or perceived as too academic and derived from the philosophical domain. Those concepts needed to be matched with the terms that would be understandable for the people working in the organization. Therefore, *Subjects* was replaced with *People*, *Object* with *Tasks*, *Division of Labor* with *Functions*, and *Tools* received additional definition becoming *Methods/Tools*. Moreover, I developed additional identifiers to ensure that managers focused on the same phenomena as they constructed the specific designs. Thus, the People category was supported by the *Key Players* identifier; Methods/Tools - with *Documents, Procedures, Technologies*; Rules – with *Controls, Standards, Expectations*; Tasks –

with *Problem Space*; and Functions – with *Roles Distribution, Level of Involvement.* These identifiers, formulated in a language that was accepted and understandable in the organization, helped me to communicate rather abstract concepts embedded in the activity model.

The most significant change, however, was concerned with the model's Community category. When Community was introduced in the initial design of the tool, the pilot design exercise revealed two main issues. First, the pilot participants expressed their concern that Community and People were somewhat redundant. Although they did understand that the Community category was about identifying all the stakeholders and the overall environment where activity takes place, they argued that the activity is rather embedded in the specific organizational environment influenced by certain stakeholder groups. In other words, they proposed that the community of stakeholders belongs to the larger organizational system, as opposed to being an element of the smaller activity system. Even when they identified the Community components for their business activity for the sake of an exercise, they expressed concerns that this element did not interact much with other elements of the activity, thus not contributing to the systems' dynamics and its decision-making processes.

The second issue was about the missing time/context aspect of the activity. In the manufacturing process, the stages and phases are critical, and they form a continuous development and production cycle. Depending on the process step, the context changes, and so do the players, technologies, and rules involved in performing that step. The pilot group argued that any process constructed during the strategizing activity does not exist in isolation but takes place during a certain phase of the product lifecycle and affects certain organizational structures. Therefore, the suggestion was made to integrate the Context category into the activity model thus replacing Community. The pilot group suggested that those concepts have similar meaning, as

they both are concerned with identifying the environment, or the context, in which the activity is carried out. I tend to agree with such a perspective that is also expressed in the Activity Theory-based studies where the Community aspect is defined in environmental or contextual terms (Barab et al., 2002).

In order to assist managers further in their strategic design process, the set of questions based on the 8-step model (Mwanza, 2001) was modified to support managers' interpretations of various components of the activity system designed during the strategic episode.

The following questions were generated for each element of the activity model:

1. People *(Key Players)*: Who is directly involved and responsible?
2. Tasks *(Problem Space)*: What is the goal? What problems are being solved?
3. Methods/Tools *(Documents, Procedures, Technologies)*: How are procedures performed? What tools and methods are used?
4. Rules *(Controls, Standards, Expectations)*: What internal and external standards regulate the event?
5. Context *(Product lifetime context)*: What organizational structures and WCC stages are impacted?
6. Functions *(Roles Distribution, Level of Involvement)*: How are the roles distributed? What functions are performed?
7. Outcome (*Result)*: What is the outcome of the event?

Figure 10 demonstrates the results of the above modifications integrated in the final version of the activity-based tool used in the workshop.

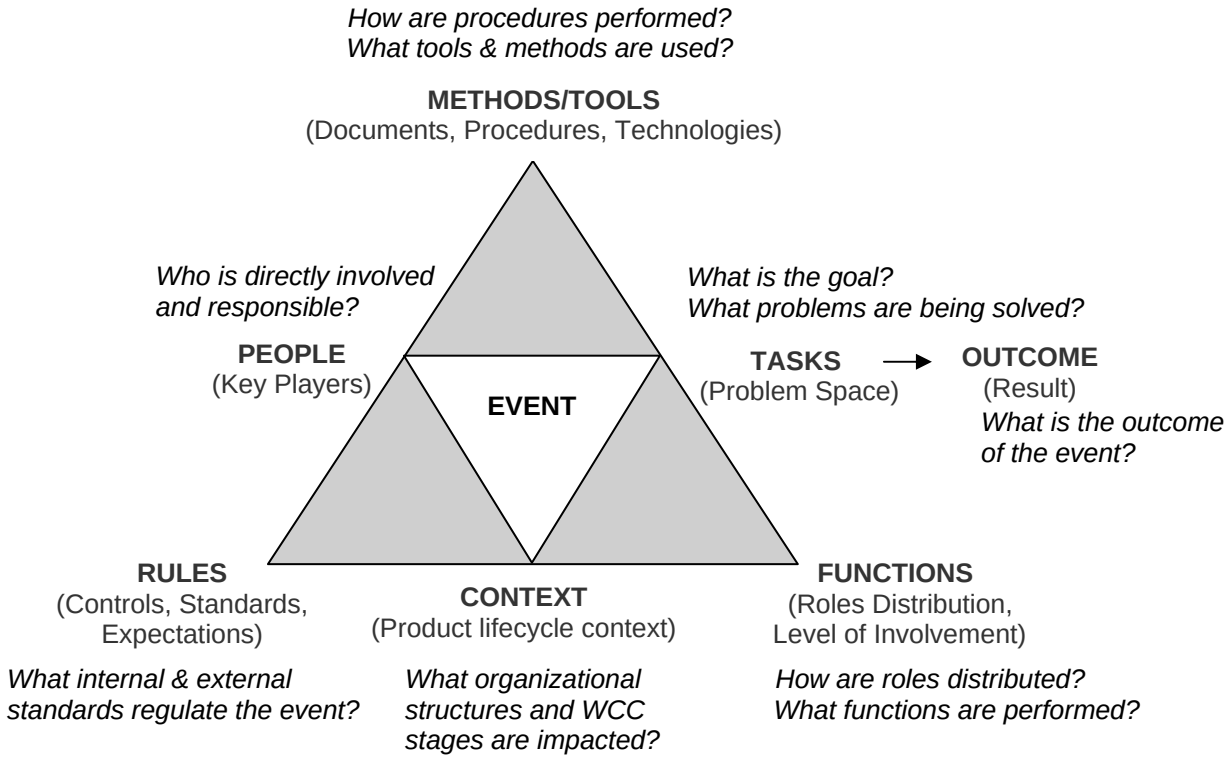


Figure 10. Activity-based Design Tool V.2

Defining procedures for examining strategic design results

Once the final version of the design tool was reviewed and approved by the pilot participants, they were asked to apply it to the Annual Product Review (APR) system. The last sixty-five minutes of the pilot design session were spent on modeling, analyzing, and redesigning the APR system. My goals in this phase of the pilot were: (a) testing the activity-based design tool conceptualized in the previous phase; (b) examining the applicability of the extended Mwanza's methodology; and (c) developing criteria for evaluating the design process.

Modeling the APR system

The first several minutes of the design session were spent on modeling the current APR system. The pilot group started with discussing the organizational expectations related to the specific APR actions and deliverables (*Tasks* and *Outcome*). They proceeded with identifying

people who were directly involved in APR preparation and execution and discussed their roles in the APR process. Next, they listed the available templates, rubrics, and technical documents supporting the APR process and talked about external and MTS-based requirements for conducting APRs and preparing APR reports.

As the components of the APR system emerged in the design, the participants made comments about positive and problematic aspects of the system:

> *"Well, we have QPPAs [Quality Process and Product Assessments] and PQEs [Product Quality Evaluations] quite developed over the past two years, so it won't be that difficult to make transition to the APR model."* (Manager, Quality)

As the discrepancies in the system were revealed during the discussion, some of the managers proposed changes to the current APR design:

> *"We need to include statisticians under People. I wonder why it never occurred to anyone that MTS cannot put together a decent APR report if we do not involve the statistics group!"* (Manager, Quality)

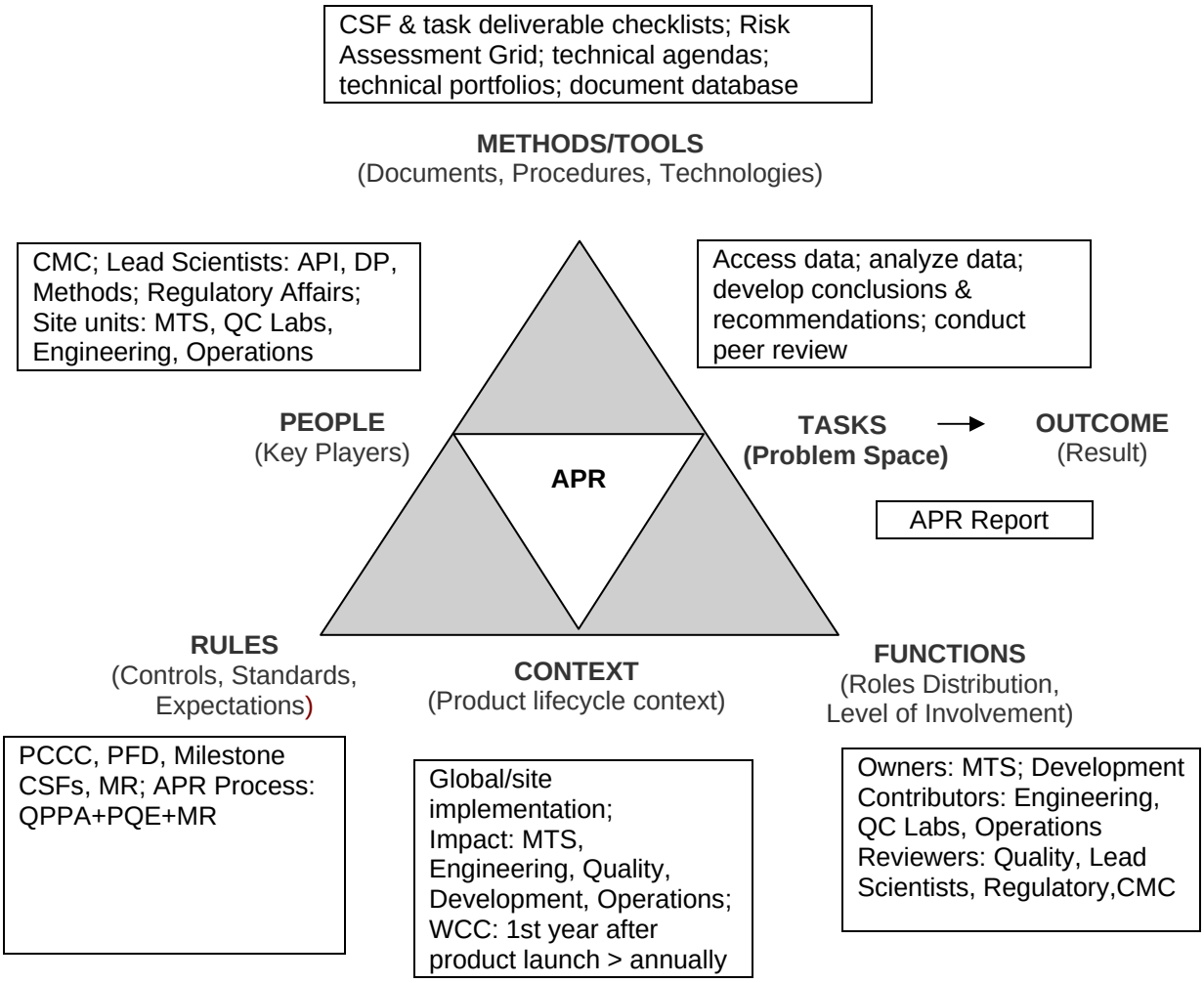
> *"MR [Manufacturability Review] 2-pagers can be listed under Methods . . . Jim is still working on them, and they are mostly for defining the WCC [World-Class Commercialization] gates, but, I think, they contain some useful information that would help with the APR deliverables."* (Manager, MTS)

In both instances, the propositions were noted, but the group decided to map the system "as is" before discussing any changes:

> *"Let's write down everything we have today on APR. This way, we'll see what's good, what's missing, and we'll go from there."* (Team Leader, MTS)

The Context component of the system was still challenging to the pilot group, and they had difficulty discussing it until I offered more specific questions: How does the APR affect the product lifecycle? How does it impact our processes? Whom does it help? What organizational units can use the APR and how?

The first iteration of the APR system constructed by the pilot group is presented in Figure 11.



NOTE: For abbreviations used in this design, see Appendix L.

Figure 11. Initial APR System

Analyzing the APR system

Once the current system was mapped onto the activity tool, the pilot group engaged in discussions of interactions between the APR system components they identified. The following guiding questions based on Mwanza's methodological approach (Mwanza, 2001) were developed to structure the discussion:

1. *People – Methods/Tools – Tasks*: How do technical documents, procedures, and technologies help the key players perform their tasks?
2. *People – Rules – Tasks*: What impact do external and internal regulations and performance expectations have on task completion?
3. *People – Functions – Tasks*: How does role distribution among key players help to achieve the event's goals?
4. *Methods/Tools – Context – Tasks*: What is the impact of the context in which the event takes place on the technical documents, procedures, and technologies used for completing the tasks?
5. *Rules – Context – Tasks*: How does the context of the event determine the rules regulating task completion?
6. *Functions – Context – Tasks*: How does the context of the event affect the distribution of responsibilities among the functional areas involved in execution of the tasks?

The goal of this interaction analysis was to examine to what extent managers are able::

- to identify and to substantiate strong linkages between the system components that help drive the event towards successful completion,
- to identify gaps and contradictions presenting the barriers to successful completion of the event and to explain the risks associated with them, and
- to formulate specific approaches for eliminating or reducing the identified gaps and contradictions.

Since the intent was to allow the process to emerge from managerial conversation, the pilot group received only general guidance on completing this activity. The managers

were asked to use the above questions to frame their conversation and focus on the following objectives:

- In each of the relationships you explore through these questions, please identify: (a) strong linkages that you can leverage to support the strategy implementation process; (b) gaps that need to be filled in order make the APR process more efficient and compliant with external and internal requirements; and (c) contradictions, or conflicts, within the APR system that have negative impact and need to be addressed through introducing some change.
- Propose and document changes that address your conclusions about the strengths and weaknesses of the APR system using the activity-based design tool.

The pilot group spent the next fifteen minutes on analysis of strong and problematic aspects of the APR system following the guiding questions. Among the strengths was mentioned availability of the well-structured, comprehensive documentation database, PILARS, which allowed immediate access to technical reports and statistical summaries required for preparation of APR reports (*People – Methods/ Tools – Tasks*). Another strong relationship between the system components was identified between *People*, *Rules*, and *Tasks*: a Process Flow Document, or PFD, was a newly introduced requirement that contained drug manufacturing requirements approved by the FDA, a step-by-step description of the production process, and criteria for standard processing. This document assisted employees responsible for the APR.

The gaps identified in the current APR system included:

- a lack of examples of similar industry practices that would serve as external benchmarks for those responsible for APR development (*People – Rules – Tasks*),

- a lack of consideration for Manufacturability Reviews, process milestone checks, and documents associated with them (*People – Rules – Tasks* and *People – Methods/Tools – Tasks)*, and
- a lack of a template for APR that would ensure consistency of the annual review among the sites and networks (*People – Methods/Tools – Tasks*):

> *"I would like to know how to determine if we have a good APR. Does it meet essential elements? When will all sites have one and what is a best practices example? During APR approval, I think hitting essential criteria is the goal. If we miss them, do not approve or approve at risk with missing critical elements. But they need to be identified and justified first."* (Manager, MTS)

Finally, the pilot group discussed a tension within the APR system that negatively impacted the whole process of APR development and management. This tension was related to the poor role distribution and ambiguity in assigning specific tasks to all the functional units involved in the APR process (*People – Functions – Tasks*):

> *"We need clarification on who owns APR, who contributes to it, and who does the final approval."* (Team Leader, MTS)

Redesigning the APR system

Once the system relationships were explored, the pilot group engaged in brainstorming potential modifications to their initial designs. Approximately twenty minutes were spent on negotiating specific solutions that would address the identified gaps and contradictions. The APR template, Manufacturability Review guidance documents, and schedule were integrated under the *Methods/Tools* category and Manufacturability Review was included as one of the internal processes guiding the APR development (*Rules* category). The *Rules* category also acquired an *Industry Practices* component to be used as a means for external benchmarking. The statistics group was added under the *People* category, as their involvement was deemed critical for the APR process, which involved extremely large amount of statistical analysis. Finally, ownership

of the APR process was clarified (*Functions* category): the group suggested assigning the roles of owner, contributor, and reviewer to the particular organizational units listed under *People* category.

An interesting observation made during the pilot session was that the participants assumed complete ownership over the design process and guided it virtually without my assistance. Thus, once the changes were identified, one of the managers suggested testing them using one of the plants as a context. In the course of the testing, the group discovered another gap: a lack of involvement of the statistical specialists whose role is critical preparing the process data analysis for the annual review. Historically, statistics specialists were not involved in the site operations and existed as a corporate group reviewing the results of the local efforts. The pilot participants argued that to be more efficient, every plant needed to include a statistical group who would work closely with those who monitored and recorded the data within the specific operational context.

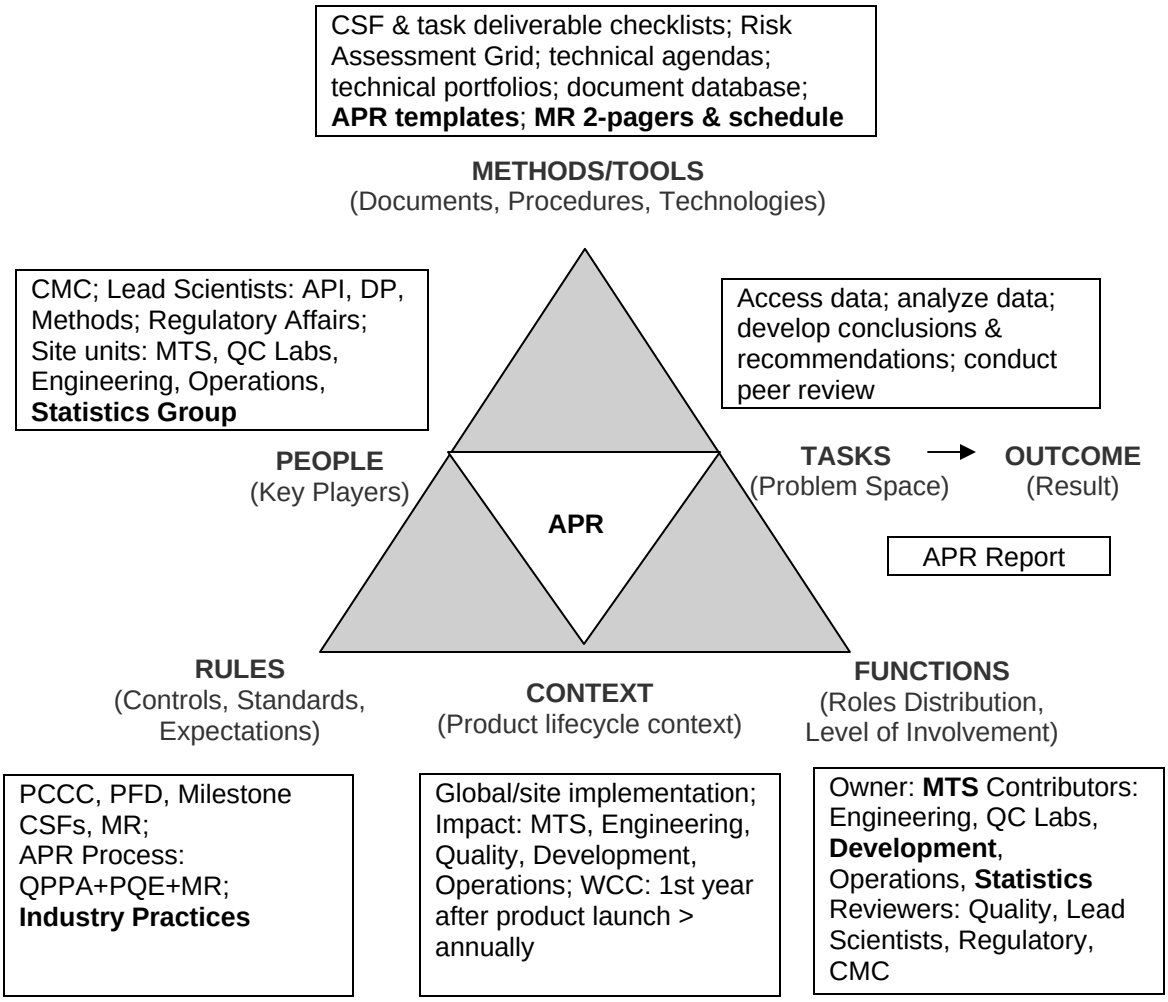
The examination of the new model also triggered debates about a potential impact of the proposed changes on other critical manufacturing processes:

> *"I think we need to talk about feasibility of the MTS ownership over several major projects at the same time. What if the group has to manage APR and, at the same time, lead the transfer to the overseas location, or work with Development on accepting a new product? We have to be realistic about how much we ask people to do."* (Team Leader, MTS)

Another interesting observation was related to an attempt to plan specific actions aimed at implementing the proposed changes. Although Mwanza's model does not suggest any steps beyond the identification of a system's problematic areas, the pilot group engaged in a brief discussion of what could be done to make those changes happen:

"First of all, statistical training is needed. Then we'll see what we can take care of ourselves, and what the stats people can help us with. We need to start somewhere if we want this to be executed anytime soon." (Manager, MTS)

Figure 12 demonstrates a modified APR system. The item in bold indicate changes made to the initial design.



NOTE: For abbreviations used in this design, see Appendix L.

Figure 12. Modified APR Activity System

Based on the observations and documented results of the pilot design session, the following propositions for evaluating the effectiveness of the Activity Theory-based design framework were generated for the main study:

1. The strategic design documents produced by the workshop participants will exhibit evidence of identified components of the business systems.
2. The strategic design documents will exhibit evidence of identified strong linkages between the system components.
3. The strategic design documents will exhibit evidence of identified contradictions (gaps and/or tensions) between the system components.
4. The strategic design documents will evolve during the strategic episode thus demonstrating change in business system structures and component relationships.

Identifying Units of Analysis for Strategic Discourse and Developing a Coding Scheme

Another major task of the pilot study was making a decision regarding the unit of analysis of the interactions during the strategic episode and developing a coding scheme based on the phases of the expansive learning cycle for analyzing the conceptual strategic discourse of collaborating managers. The expansive learning cycle (Engeström, 1999b) divides the process of knowledge construction into a sequence of seven epistemic actions:

1. questioning accepted practice,
2. analysis of the problematic situation,
3. constructing a model of the new idea that offers a solution to the problematic situation,
4. examining the model potentials and limitations,
5. concretizing the model by means of practical applications and conceptual extensions,
6. reflecting on learning process, and
7. consolidating the outcomes of the learning process into a new form of practice.

Unfortunately, Engeström (1999b) provides a rather limited explanation of how the process of movement through the phases is reflected in the discourse. He uses the concept of "turn" referring to numbered turns of talk in the discussion in order to mark the transitional points from one phase to another and does not elaborate on the strategy used for identifying conversational units comprising each phase.

In this study, the decision was made to focus on dialogical sequences, or speech segments as units of analysis for the coding of discussions. The dialogical sequence was operationally defined for this study as a unit of conversation comprised of one or more sentences linked to a single theme or addressing a single problem. According to the theory of dialogism (Bakhtin, 1981), language must be viewed as a part of a larger social context that affects future meanings. Meaning is negotiated and constructed as a result of cognitive conflict in social interactions. Taking advice from this theory, this study focuses not on individual messages in the analysis of the strategic conversations, but on sequences of messages and transitions between those sequences that indicate advancement of the conversation through the phases of social construction of new knowledge.

The pilot discussion was audio recorded and transcribed verbatim. Analysis of the discussion transcripts was supported with the observation notes that I made during the task. The notes contained comments on the time spent on specific topics and indications of the topic changes. First, the total number of conversational fragments in the transcript (68 fragments) was identified using Engeström's concept of "turn" to be able to mark the logical transition points in the conversation flow. Next, the on-task conversational fragments were separated from off-task conversational fragments related to logistical matters or clarifications of business terminology.

The off-task conversational fragments, which comprised approximately 14% of the total conversation data pool (6 fragments), were not analyzed.

The on-task conversational fragments were then unitized into dialogical sequences for further analysis. Sixteen types of dialogical sequences emerged from the data. Dialogical sequence frequencies and percentage were calculated, and temporary alphanumeric indicators were assigned to each of the sequence for use in further analysis. Table 3 lists the dialogical sequences in order from highest to lowest frequency of occurrence in the pilot discourse.

Table 3

Pilot study dialogical sequences

#	Dialogical sequence	Examples	Indicator	Frequency (N=62)	%
1	Propose and justify change	I think having a separate PQE for process systems is a burden to some sites, especially small ones. We should align PQE to the APR for different products. This way we can annually evaluate everything related to the product, including systems, and eliminate having two different schedules.	DS1	9	14
2	Examine gaps in the current system	The linkage between APR, the PFD, and the supporting validation packages is weak, if not absent. The APR appears to use different measures and criteria for acceptability than those used in the PFD or validation packages.	DS2	8	13
3	Examine contradictions in the current system	Who is accountable for the final APR report? MTS or process engineering? We do so much redundant work just because we never bothered to establish the roles for each function! If we clearly define who is responsible for what in APR process, we all will be much more efficient.	DS3	7	11
4	Integrate components into current system	Amy, could you check if I missed something under Rules category. We have QPPAs, PQEs that will merge, I am	DS4	5	8

	design	including FDA requirements. Wait a second… APR is our internal process, so no FDA document is listed here, right? Now, PCCC, of course… I think, this is it. Let's move on to the Tools piece.			
5	Negotiate components/ relationships of the changed system	A: It looks like that we still need to include the statistics into this triangle. What do you think? B: Well, their work is typically outside our area… A: But if we want to get serious about statistics, we have to include them. APR is 90% about statistics.	DS5	5	8
6	Criticize the proposed change	We don't use APR, we use PQE at our site. Why change it? We are reinventing the wheel. Again. It will take a lot of time, a lot… And we need to find people to make this transition - we do not have anyone to work on it right now.	DS6	5	8
7	Negotiate change/consider alternatives	I really like the idea of having an APR template, but do you think it will work OK for all the sites? The contexts are so different! Can we develop something else to help them?	DS7	4	6
8	Define problems in current system	External benchmarks are missing – we definitely need to discuss it.	DS8	4	6
9	Provide/Seek explanation of current system	I need a better understanding of how APR is related to my day-to-day activities. Where does it fit?	DS9	3	5
10	Negotiate current system design	We already have a high level preliminary process document; do you think we still need PQEs here? I guess, it will be too much redundancy….	DS10	3	5
11	Examine strong aspects of the system	Although we do not have the template yet, but the SFRs and risk assessment grids provide quite a bit of explanation on what's important. If you follow them closely, there is no way you can miss the critical stuff.	DS11	3	5

12	Discuss change implications for internal environment	I think we need to talk about feasibility of the MTS ownership over several major projects at the same time. What if the group has to manage APR and at the same time lead the transfer to the overseas location, or work with Development on accepting a new product? We have to be realistic about how much we ask people to do.	DS12	2	3
13	Use specific business examples for testing changed system	Let's say the APR is being prepared at the site. Let's try to walk through this triangle, step by step, to see what's missing here. OK… we need MTS, we need stats people…. *(cont'd)*	DS13	1	2
14	Discuss change implementation steps	Shall we now focus on what must be done to have those changes implemented? Both at the site and global levels. I think, first of all, we need the approved MR gates to know exactly where we take data measurements to include in the report.	DS14	1	2
15	Integrate change into initial system redesign	We need to make some decision here. We cannot go on forever. Let's include all the suggestions and test this model to see how it works. I think, everybody agrees that definition of roles should be included.	DS15	1	2
16	Integrate change into final system redesign	Ok, let's write down everything we want to have in the final version. First, we're adding all MR stuff, the template, and industry practices, right?..	DS16	1	2

A code-recode procedure was used to establish consistency in the coding of dialogical sequences over time. Two coders (a representative of the MTS Communications Group and a principal researcher) recoded the pilot data two weeks after the initial coding was completed, finding 87% (Coder 1) and 85% (Coder 2) agreement between the first and second coding. The inter-rater reliability was established through an iterative refinement of what constituted the scope and length of dialogical sequences until better than 80% agreement was reached between the coders (Bauer, 2000). Final inter-rater agreement was 93%.

The next step in the analysis was identifying the pattern of dialogical sequences that formed a discussion flow thus allowing the stages to emerge. The stages were identified and labeled based on:

- the prevalence of the specific categories of dialogical sequences at certain time periods;
- time periods spent on discussing specific topics indicated in observation notes; and
- the participants' statements indicating the change in conversation flow.

For example, during the first ten minutes, the pilot group was engaged in discussing and mapping the APR components using the triangle tool before they evidently progressed to the next stage by saying: *"All right, let's see now how we can deal with these issues here. I suggest we take turns and comment on the problem points on this drawing."* (Team Leader, MTS). This first time period of discussion contained the following dialogical sequences:

- DS1: Propose & justify change - 2 (3%)
- DS4: Define problems in the current system - 7 (11%)
- DS8: Provide/Seek explanation of the current system - 4 (7%)
- DS9: Define strong aspects of current system - 3 (5%)

As we see from the analysis of the first 10-minute conversation fragment, all the dialogical sequences related to examination of the current APR system appeared in the beginning of the conversation. There were two instances in the discussion when a pilot group participant offered a solution to the problem identified as the APR drawing progressed, but her colleagues requested her to postpone the problem analysis until the drawing was complete.

Based on the analysis of conversation transcripts and observation notes, the following stages of the pilot design session were identified (Table 4):

- Stage 1: Modeling the current system
- Stage 2: Examining the current system and formulating problems
- Stage 3: Negotiating changes and modeling a new system
- Stage 4: Testing and modifying the new system
- Stage 5: Planning implementation of the new system

Table 4

Pilot study conversation flow

Stage	Description	Time	Sequences	Pilot Context (APR system)
1	Modeling current system and formulating problems	10 min	DS1: 2(3%) DS4: 7(11%) DS8: 4(6%) DS9: 4(6%) DS10: 3(5%)	- Discussing the current status of APR system: identifying participants, processes, and requirements. - Negotiating components. - Defining problems (unsubstantiated problem statements). - Mapping the current system. - Proposing changes to existing APR system (isolated episodes; postponed by participants until later stages of the discussion).
2	Examining current system	15 min	DS2: 8(13%) DS3: 7(11%) DS11: 3(5%)	- Analyzing strong aspects of the system that can be leveraged; justifying their value and position in the current system. - Conducting in-depth risk analysis of the gaps and contradictions; demonstrating their impact on APR system.
3	Negotiating changes and modeling new system	19 min	DS1: 7(11%) DS6: 5(8%) DS7: 4(6%) DS15: 1(2%)	- Discussing the ways the problems may be addressed; identifying pros and cons of the potential solutions. - Exploring alternative problem solutions and coming to an agreement regarding the final modifications of the APR system. - Making changes to the APR system.

4	Testing and modifying new system	13 min	DS5: 5(8%) DS13: 1(2%) DS16: 1(2%)	- Experimenting with the new APR system design by applying it to a business context and identifying its potentials and limitations. - Making changes to the APR system design based on the results of its practical application analysis.
5	Planning new system implementation	8 min	DS12: 2(3%) DS14: 1(2%)	- Identifying the potential impact of the changes made in the APR system on related business processes. - Discussing specific actions focused on implementing the changes.

This flow of the pilot study strategic conversation provided the initial evidence of the progression of the conversation through the phases that were comparable to the stages of the expansive learning cycle described by Engeström (1999b). These results needed further verification through the analysis of the full-scale study data.

Table 5 compares the expansive learning cycle with the stages that emerged during the pilot design session.

Table 5

Comparison of expansive learning cycle and pilot session stages

Stage	Expansive Learning Cycle	Pilot Design Session
1	Questioning	Modeling current system and formulating problems
2	Historical and Actual-Empirical Analysis	Examining current system
3	Modeling New Solution	Negotiating changes and modeling new system
4	Examining New Model	Testing and modifying new system
5	Implementing New Model	Planning new system implementation
6	Reflecting on the Process	
7	Consolidating the New Practice	

No examples of Stages 6 and 7 were found in the pilot data. This could be explained by the limited time allocated for the pilot session, and by the "miniature" nature of the innovative learning cycle that took place during the pilot study (Engeström, 1999b). Consolidating the new practice, as Engeström suggests, takes place over time, in the context of large-scale expansive cycles of organizational transformation, where organizational members have an opportunity to establish and evaluate new practices that originated in multiple strategizing events. The decision was made to conceptualize the process of social construction of strategic knowledge as a sequence of five stages during which the conversation of strategizing actors advances from modeling a current system and indentifying problems to planning new system implementation.

Once the stages of the strategic knowledge construction were defined, the dialogical sequences were recoded based on the stage they characterized. Table 6 provides the final coding scheme that was prepared for analysis of the managerial conversations in the main study.

Table 6

Final coding scheme

Stage	Code	Description
Stage 1: Modeling current system and formulating problems	S1A	Provide/Seek explanation of current system
	S1B	Negotiate current system design
	S1C	Integrate components into current system design
	S1D	Define problems in the current system
Stage 2: Examining current system	S2A	Examine strong aspects of the system
	S2B	Examine gaps in the current system
	S2C	Examine contradictions in the current system
Stage 3: Negotiating changes and	S3A	Propose and justify change

modeling new system	S3B	Criticize the proposed change
	S3C	Negotiate change/consider alternatives
	S3D	Integrate change into initial redesign
Stage 4: Testing and modifying new system	S4A	Use specific business examples for testing changed system
	S4B	Negotiate components/ relationships of the changed system
	S4C	Integrate change into final redesign
Stage 5: Planning new system implementation	S5A	Discuss change implications for internal environment
	S5B	Discuss change implementation steps

Based on the results of the pilot discourse analysis, the following proposition for evaluating the effectiveness of the Activity Theory based design framework was generated for the main study:

- During the strategic episode, the discussions of collaborating managers will exhibit evidence of advancement through at least the first five stages of the expansive learning cycle, with a shift towards higher stages over time, thus manifesting the process of social construction of strategic knowledge.

Once the pilot session concluded, I began design and development of the workshop during which the large portion of the research data was collected. In the paragraphs below, I present the study participants and discuss the workshop activities.

Study Context

Workshop Participants

The study participant group was a convenience sample of 86 managers invited to participate in the workshop. They were the same people who participated in the needs analysis survey. The group included 89.5% MTS employees representing four manufacturing networks and 10.5% representatives of partnering organizations, Engineering and Quality Control. The average tenure at the company was reported 7.4 years. The participants included representatives of all MTS managerial levels: network directors (17.4%), project managers (31.4%), process consultants (19.8%), team leaders (14.0%), and project associates (17.4%). Appendix D summarizes demographic information of the study participants based on their network affiliation. MTS managers represented both the US and overseas manufacturing divisions.

The workshop participants were divided into four groups, each led by two facilitators. The groups worked independently in separate rooms and met for a debriefing session at the end of the workshop. The group affiliation was established by the MTS Communications group based on the proposition of equal representation from four different manufacturing networks and different functional units: MTS, Engineering, and Quality Control to give managers an opportunity to work with their colleagues from partner organizations. A color-coding system was used to communicate a group affiliation: Blue, Green, Red, and Yellow. Appendix D summarizes demographic information of the workshop participants. Each group was working on analysis and redesign of the four business systems: Process Validation (Group Blue), Technology Transfer (Group Green), Deviation Management (Group Red) and Acceptance from Development (Group Yellow).

At the beginning of the workshop, participants received a file containing a Learner's Guide, activity handouts, and a group-specific color label. Facilitators received a Facilitator's Guide (Appendix F) two week prior to the workshop, and attended a 4-hour facilitator training conducted by the MTS training consultant and myself to ensure that the workshop activities were consistent, followed the same format, and that the strategic messages were communicated adequately across the groups.

Four observers, including myself, conducted observations of the workshop activities and made notes using an observation matrix (Appendix G).

Workshop Overview

The workshop opened the global MTS conference on June 15, 2004 where managers and executives from four manufacturing networks gathered to discuss the change agenda implementation progress and address the issues that had to be urgently resolved. The workshop was designed as a sequence of three activities, Activity 1 and 3 lasted sixty minutes each, and Activity 2 lasted 40 minutes.

In the first activity, "Connecting the Dots", managers were asked to use the activity-based strategic tool to analyze the components and relationships comprising each of the four business systems and identify the issues that present barriers to system performance. They were then asked to identify and discuss the changes that would help address those issues and design the improved models of the business systems. This activity was in the focus of the research study, and only the data collected during this activity was analyzed for research purposes.

In the second activity, "Making It Real", the workshop participants worked on identifying the course of action for implementing the changes proposed in the first activity, discussed

feasible steps and timelines for implementing those changes and evaluated the advantages and disadvantages of each potential solution.

The final workshop activity, "Putting the Moose on the Table", invited managers to examine the Medex-specific issues presented in brief business scenarios. Each scenario was related to one of the four business systems they analyzed in the previous two activities. Here, managers were expected to collaboratively analyze the problems, propose solutions and evaluate them from the scientific, business, technical and regulatory compliance perspectives in order to generate an optimal solution.

The progression of the workshop activities allowed the workshop participants to learn how the MTS strategic change requirements can be interpreted at the practical level, when dealing with the specific business challenges.

Since only the first activity was in focus of the dissertation study, I will refer the reader to Appendix F for more information on the other workshop activities and will continue with description of Activity 1 - a strategic episode - during which the activity-based strategic tool was used and research data was collected.

Strategic Episode

The following paragraphs describe the design of the strategic episode outlined in both Learner's and Facilitator's Guides.

At the beginning of the strategic episode, managers were asked to review an activity-based template that was developed during the pilot session (Figure 9) provided in their Learner's Guide. They were explained that the template would be used during the exercise to assist them in the analysis of the business systems assigned to their groups. Those business systems, Process Validation, Technology Transfer, Deviation Management and Acceptance from Development,

referred to as 'events' in the activity description, were critical processes in the product lifecycle. Managers were asked to work in small teams for five minutes to generate answers to the following questions related to the business system assigned to each group:

- What is the main goal of the business event? What tasks need to be performed? What problem is being solved?
- What is the expected outcome of the event?
- What functional areas are directly involved in this event and who are the key players?
- How are the roles distributed among the key players? What expertise do these people have?
- What is the context within which this event takes place? What organizational structures are affected?
- What rules/standards regulate this event? What are the sources of those rules?
- What procedures, methods, tools and technologies are used to carry out the event?

Once the team brainstormed the answers separately, they were expected to spend next fifteen minutes discussing their propositions as a group and organizing their answers on the large template printed on the poster. Managers used the activity-based template for organizing the answers to the above questions into the categories included in the template: *People, Context, Rules, Functions, Tasks, Methods/Tools, Outcome*.

Once the answers were recorded on the poster, managers were invited to 20-minute discussion of interactions between the event components they had identified. The following guiding questions based on Mwanza's methodology (Mwanza, 2001) were used:

- *People – Methods/Tools – Tasks*: How do technical documents, procedures and technologies affect the ways the key players perform their tasks?
- *People – Rules – Tasks*: How do the external and internal regulations and performance expectations affect the task completion?
- *People – Functions – Tasks*: How does role distribution among key players impact the achievement of the event's goals?
- *Methods/Tools – Context – Tasks*: What is the impact of the context in which the event takes place on the technical documents, procedures, and technologies used for completing the tasks?
- *Rules – Context – Tasks*: How does the context of the event determine the rules regulating task completion?
- *Functions – Context – Tasks*: How does the context of the event affect the distribution of responsibilities among the functional areas involved in execution of the tasks?

Facilitators working with specific groups assisted managers in this analytical step by clarifying the questions and interpreting them in the context of the event under analysis. For example, Group Blue, which focused on Process Validation system, examined the relationships between the system components using the following questions:

- *People – Methods/Tools – Tasks*: How do standard operating procedures, process specifications and process validation protocols affect the ways the MTS and its partner groups run process validation lots and analyze and report the data?
- *People – Rules – Tasks*: How do the FDA requirements and corporate regulations, such as quality policies and standards impact the completion of validation tasks?

- *People – Functions – Tasks*: How do the roles and responsibilities regarding process validation are distributed among MTS, Quality, Development, Quality Control Laboratories, Engineering, Operations and Statistics? How does this division of responsibilities affect the completion of validation tasks?
- *Methods/Tools – Context – Tasks*: Is there a relationship between the specific WCC stages and the ways validation is managed and documented?
- *Rules – Context – Tasks*: How do the specific WCC stages (e.g., transferring the process from Development to Manufacturing versus transferring the process to a new facility) determine the use of technical requirements according to which process validation is performed and documented? Are there different rules for new process validation versus revalidation of existing process?
- *Functions – Context – Tasks*: Do the roles of functional units involved in validation; MTS, Quality, Engineering, Operations and others change based on the context in which validation is performed, for example, validating at the third party plant or validating a new process just transferred from Development? If so, in what way do they change?

As the learners analyzed the system's dynamics using the guiding questions, they were asked to identify, justify and record: (a) strong relationships between the system components that helped driving the event towards successful completion, and (b) gaps and contradictions that present barriers to the successful completion of the event.

Although the workshop participants used the guiding questions provided by the template, they were given an opportunity to explore the relationships between the system components they identified and generate any questions that would assist their inquiry into the nature of those

relationships. When designing this task, I intentionally did not place constraints on the ways managers would approach the analysis of system relationships having two reasons in mind. First, managers undoubtedly knew the context of their work more than any design could provide and they would have a more meaningful strategizing process if they had an opportunity to regulate their own discussions focusing on the issues they deemed the most important. Second, I expected them to explore all possible relationships between the system components, not just the ones predetermined by the activity design, so the managers would be able to identify more effectively system gaps and contradictions.

Once the groups identified the strengths and weaknesses of the systems under analysis, they were asked to brainstorm the potential ways of eliminating or reducing the identified gaps and contradictions and make necessary modifications to their initial system designs on the posters to reflect their recommendations. This final part of the episode was expected to take approximately twenty minutes.

Several data sets were collected during the strategic episode, including observation notes, audio records of the group discussions when they consolidated their notes into the poster designs, activity worksheets, and the posters with initial and modified designs. This data, along with the pre- and post-workshop surveys constituted primary research data. In the next several paragraphs, I provide a detailed description of all the data collected and analyzed in this dissertation study, discuss their role in addressing the research questions and their alignment with the project phases. The outline of the data collection procedures will follow the description of the data.

Data Collection Process

As mentioned in previous sections, both qualitative and quantitative data collection methods were used in this study including surveys, observations, interviews, focus groups, and document analysis. Table 7 provides a summary of the data types collected for this study.

Table 7

Summary of data types

Data type	Method	Collection period	Details
Quantitative	Surveys	Phase 1	153-item written questionnaire 86 individual questionnaires (response rate 100%)
		Phase 3	74-item written questionnaire 79 individual questionnaires (response rate 92%)
Qualitative	Documents	Phase 1	Strategic documents: 1 change agenda document; 26 presentations; 37 reports and strategic summaries; 5 video broadcasts; 14 tutorials
		Phase 2	8 design documents produced by four teams of managers during the workshop
		Phase 2	16 Activity 1 Worksheets completed during the workshop
		Phase 2	Workshop Participant's & Facilitator's Guides
		Phase 3	4 change agenda implementation plans representing 4 manufacturing networks
	Interviews	Phase 1	1 individual interview with MTS executive
		Phase 1	7 individual interviews with members of the strategic planning group
		Phase 3	8 individual interviews with MTS managers
	Focus groups	Phase 1	2 focus groups with members of the strategic planning group (FG1: n=3; FG2: n=4)
		Phase 3	2 focus groups with managers participated in the workshop (FG3: n=3; FG4: n=3)

Observations	Phase 2	4 observation documents of the workshop sessions
Conversation records	Phase 2	4 audio recordings of the workshop sessions

The primary research data included: (a) surveys administered before and after the workshop, (b) design documents and related activity worksheets produced during the workshop, and (c) workshop conversation records. The secondary data included (a) interviews and focus groups that followed the workshop, (b) observation notes of the strategizing episode, and (c) change agenda implementation action plans submitted by MTS managers after the workshop delivery.

Some of the data, such as MTS strategic documents and interview records with executives and the strategic planning group conducted prior to the workshop, were collected under the scope of the consulting project. Although they are listed in the next section as data sources that informed the design of the workshop and shaped the context of the research study, they are not considered research data.

The data in this study was collected and analyzed concurrently in order to inform the consequent research steps. I organize the description of the data sources and data collection procedures based on the project phases discussed previously in this manuscript.

Data Collection: Phase 1

Documents

The documents collected and analyzed during the first phase of the project were critical for developing understanding of the strategic content areas the organization was focusing on. The

format of the documents varied from slide shows to text documents to video fragments of conference presentations and discussions.

The documents used in Phase 1 of the study could be grouped into the following categories:

1. Change agenda documentation, a set of strategic directions and performance expectations organized into four critical business areas:
   - People: Capability, Capacity, and Development; Training and Development; Organization Structure
   - Processes: Project Management, Capacity Planning and Time Entry, Technical Governance, Validation, Statistics
   - Products: Technical Evaluation Documentation, Documentation Management
   - Technology: Technology Advancement and Development, Process Analytical Technology, Data Management
2. PowerPoint presentations containing strategic messages, best practices, and examples of implementing innovating processes and management practices within the company and the industry sector.
3. Reports and summaries from the workplace produced by innovating managers.
4. Video broadcasts of the executive talks at the conferences, workshops, and briefings focused on four critical business areas of the change agenda outlined above.
5. Tutorials designed to assist MTS managers in managing process validation, quality product evaluations, and other critical business processes.

All the documents listed above were provided by the MTS Communications group or obtained from the MTS Intranet site. The catalogue of the strategic documents from Phase 1 of the study is provided in Appendix A.

Interviews and Focus Groups

Semi-structured interviews were conducted with the MTS vice-president and seven members of the strategic planning group (Appendix C). Additionally, two focus groups were conducted with the members of the strategic planning group as the individual interview follow-ups. The MTS training consultant scheduled 2-hour sessions at one of the MTS facilities. Typically, at the interviews and focus group meetings, I was accompanied by the MTS training consultant who participated in the discussions and made notes for post interview analysis. All discussions were audio recorded.

Every interview session focused on one or two of the strategic content areas identified during the document analysis. The interviews and focus groups attempted to (a) elicit the interviewees' point of view regarding the importance of those areas for their organization, (b) reflect on the current processes from the improvement perspective in those strategic areas, and (c) to discuss the barriers to changing business process in those strategic areas. A basic set of starter questions were used at each discussion, and they typically led to more detailed and specific questions related to the participants' responses.

Below are the starter questions used in the interview session related to *process validation*, one of the several strategic content areas. Similar questions were used for every strategic content area explored in Phase 1.

- What process validation activities are currently in place, and who is involved in planning and executing them?

- Are there any issues related to process validation that MTS currently experiences? Are there any specific aspects of process validation that you consider problematic? Why, from your perspective, is process validation included in the change agenda?
- How are the current process validation activities, if they exist, different from the process validation expectations and requirements outlined in the change agenda? What new is proposed by the change agenda in terms of process validation?
- What value does the proposed process validation change bring to the MTS organization, its functional units, and individual employees?
- What must be done in terms of communication and employee education and support to ensure that process validation expectations and requirements outlined in the change agenda are fulfilled?

The interviews and focus groups were conducted as usual business meetings rather than as structured interview sessions. They evolved around the set of guiding questions followed by more focused questions that were built upon the participants' responses. (Strauss and Corbin (1994) emphasize the importance of open-ended interviews as they allow the emergence of other potentially relevant concepts. The questions were occasionally modified during the discussions to allow emerging issues to be considered. Due to time constraints, the recordings of the interviews and focus groups were not transcribed at the time they were collected. I reviewed every recording and made notes about the issues of change implementation as related to the topics outlined in the change agenda document.

Survey

The 153-item survey questionnaire (Appendix B) was administered to the study participants in Phase 1 in order to obtain information from the MTS managers about their current strategic competencies and received the feedback on their learning needs and the challenges they experienced when implementing change. The survey questionnaire was organized into the following sections:

1. General information: position, tenure, network affiliation.
2. Content knowledge in eight strategic areas: development, process validation, process flow, equipment qualification, technical and quality evaluations, countermeasures, site quality planning, World-Class Commercialization process.
3. Knowledge level of strategic concepts and processes: matrix-based assignments asked about interactions between roles, processes, and requirements in the context of several critical manufacturing events.
4. Strategy implementation capability through:
    a. demonstrating strategic problem-solving skills, and
    b. self-assessment of the following strategic competencies:
        - assigning roles and tasks in change-related activities,
        - planning and managing change-related activities,
        - evaluating impact of change on external environment,
        - evaluating impact of change on internal environment,
        - identifying and managing strong organizational aspects supporting change, and
        - identifying and managing barriers to change implementation.

5. Communication needs as related to strategic knowledge distribution.
6. Training needs as related to strategic content and skills acquisition.
7. Organizational support needs as related to strategy implementation.

The survey contained a comments section for each item that gave the managers an opportunity to elaborate on the answers they selected, and it contained a set of open-ended questions asking managers to provide critical strategy-related topics for discussions or to formulate strategy-related questions for the organization's leadership to address.

The text of the e-mail message requesting participation in the survey is provided in Appendix E. The responses were sent by the representative of the MTS Communications group, either by interoffice mail or by e-mail, were copied, and the names on the copies were coded by 3-digit numerical codes using the master code from Phase 1 surveys. The copies were then sent to me for further statistical analysis. The MTS Communications group retained the original responses.

Data Collection: Phase 2

Documents

The documentation collected during the strategic episode included the following:

- Eight design sketches completed on the posters by four groups of managers participated in the workshop. One set of sketches presented the current depictions of the MTS business systems that managers analyzed: Acceptance from Development, Technology Transfer, Process Validation, and Deviation Management. Another set of sketches presented the changes to the original designs.

- Activity worksheets (see Appendix F) completed by manager teams with notes related to the designs, such as lists of system components, identified strong linkages, gaps and contradictions between the system components.

All the documents were collected by a representative of the MTS Communication group after the workshop and all the manual notes and design sketches were converted into a digital format and sent to me for further analysis. The MTS Communications group retained the original documents.

Observations

The observation notes were made manually during the workshop design sessions by the principal researcher and three assisting observers. Observational matrix provided in Appendix G was used for assisting the observers in making notes and ensuring consistency across the notes made by four different observers. All the notes contained time records and corresponding topics of discussion. Some records were accompanied by the observer's comments on the most critical or controversial issues brought to the discussions:

> *"8:50am: Talking about corporate policies and standards for validation and recording them under Rules. Comment: Quick argument about mismatching content on policies and standards – decided to address later.*
>
> *8:56am: Moved to Tools – discussing protocols and who is responsible for them.*
>
> *9:07am: Discuss roles for MTS, Eng* [Engineering] *and QC* [Quality Control]. *Talk about ownership and contributing roles. Comment: all agree that roles are not defined at all. A lot of discussion on redundancy and multiple review circles for critical docs."* (Observer 1, Group Blue)

The notes were not consistent among the observers; some contained more accurate record of the strategizing process than others did; therefore, they were used as secondary evidence supporting the records of managerial discourse.

Discourse Records

Audio records of the discursive exchange of the managers participating in the workshop activities were made by digital audio recorders. Most audio fragments (approximately 80%) were partially transcribed, or the detailed notes were made on the most critical elements of the recorded discussions. Some of the audio files had poor sound quality and were excluded from analysis.

Data Collection: Phase 3

Documents

During the final phase of the study, I was provided with the change agenda implementation plans submitted to the MTS leadership by representatives of four manufacturing networks who attended the workshop. These documents were not considered by the research plan, but they were included in the analysis as they provided additional evidence on managerial strategic learning. The change agenda implementation plans were requested by the MTS vice-president who expected the conference attendees to reflect on business situation in their networks and outline the plan for implementing change agenda requirements for the next year and half. These plans provided an opportunity to examine the transfer of the strategic concepts that managers learned during the strategic episode into their real business environment. The main limitations of these documents were (a) lack of information about the authors of these plans and (b) free format of the plans that required the development of proxy measures in order to conduct the analysis.

Survey

In Phase 3, a 74-item survey questionnaire was designed to obtain the data on learning that resulted from participating in the collaborative design session, and to compare it with the initial survey outputs in order to measure learning gains (Appendix H).

The Phase 3 survey questionnaire was organized into the following sections:

1. General information: position, tenure, network affiliation.
2. Knowledge level of strategic concepts and processes: matrix-based assignments asked about interactions between roles, processes, and requirements in the context of several critical manufacturing events.
3. Strategy implementation capability through:
    a. demonstrating strategic problem-solving skills, and
    b. self-assessment of the following strategic competencies:
        - assigning roles and tasks in change-related activities,
        - planning and managing change-related activities,
        - evaluating impact of change on external environment,
        - evaluating impact of change on internal environment,
        - identifying and managing strong organizational aspects supporting change, and
        - identifying and managing barriers to change implementation.
4. Feedback on logistical aspects of the workshop.

Sections 2 and 3 contained the identical questions to the ones provided in the pre-workshop survey for the purposes of evaluating the learning gains resulted from participating in the strategic episode.

The text of the e-mail message requesting participation in the survey is provided in Appendix I. The responses were sent by the representative of the MTS Communications group, either by interoffice mail or by e-mail, were copied, and the names on the copies were coded by 3-digit numerical codes using the master code from Phase 1 surveys. The copies were then sent to me for further statistical analysis. The MTS Communications group retained the original responses.

Interviews and Focus Groups

Another series of semi-structured interviews and focus groups was conducted to obtain data about participants' reflection on the strategizing experience and learning from peer collaboration, and their plans to integrate what they learned into their business planning documentation (Appendix K). As in Phase 1, participants' responses to the general, broad questions that opened the interview session typically led to elaborations and to questions that were more specific. Two out of eight interviews were conducted over the phone, and the detailed notes were made immediately after the interviews. Six interviews and two focus groups were audio recorded, and selected fragments most closely addressing the research questions were transcribed. All interview and focus group records were extensively reviewed from the research questions perspective and for emergent themes.

Data Management and Analysis

The study data was analyzed in two phases. The MTS strategic documents and the outputs of the needs analysis survey were analyzed prior to delivering the workshop. The results of this early analytical stage informed the design of the workshop and content selection. The main data analysis process took place after the workshop delivery. In this section, I will discuss: (a) procedures established for organizing the data collected during and after the workshop, (b)

analytical strategy that guided examination of that data, and (c) data analysis steps for each data category.

Data Management Procedures

Due to the extensive amount of data collected for this study, the first step in the analysis was data organization designed for ease of access and efficient analysis. The following procedures were established for data management:

1. MTS Strategic documents were first organized into several categories based on the topics and format (e.g., validation > tutorial) in the strategic data folder and then were assigned a file name in accordance with the established naming convention for the study's digital data (e.g., validation_tutorial_093003.pdf).
2. All the interview and focus group audio records were transcribed, and the transcriptions were sanitized (the names of MTS employees were replaced by code names). The sanitized transcriptions were organized by format, source, topic of discussion, and date (e.g., Focus Group > Strategic Planning Team > Technology Transfer > November 23, 2003) in the interviews data folder and were assigned a file name in accordance with the established naming convention for the study's digital data (e.g., "focusgroup_spteam_techtransfer_112303.doc").
3. The survey responses were transferred to me by the MTS Communications group in already sanitized form, and the electronic files were titled based on the respondents' code names (e.g., "001.doc", "002.doc"). The survey outputs were organized in separate folders based on the study phase in which the surveys were administered (before or after the workshop delivery).

4. Observational notes were organized by group name and design theme (e.g., Observations > Group Blue > Validation) in the observations data folder and were assigned a file name in accordance with the established naming convention for the study's digital data (e.g., "observations_groupblue_validation.doc"). Next, the data from individual observation files was transferred to a Microsoft Excel file containing a cross-analysis table that allowed for time-based data comparison across participant groups. For example, I could compare the observations on all four participant groups made during the first 15 minutes of the workshop design activity.
5. Design sketches produced by managers on the flip pads during the workshop were converted to the Microsoft Word format with indications of changes made during the design. The sketches were organized into four separate electronic files in the design data folder based on the group that generated them and were assigned individual titles based on the source and design theme (e.g., Design > Group Red > Deviation: "design_groupred_deviation.doc").
6. Audio records of the strategic conversations were assigned the titles based on the source and design theme (e.g., Audio > Group Yellow > Acceptance: "audio_groupyellow_acceptance.wav"), then each audio files was transcribed and converted into the Microsoft Word format (e.g., "audio_groupyellow_ acceptance.doc").
7. Workshop notes generated by the participants were made on the workshop activity handouts and were converted into Microsoft Word format and organized

in four files based on the source and design theme (e.g., Notes > Group Green > Technology Transfer: "notes_groupgreen_techtransfer.doc").

8. Change agenda implementation plans submitted several weeks after the workshop delivery as electronic mail attachments were organized based on the network and date (e.g., Action Plan > SMBN > July 19, 2004: "actionplan_smbn_071904.doc").

Analytical Strategy

The analytical strategy for this study integrates several approaches: (a) content analysis (Krippendorff, 1980; Weber, 1990) of the observational data and workshop design outputs; (b) critical discourse analysis (Fairclough, 2003; Van Dijk, 1997; Weiss & Wodak, 2003) of managerial conversations during the strategic episode, and (c) descriptive statistical analysis of the survey results. The interviews, focus groups, and change agenda implementation plans were analyzed qualitatively.

The categories for the critical discourse analysis and content analysis were derived from Engeström's expansive learning framework (Engeström, 1999b) and the methodology developed by Mwanza (2001). The process for developing the analytical approach for examining the design documents produced by the managers and establishing a coding scheme for analyzing strategic discourse is discussed earlier in the Pilot Study section.

The following propositions for evaluating the effectiveness of the activity-based strategic tool in the managerial strategizing process were generated for this study:

1. The strategic design documents produced by the workshop participants will exhibit evidence of identified components of the business systems.

2. The strategic design documents will exhibit evidence of identified strong linkages between the system components.
3. The strategic design documents will exhibit evidence of identified contradictions (gaps and/or tensions) between the system components.
4. The strategic design documents will evolve during the strategic episode thus demonstrating change in business system structures and component relationships.
5. During the strategic episode, the discussions of collaborating managers will advance through five stages of the social construction of strategic knowledge, with a shift towards higher stages over time.
6. The managerial discourse will contain identification and analysis of strong relationships, gaps and contradictions between the system components as well as substantiated change propositions thus providing evidence of managerial strategizing activity.
7. The results of the post-workshop survey will demonstrate learning gains in relation to knowledge of the strategic concepts and their application in ill-structured problem solving contexts.
8. The workshop participants' self-assessment of the strategic skills in the post-workshop survey will improve in comparison to the initial survey.
9. The change agenda implementation plans produced after the workshop will contain the evidence of the transfer of the strategic concepts and design approach learned during the strategic episode into specific actionable items.

Considering the fact that the strategy workshop included two more activities that are beyond the scope of this study, as well as the managers' participation in the strategy conference

that immediately followed the workshop, the alternative factors contributing to the results reported after the training intervention were also explored. Such evaluation is necessary for determining whether the theoretical effects of the action research can be attributed only to the undertaken intervention among many other organizational actions simultaneously taking place in the researched context (Baskerville & Wood-Harper, 1996).

Data Analysis Process

The analysis of the study data included qualitative and quantitative methods. As indicated earlier, analyses were undertaken by means of critical discourse analysis (van Dijk, 1999; Wodak, 2002), descriptive statistics, content analysis (Krippendorf, 2004), and the emergent design approach (Lincoln & Guba, 1985).

Analysis of strategic designs

The first research question on the use of Activity Theory for identification, analysis, and resolution of strategic issues was addressed through examination of the design documents produced by the managers participating in the strategizing process that utilized an activity-based triangular tool. For detailed description of the design task, see Appendix F. The research propositions related to the strategic design stated the following:

- the strategic design documents produced by the workshop participants will exhibit evidence of identified components of the business systems,
- the strategic design documents will exhibit evidence of identified strong linkages between the system components,
- the strategic design documents will exhibit evidence of identified contradictions (gaps and/or tensions) between the system components, and

- the strategic design documents will evolve during the strategic episode thus demonstrating change in business system structures and component relationships.

In order to address the research question and test the propositions related to the strategic design, several analytical steps were completed. Eight triangular drawings produced by four groups of managers were included in the analysis. Each group focused on a specific business system based on a strategically important manufacturing event: Group Blue - Process Validation; Group Red - Deviation Management; Group Green - Technology Transfer; and Group Yellow - Acceptance from Development. The first set of four triangles represented current design of the systems, while the second set demonstrated changes in the system's components and relationships that emerged during the collaborative design session.

The first set of activity triangles presenting current systems was examined using the 8-step model (Mwanza, 2001), which is concerned with development of the graphical representation of a system and its components. The goal of this analytical step was to examine the completeness of the system's representation and managers' ability to translate various system components into a conceptual model.

Activity 1 worksheets and conversation records were then reviewed to obtain the evidence of identified strengths, gaps and contradictions within each system related to six interactional schemes (Mwanza, 2001):

1. *People – Methods/Tools – Tasks*: How do technical documents, procedures, and technologies help the key players perform their tasks?
2. *People – Rules – Tasks*: What impact do external and internal regulations and performance expectations have on task completion?

3. *People – Functions – Tasks*: How does role distribution among key players help to achieve the event's goals?
4. *Methods/Tools – Context – Tasks*: What is the impact of the context in which the event takes place on the technical documents, procedures, and technologies used for completing the tasks?
5. *Rules – Context – Tasks*: How does the context of the event determine the rules regulating task completion?
6. *Functions – Context – Tasks*: How does the context of the event affect the distribution of responsibilities among the functional areas involved in execution of the tasks?

Next, activity 1 worksheets and conversation records were reviewed for emergent themes that did not fit Mwanza's interactional schemes, and four additional interactional schemes were introduced based on the findings. Comparison of the original framework of interactional schemes with the final framework developed through the data analysis is provided in Chapter 5: Results.

Finally, activity 1 worksheets, conversation records, and the second set of activity triangles were examined to obtain the evidence of the system changes that would address the identified gaps and contradictions.

Analysis of Strategic Discourse

To answer the second research question on the evidence of the social construction of strategic knowledge, interactions of the workshop participants during the strategic episode were analyzed from the perspective of a critical discourse analysis, or CDA (Fairclough, 2000, 2003; van Dijk, 1997, 1999; Wodak, 2002). CDA views language as social practice and considers the context in which discourse takes place to be critical, implying "a dialectical relationship between

a particular discursive event and the situation(s), institution(s) and social structure(s) that frame it" (Wodak, 2002, p.7). My analytical position is grounded in socio-cognitive theory of van Dijk (1993) that regards discourse as a form of contextualized knowledge and memory, as opposed to simple written or oral utterances. The researchers acknowledge that CDA does not have a unitary methodology that could be applied for analysis of discursive data (van Dijk, 1999; Wodak, 2002). In this study, the strategic conversations of managers were analyzed using the dialogical sequence coding scheme developed during the pilot study (see Table 5).

In order to ensure reliability of the analytical approach, a specific process was established for developing a consistent coding approach and reaching at least 80% agreement between the coders (Bauer, 2000). Four coders were assigned to analyze the data sets generated by four participant groups. The coders first worked together to identify dialogical sequences and separate on-tasks sequences from off-task ones that were excluded from the analysis. This step resulted in identifying 72 on-task sequences for Team Blue, 63 sequences for Team Red, 69 sequences for Team Green, and 31 sequences for Team Yellow. In total, 235 dialogical sequences were included into analysis. Approximately 10% of discussion records from each of the four participant groups were selected for the initial analysis to ensure the coders became familiar with the conversation style of each group. The coders worked independently to assign a code to each dialogical sequence in the data subset and met to compare their results. Twenty-three dialogical sequences were coded with 88% agreement (20 out of 23 in agreement).

The coders independently continued coding the remainder of the data: Team Blue – 65 sequences; Team Red – 57 sequences; Team Green – 62 sequences; and Team Yellow – 28 sequences. The coders met again to compare and discuss their results. The agreement of 96%

was reached (204 out of 212 in agreement). When disagreement occurred, the following steps were taken to reach consensus on the coding:

- Each coder stated their reasons for code assignment.
- If the reasons were accepted, the sequence was coded accordingly.
- If the reasons were not accepted, the coders first clarified the meaning of the code in question, then collaboratively recoded the data subset that included the problematic sequence (typically, a conversational fragment between two logical transition points in the discussion).
- When multiple examples of a phenomenon occurred that did not fit the established coding scheme, a new coding category was added and the entire data set was recoded using the modified scheme. This happened once, when a new dialogical sequence emerged repeatedly in the discussion of Team Blue: discussing impact on external environment. Comparison of the original coding scheme with the final coding scheme created through the data analysis is provided in Chapter 5: Results.

The overall inter-rater reliability in the analysis of dialogical sequences was 92% (216 out of 235 in agreement).

Analysis of Surveys

The research question on the advancement of managerial strategic knowledge and ability to plan organizational change actions was addressed through the analysis of the outputs of the follow-up survey and their comparison with the results obtained from the same participants who responded to the needs analysis survey before the workshop. Two identical sections in the pre-workshop survey (Appendix B) and the post-workshop survey (Appendix H) were analyzed to

compare the results of the managers' responses before and after the strategic episode. The remaining sections of the surveys were not directly related to the goals of this research study, and therefore were excluded from analysis. Section "Change Agenda Concepts & Processes" asked managers to identify main actors, processes, and documentation required for managing critical business events: Acceptance from Development, Process Validation, Technology Transfer, and Deviation Management – the same events managers worked on during the strategic episode.

Section "Change Agenda Implementation Strategies" contained two groups of questions. First group included Medex-specific problem scenarios that asked managers to (a) analyze the causes and potential impact of the problem from scientific, business, and compliance perspectives and (b) select actions for addressing the problem. The second group of questions contained fifteen Likert scale items asking managers to evaluate their strategic competencies in the following six categories:

- assigning roles and tasks in change-related activities,
- planning and managing change-related activities,
- evaluating impact of change on external environment,
- evaluating impact of change on internal environment,
- identifying and managing strong organizational aspects supporting change, and
- identifying and managing barriers to change implementation.

For analysis purposes, the above data were organized into three categories: (a) knowledge of strategic concepts and processes, (b) strategic problem solving, and (c) self-assessment of strategic competencies.

The descriptive statistical analysis of survey responses was performed, and comparative analysis of the results of pre-and post-workshop survey results was conducted. The differences

between group responses were also explored and compared with the analysis of the design and discourse data obtained from each group to generate interpretations of the inter-group differences from multiple perspectives.

The results of the survey analysis were triangulated by the data obtained from the post-workshop interviews in order to isolate the effect of the training intervention and more accurately assess the extent to which a strategizing activity contributed to the advancement of strategic knowledge among the MTS employees. Specifically, a participant estimation method was used to obtain information directly from the workshop participants (see Appendix K). This approach is based on the assumption that study participants are capable of determining the amount of improvement in their performance that can be attributed to the study actions (Phillips & Stone, 2002).

Analysis of Interviews and Focus Groups

Interviews and focus group transcripts were read to support the evidence obtained from the survey, design and discourse data and for emergent themes. Interviews and focus groups were intentionally semi-structured as their main goal was to obtain clarifications and participants' perspectives on the strategizing process, their group dynamics and their explanation of the challenges they faced during strategic work. Thus, the group differences related to construction, analysis and redesign of the business systems prompted a series of questions on group composition, power relationships within low performing groups, strategies for dealing with disagreement. These and other questions aimed at identifying the factors that potentially contributed to the variability of the results obtained from the groups, which followed the same process and used the same strategic tool.

A qualitative emerging design framework (Lincoln & Guba, 1985) provided an analytical approach for uncovering themes that emerged from the data without predetermining them.

Analysis of Change Agenda Implementation Plans

Change agenda implementation plans, as indicated earlier, were not the part of the originally planned research data pool. They were offered to me by the MTS Communications group as an additional data source that could provide the evidence of transfer of the activity-based approach to the work setting. The workshop participants were asked by the MTS leadership to develop these plans immediately after the workshop. The plans were expected to contain evaluation of the current situation at the plants as related to the change agenda implementation and list specific change actions. When preparing the plans, managers were asked to use the resources they generated during the workshop strategizing exercise.

Since the plans were not part of the research design, they did not contain information about their authors with exception of the fact that they all participated in the strategic episode. Therefore, I did not have an opportunity to explore the relationship between managerial group performance during the strategic episode and their ability to apply strategizing techniques at the workplace. Despite this limitation, the plans were still included in the analysis as they provided invaluable evidence of strategic knowledge transfer, which, considering the limited time span of the research project, was critical and, perhaps, the only way to obtain any information about how managers actually used their strategizing experience in real work context. As the managers were obviously not required to follow the triangle-based design approach when they worked on their change agenda implementation plans, using the activity-based tool for evaluating those documents was not feasible. The following proxy measures were developed for assessing the level of transfer demonstrated by the change agenda implementation plans:

- Criterion 1: The plans will contain evidence of the identified seven component groups for each business process they outline, organized into categories consistent with the elements of the activity-based strategic tool: *People, Tasks, Outcome, Functions, Rules, Methods/Tools,* and *Context*.
- Criterion 2: The plans will contain evidence of identified strengths, gaps and contradictions related to each business process they outline.

Disciplined Inquiry

Quality of the Case

The quality and rigor of the empirical research in social sciences, including case studies, has been historically established by the following four logical tests of validity and reliability (Eisenhart & Howe, 1992; Kidder & Judd, 1986; Yin, 2003):

- *Construct validity*: establishing correct operational measures for the concepts being studies
- *Internal validity*: establishing the degree of causal relationship between certain research conditions (used only in causal or explanatory studies)
- *External validity*: establishing the degree to which the propositions, inferences, or conclusions of the research study can be generalized
- *Reliability*: demonstrating consistency, or repeatability, of the research measures and procedures

Table 8 summarizes the case study tactics recommended by literature for demonstrating quality of the case study research design.

Table 8

Criteria for establishing study quality in case study research (Adapted from Yin, 2003)

Tests	Case study tactics	Phase of research
Construct validity	Use multiple sources of evidence	Data collection
	Establish chain of evidence	Data collection
	Have key informants review draft case study report	Composition
Internal validity	Do pattern-matching	Data analysis
	Do explanation-building	Data analysis
	Address rival explanations	Data analysis
	Use logic models	Data analysis
External validity	Use theory in single-case studies	Research design
	Use replication logic in multiple-case studies	Research design
Reliability	Use case study protocol	Data collection
	Develop case study database	Data collection

One of the challenges of case study research has been the perceived weaknesses of the approach in terms of criteria of scientific rigor, such as validity and reliability (Yin, 2003). Case research is perceived to have little generalizability due to the data that are often characterized as subjective (e.g., narrative) in nature. In order to address this concern, the following procedures were performed to ensure validity and reliability of this dissertation study:

Using multiple sources of evidence. Data triangulation approach was used for examining multiple data sources (documents, interviews, observations, audio records, surveys) were used at different times of the data collection period. Both qualitative and quantitative data collection methods provided the means for (a) verifying the consistency and reliability of the data and the researcher's interpretations, (b) ensuring convergence among the data obtained from different

sources and methods, (c) confirming the initial theoretical propositions, and (d) identifying and analyzing inconsistencies and contradictions among the data. Use of multiple observers of the strategic episode allowed me to capture a broader set of data, and the use of multiple researchers made it possible to test the reliability of the data analysis procedures (e.g., coding of interactions during the strategic episode) and reveal various aspects of the same phenomena.

Establishing chain of evidence. To address the methodological problem of construct validity and increase the overall quality of this case study, a "chain of evidence" has been established between the research questions, the data collected, the findings, and their interpretations. This approach allows the reader "to follow the derivation of any evidence, ranging from initial research questions to ultimate case study conclusions" (Yin, 2003, p. 105). The structure of this case's report that includes clear cross-referencing to the study questions, research propositions, methodological procedures and to the resulting evidence allows the reader to move from one part of the case study process to another following the links between the study protocol and the initial study questions.

Conducting member checking. The tactic of early reviews by key informants was implemented through member checking procedures. Informal member checks were conducted during the data collection process, particularly during the interviews and focus groups. When conducting interviews, I periodically asked for clarification and confirmation of the points discussed. A formal member check was performed twice: at the end of Phase 1 upon completion of the first set of interviews and administering the pre-workshop survey and during Phase 3 after the follow-up interviews. An e-mail request to participate in the first member check was sent to four representatives of the strategic planning group and to seven managers representing four manufacturing networks, a global MTS organization, and two partner organizations, Engineering

and Quality. They were asked to read the interpretations contained in the report I prepared for MTS and provide comments and corrections. The members of the strategic planning group were additionally asked to review the interview notes and compare them with audio recordings of the discussions. During the second member check, I sent an e-mail request for participation to five individuals who were interviewed by phone and asked to review my interview notes and comment on their accuracy. Three managers responded with elaborations or clarifications of their interview comments. All clarifications were of technical nature and were related to my misinterpretations of the organizational logistics or scientific and business terminology. Additionally, one of the managers expressed a concern about the sensitivity of one of his comment regarding the MTS leadership position and requested that this comment be deleted from the notes and not considered during the analysis. Appendix O contains the specific instructions sent to the individuals who participated in both member checking procedures.

In addition to the participants' member checks, I frequently tested my ideas and conclusions derived from observations, interviews, and document analysis with the MTS training representative and two members of the MTS Communications group in order to minimize personal subjectivity and verify accuracy of my interpretations.

Relying on theoretical propositions. A number of theoretical frameworks and concepts guided this study and informed the data analysis and interpretations, including: Activity Theory, strategy-as-practice theoretical framework, action research, sociocultural learning theory, and expansive learning cycle framework. The objectives and design of this case study were based on several propositions developed for guiding data collection plan and development of an analytical strategy (Yin, 2003). These propositions regarding (a) the use of the activity-based tool for analysis and redesign of business systems, and (b) the gradual construction of strategic

knowledge during a collaborative strategic episode, both are examples of a theoretical orientation guiding the case study analysis in this dissertation project.

Developing a case description and creating a case study database. A detailed description of this study context, procedures, participants and their interactions, and specific resources and tools allows readers to determine the extent to which the findings can be applied to their own contexts. Availability of well-organized evidence collected during the study increases reliability of the research as it allows other researchers to review the evidence directly and not be limited to written reports. Reliability in this study was supported by the systematic organization of the case study data (survey outputs, interview notes and audio recordings, observation notes, design outputs from the workshop, action plans), project documents and reports, the researcher's reflective notes, and statistical analysis files. External audit of the data collected was conducted by the Medex Patent Agreement Group responsible for internal data release for research and publication purposes.

Ethical Considerations

Alvesson and Sköldberg (2000) argue that "the researcher's repertoire of interpretations limit the possibilities of making certain interpretations" (p.250). Therefore, the researchers are expected to reflect on their cognitive and emotional biases that may have an impact on their evaluation of the research results.

Assumptions & Personal Biases

My choice of the context and methodology for this study was largely determined by my educational background and professional experience as a corporate instructional strategy consultant. Most of the projects I worked on involved exploration of how to enable and facilitate the learning process of professionals who have very specific, practical objectives of immediate

application of newly acquired knowledge at the workplace. Moreover, the working environment of those learners has always required some degree of teamwork and knowledge exchange. At the same time, it assumed a personal accountability and responsibility of individuals for their learning process and outcomes.

The organization that I worked with had been practicing a predominantly didactic, information transmission model in order to educate its employees. Learning materials were developed to the best of the training department's ability and were distributed to the employees via traditional classroom-based lecture/presentation format or self-studies. My role in the projects was to help the organization to analyze the process-related issues and design interventions that would enable the development of solutions. I was also expected to generate recommendations regarding activities that would allow organizational performance improvement in the future.

The corporate project that provided the context for my dissertation study was approached from the social learning perspective as opposed to the didactic one. I chose to introduce a new learning approach that takes into account the meanings of the strategy provided by individuals, as well as recognizes the representation of the strategy as it occurs in social negotiations between those individuals (Charmaz, 2000; Mir & Watson, 2000; Schwandt, 2000). I realized that my assumptions regarding the collaborative knowledge construction as well as the attempt to introduce the value of managerial strategic contributions could be challenged by the organization's leadership and face skepticism from the managers. During the analysis phase, when I was contemplating the design of the workshop, the study participants emphasized the utmost importance of their involvement in strategic planning. They viewed this workshop as a unique opportunity to communicate to the leaders their position and concerns related to specific

strategic directions. At the same time, they commented on the low likelihood that the participatory strategizing approach would be sustained beyond the context of the learning event that was planned. It was still largely my responsibility to decide what type of event or program to design to assist managers in their interpretation and implementation of strategic messages. Considering the context, I could have been cautious and suggested yet another presentation or a content-focused self-study in an attempt to improve the situation. However, drawing from my consulting and personal experience, I assumed that the participatory strategizing process would help managers to understand and appreciate the complexity of strategic development, and bring the value and sense of ownership over the strategic decisions they shared with their leaders.

I was given an opportunity to introduce an alternative approach, and I used it when designing the learning environment that offered a collaborative strategizing action. I disagreed with the initial approach that the organization's leadership used for communicating strategic change agenda (and most likely continued to use after my study ended). However, I applaud the organization's willingness to explore alternative ways to teach and learn strategic content and process, and I am thankful to the executives and the strategy planning team who gave their managers an opportunity to contribute to organization's strategic development.

Confidentiality

In an effort to adhere to the standards of ethical research and to comply with the Medex confidentiality and non-disclosure requirements, a full approval was received from the company's Patent Agreement Group whose responsibility is to protect the confidentiality of the company's employees and its intellectual property. I received permission to access and use the data already collected as part of the company's internal research project as well as to collect additional data necessary for completing this dissertation study. All the compliance requirements

related to accessing the existing data and collecting new data, as well as the researcher's rights and limitations regarding publishing the results of this study, are stated in the Confidentiality and Non-Use Agreement signed by the company's legal representative on May 19, 2004.

The approval from the Indiana University Human Subjects Committee (Protocol 04-9142) was also obtained for collecting additional data that was not included in the original set of data collected as a part of the company's internal research project (Appendices A and B). No individual's identity, corporation's identity, or corporate division's identity was revealed in this study. All the corporate titles and abbreviations used in the study are fictitious, and developed to preserve privacy and confidentiality. The data was sanitized to eliminate potential identifiers, and the names of the individual participants included in the data were coded with numeric codes. The participation in the study was voluntary, and the participants were informed of the study's goals and requirements.

CHAPTER FIVE: FINDINGS AND DISCUSSION

This chapter discusses the process and learning outcomes of the collaborative strategic episode in which the MTS managers used an activity-based strategic tool to both analyze current business systems and negotiate the changes needed for improving system performance. This study argues that strategic knowledge can be demonstrated, through the increased test scores of managers or their self-assessment of their strategic skills, and that strategic knowledge is progressively constructed during the collaborative strategizing activity. Therefore, the evidence of knowledge construction can be obtained through (a) evaluation of the strategic artifacts produced by collaborating managers and (b) examination of their conversations. Therefore, in addition to presenting the results of the survey-based assessment of managerial strategic

competencies and the evidence of strategic learning transfer to the workplace, this chapter provides a closer look at the very process of strategizing in which managers engaged in their workshop tasks used an activity-based strategic tool as a guide. The evidence of strategic learning embedded into managerial discourse and design decisions during a strategizing activity is also discussed. The analysis of this data is complemented by managerial reflection on the strategizing experience and individual learning outcomes obtained through the post-workshop interviews.

Linking Data to Research Questions and Propositions

Two primary research questions of this study focus on both the process of strategizing and its learning outcomes:

- How was the activity-based strategic tool used in the strategizing process of middle managers?
- What was the impact of the strategizing experience on managerial learning?

Additional questions were formulated in order to examine the specific aspects of the strategizing process and its outcomes. Thus, the process aspect (primary research question 1) including strategic analysis and redesign of the business systems and associated managerial discourse is addressed through the following questions:

- How did the use of the activity-based strategic tool affect identification, analysis, and resolution of organizational issues?
- What was the evidence of the social construction of strategic knowledge during the strategic episode that utilized the activity-based strategic tool?

The impact of the strategizing experience on managerial learning (primary research question 2) is addressed through the following questions:

- How did the use of the activity-based strategic tool contribute to the advancement of managerial strategic competencies?
- What was the evidence of transfer of learning from the strategic episode to the workplace context?

The paragraphs below summarize the relationships between the research questions, study propositions and the data.

Research Question 1. The research question regarding the use of the activity-based strategic tool for identification and analysis of the strategic issues was addressed primarily through examination of the design documents and worksheets produced during the strategic episode. The following research propositions were tested during data analysis:

- The strategic design documents produced by the workshop participants will exhibit evidence of identified components of the business systems
- The strategic design documents will exhibit evidence of identified strong linkages between the system components
- The strategic design documents will exhibit evidence of identified contradictions (gaps and/or tensions) between the system components
- The strategic design documents will evolve during the strategic episode thus demonstrating change in business system structures and component relationships

Document analysis was triangulated by the data obtained from observation notes and audio records of managerial conversations during the strategic episode.

Research Question 2. The research question that focused on social construction of knowledge during the collaborative strategic episode was addressed through examination of

audio records of managerial conversations during the strategic episode. The following research propositions were tested during the discourse analysis:

- During the strategic episode, the discussions of collaborating managers will advance through five stages of social construction of strategic knowledge, with a shift towards higher stages over time.
- The managerial discourse will contain identification and analysis of strong relationships, gaps and contradictions between the system components as well as substantiated change propositions, thus providing evidence of managerial strategizing activity.

Analysis of the audio records was supported by review of the observation notes and worksheets produced during the strategic episode.

Research Question 3. The question regarding the advancement of managerial strategic competencies was addressed through comparative analysis of the pre-workshop and post-workshop survey results. The following research propositions were tested during the survey analysis:

- The results of the post-workshop survey will demonstrate learning gains in relation to knowledge of the strategic concepts and their application in ill-structured problem solving contexts.
- The workshop participants' self-assessment of their strategic skills in the post-workshop survey will improve in comparison to the initial survey.

The results of the survey analysis were supported by managers' reflection on their strategic learning provided through the post-workshop interviews and focus groups.

Research Question 4. The question focused on application of strategic knowledge in the workplace context was addressed through analyzing the change agenda implementation plans submitted after the workshop. The following research proposition was tested during the analysis of the plans:

- The change agenda implementation plans produced after the workshop will contain evidence of the transfer of the strategic concepts and of the design approach learned during the strategic episode into specific actionable items.

Table 9 presents the connection between the research questions and the types of data collected for this study.

Table 9

Connections between research questions and data categories

D = Documents
S = Surveys
I = Interviews
F = Focus Groups
O = Observations
C = Conversation Records

Primary research questions	Secondary research questions	D	S	I	F	O	C
How was the activity-based strategic tool used in the strategizing process of middle managers?	How did the use of the activity-based strategic tool affect identification, analysis, and resolution of organizational issues?	X				X	X
	What was the evidence of the social construction of strategic knowledge during the strategic episode that utilized the activity-based strategic tool?	X				X	X
What was the impact of the strategizing experience on managerial learning?	How did the use of the activity-based strategic tool contribute to the advancement		X	X	X		

of managerial strategic competencies?			
What was the evidence of transfer of learning from the strategic episode to the workplace context?	X	X	X

The following sections discuss two major categories of findings. First, I present the assessment of managers' strategic competencies and their application in the workplace through (a) comparison of the survey responses provided before and after participating in the strategic episode, (b) analysis of the change agenda implementation plans, and (c) managers' reflection on what has been learned from the strategizing experience. Then we will look at the strategizing process that led to those outcomes: I present the evidence of collaborative strategic learning embedded in the design artifacts produced during the strategic episode and demonstrated through the discourse of strategizing managers. This chapter will conclude with a discussion of managerial reflection on the strategizing experience that provides (a) additional information on the collaborative dynamics of the strategic episode and (b) managers' perspectives on the factors that influenced strategizing task performance.

Since the outcomes of data analysis are discussed in terms of differences between the four groups of managers participated in this study, it is worth pausing here to summarize the makeup of each group.

Eighty-six managers were divided into four groups, each led by two facilitators. A color-coding system was used to communicate a group affiliation: Blue, Green, Red, and Yellow. Each group was further divided into four small teams, 5-6 participants on each team. One person on each team was responsible for making notes in the activity worksheets, which were collected and analyzed along with the audio and observation records. The groups worked independently in

separate rooms and met for a debriefing session at the end of each workshop activity. Each group worked on analysis and redesign of one of the four business systems: Process Validation (Group Blue), Technology Transfer (Group Green), Deviation Management (Group Red) and Acceptance from Development (Group Yellow). The teams in every group spent approximately five minutes in the beginning of the strategic episode to review the Learner's Guide, to make notes related to the strategic analysis and to design assignment and to help each other clarify the goals and outcomes of the strategic episode. Then all the teams engaged in the whole-group analysis and redesign of the business systems to which they were assigned using their notes. The observation notes and audio recordings were made during those whole-group portions of the episode.

The group affiliation was established by the MTS Communications group based on the proposition of equal representation from four different manufacturing networks and different functional units: MTS, Engineering, and Quality Control, in order to give managers an opportunity to work with their colleagues from partner organizations. Other business considerations were taken into account by the MTS Communications group when assigning group membership to individual workshop participants.

Group Blue was represented by twenty (95%) MTS managers and one Quality Control manager (5%) who held the following positions at Medex Manufacturing: Senior Associates (3; 14%), Team Leaders (3; 14%), Process Consultants (4; 20%), Managers (8; 38%), and Directors (3; 14%).

Group Green was represented by twenty-one (92%) MTS managers, one manager from the Engineering organization (4%) and one Quality Control manager (4%) who held the

following positions at Medex Manufacturing: Senior Associates (2; 10%), Team Leaders (4; 17%), Process Consultants (4; 17%), Managers (10; 43%), and Directors (3; 13%).

Group Red was represented by nineteen (95%) MTS managers and one manager from the Engineering organization (5%) who held the following positions at Medex Manufacturing: Senior Associates (4; 20%), Team Leaders (2; 10%), Process Consultants (3; 15%), Managers (8; 40%), and Directors (3; 15%).

Group Yellow was represented by seventeen (77%) MTS managers, two managers from the Engineering organization (9%) and three Quality Control managers (14%) who were held the following positions at Medex Manufacturing: Senior Associates (6; 27%), Team Leaders (2; 9%), Process Consultants (3; 14%), Managers (7; 32%), and Directors (4; 18%).

Approximately 30% of all the managers who participated in the strategic episode represented Medex overseas plants ('affiliates'). This estimation is based only on the data obtained from the follow-up interviews. Since the consulting project was not focused on examining differences between the performance of domestic and overseas MTS branches, information on the country of origin and language proficiency level was not collected by the survey. This was one of the major limitations of the project because the research findings revealed a relationship between the group composition and its performance.

Assessment of Strategic Learning

The research question on the impact of the strategizing experience on managerial learning was addressed through analysis of (a) the surveys conducted before and after the workshop where the strategic episode took place, and (b) the change agenda implementation plans submitted after the workshop by the managers who participated in the strategic episode.

Evaluation of Strategic Competencies: Survey Results

The pre-workshop and post-workshop survey responses were compared for evidence of advancement of managers' strategic knowledge after their participation in the strategic episode. The goal of this analysis was to address the research question on how the use of the activity-based strategic tool contributed to the advancement of managerial strategic competencies. The study propositions related to the survey data suggested that (a) the results of the post-workshop survey would demonstrate learning gains in relation to knowledge of the strategic concepts and their application in ill-structured problem solving contexts, and (b) managers' self-assessment of strategic competencies in the post-workshop survey would improve in comparison to the pre-workshop survey.

Two sections of the pre-workshop survey (Appendix B) and post-workshop survey (Appendix H) were analyzed to compare the results of the managers' responses before and after the strategic episode. The first group of questions focused on managerial knowledge of change agenda concepts and processes presented in a format similar to the one used during the strategic design session: managers were asked to identify main actors, processes, and documentation required for managing critical MTS events. The pre-workshop survey contained seven critical events, while the post-workshop survey contained a subset of four events: Acceptance from Development, Process Validation, Technology Transfer, and Deviation Management – the same events managers worked on during the strategic episode. Managers' responses related to the remaining three events in the pre-workshop survey were excluded from the analysis. For analysis purposes, this group of survey responses was organized under the category Strategic Concepts and Processes.

Another group of questions was concerned with managerial strategic planning, decision making and problem solving capabilities. The first subset of questions in this group contained two Medex-specific problem scenarios that asked managers: (a) to analyze the causes and potential impact of the problem from scientific, business, and compliance perspectives, and (b) to recommend actions for addressing the problem. For analysis purposes, this subset of survey responses was organized under the category Strategic Problem Solving.

The second subset of questions contained fifteen Likert scale items asking managers to evaluate their strategic competencies organized in the following categories:

- assigning roles and tasks in change-related activities,
- planning and managing change-related activities,
- evaluating impact of change on external environment,
- evaluating impact of change on internal environment,
- identifying and managing strong organizational aspects supporting change, and
- identifying and managing barriers to change implementation.

For analysis purposes, this subset of survey responses was organized under the category Self-Assessment of Strategic Competencies.

In the paragraphs below, I present and discuss the outcomes of the analysis of both pre-workshop and post-workshop surveys and compare them for evaluating strategic learning gains. The detailed statistical results are provided in Appendix R.

Strategic Concepts and Processes

The need for collecting this category of data was defined at the interviews with the members of the MTS strategic planning group during the first phase of the project. It was grounded in several major issues experienced by the MTS organization at that time: ambiguity of

roles and responsibilities, insufficient understanding of the sequence and interdependency of the new procedures prescribed by the change agenda, and confusion about new documentation requirements.

At the time of this study, there was no guiding documentation clearly dividing between functional groups the process management and preparation or document review responsibilities that related to the critical manufacturing events (Acceptance from Development, Process Validation, Technology Transfer, Deviation Management). There was certainly a basic shared understanding that particular specialists needed to be involved in each event; however, when it came to specific actions, such as writing a validation protocol or signing a deviation report, the role ambiguity created certain tension between functional groups, especially in situations in which two different plants or vendors were involved. One good example is the tension between the MTS scientists investigating an accident at the plant and a quality control unit concerned with the impact of that accident on the product quality and patient safety. Although both functional groups had a shared goal to collect data and resolve the problem, they were not always on the same page regarding the timeline, scope, focus and technical aspects of investigation. Definition of leading and supporting roles would contribute to more efficient investigation process and eliminate unnecessary redundancies or omissions.

Another example is the tension between transferring and receiving groups during the process of technology transfer from one plant to another. Who would prepare transfer documentation? Who would authorize the transfer? Who would sign the equipment qualification and process validation reports once these processes are completed at the receiving site? These and many other technical questions were the focus of numerous MTS business meetings where managers had to go through lengthy explanations, clarifications and negotiations of

responsibilities. Lack of clearly defined roles resulted in process delays and multiple document review cycles. It also caused situations in which some employees whose expertise was needed were left out of the process while others were charged with an overwhelming number of tasks:

> *"Let's take qualification. Who is responsible and accountable for equipment assessment before the transfer? Is this intended as a 'red light'/'green light' for validation? If so, who owns the 'go' or 'no go' decision*?" (Manager, MTS strategic planning group)

Another challenge mentioned in the interviews was related to a large number of new procedures required by the change agenda to be performed as the employees engaged in one of the critical events, for example, Technology Transfer. Activities, such as risk assessment, manufacturability review or computer system validation, were not conducted before, and managers across the plants and networks had different understanding of how and when these activities needed to be conducted:

> *"The role of MRs [Manufacturability Reviews] in capital site projects is unclear. The role of the MR as a gate keeping process for validation readiness is unclear. The raw material management and quality systems integration, especially with third parties, from the scope of the MR is unclear. It appears that the development group has a different MR process. We need to clarify the use of MR in all these contexts."* (Senior Research Advisor, MTS strategic planning group)

A similar problem occurred when the MTS leadership instituted a series of new documents required to be prepared prior or during the major manufacturing events. For example, before transferring the drug production from the laboratory environment to manufacturing facilities (Acceptance from Development), managers were required to present a Development History Report, a summary of the laboratory studies and major changes made during the years of drug development. They were also required to have in place a Process Flow Document, a detailed guidance for conducting each manufacturing operation according to the established criteria. Once the process was transferred, managers were required to submit the first Equipment Qualification and Process Validation reports as well as an Annual Product Review, the

documents that provided scientific and technical assurance of the quality of the products and manufacturing process. These and many other documents were new to the MTS managers, whose understanding of the scope and time of delivery of these documents was varying:

> "*Development work is currently not done at the sites that make legacy products. We get a lot of confusion from the Greenburg folks, for example. There are aspects of the DHR [Development History Report] that are unknown within their group. It was not required ten, or even five, years ago. They need to know why we require DHR, when it is required, and who will drive the DHR process at the site."* (Consultant, MTS strategic planning group)

The survey section addressing the above issues was designed to obtain the data on managerial knowledge according to whether or not the questions were answered correctly. Percentages of correct answers of both pre- and post-workshop surveys were calculated for each group, and comparative analysis was conducted (a) for each group to evaluate the difference between the scores before and after the workshop, and (b) between groups to evaluate the difference between the scores before and after the workshop.

Three questions included in this survey section were designed in a matrix format, listing major manufacturing events horizontally and functional groups (Question 1), business activities (Question 2) and required documents (Question 3) vertically (see Appendices B and H for details). Managers were asked to assign a specific indicator to the vertical items depending on their role in the context of each manufacturing event. Let's illustrate this design with examples for Event 4: Validation. In Question 1, *Role Distribution*, managers were asked to indicate which role MTS, Engineering, Quality Control and other functional groups played during Validation: owner, contributor, or reviewer. In Question 2, *Process Requirements*, managers were asked to indicate whether one of the listed activities, for example, risk assessment or gap assessment, must be conducted prior or during the Validation event. In Question 3, *Documentation Requirements*, managers coded technical documents associated with the major manufacturing

events as key inputs or key outputs. For example, managers were asked which documents were required to begin Technology Transfer ("key inputs"), and which documents were required to be produced during the Technology Transfer ("key outputs").

The following paragraphs present the results of the managerial responses to the survey questions discussed above. Figures 13-15 compare the percentages of correct answers for each group in pre- and post-workshop surveys. The percentages were calculated by (a) combining individual correct scores into group scores and (b) combining group scores for individual events into the final group score.

Question 1: Role Distribution. The survey question related to role distribution asked learners to assign the roles of owner, contributor and reviewer to eight functional units involved in planning and implementation of the critical manufacturing events.

In the pre-workshop survey, all four groups demonstrated limited understanding of how the roles are assigned during implementation of the four critical MTS events. Group Red had the highest number of correct answers: 48% (average percentage of correct answers for four events). Group Green had the lowest number of correct answers: 34% (average percentage of correct answers for four questions).

In the post-workshop survey, all groups demonstrated an increase in the number of correct answers to the question related to distribution of roles. The percentages of correct answers from the Blue, Green, and Red groups doubled or nearly doubled (Figure 13). Thus, Group Green increased their performance by 57%, from 34% in the pre-workshop survey to 91% in the post-workshop survey (average percentage of correct answers across four events). Group Green was followed by Groups Blue and Red that increased their percentage of correct answers by 53% and 39%, respectively. Although the number of correct scores provided by Group

Yellow increased from 42% in the pre-workshop survey to 54% in the post-workshop survey, this group demonstrated least progress among all four groups in developing understanding of the role distribution during implementation of the critical MTS events.

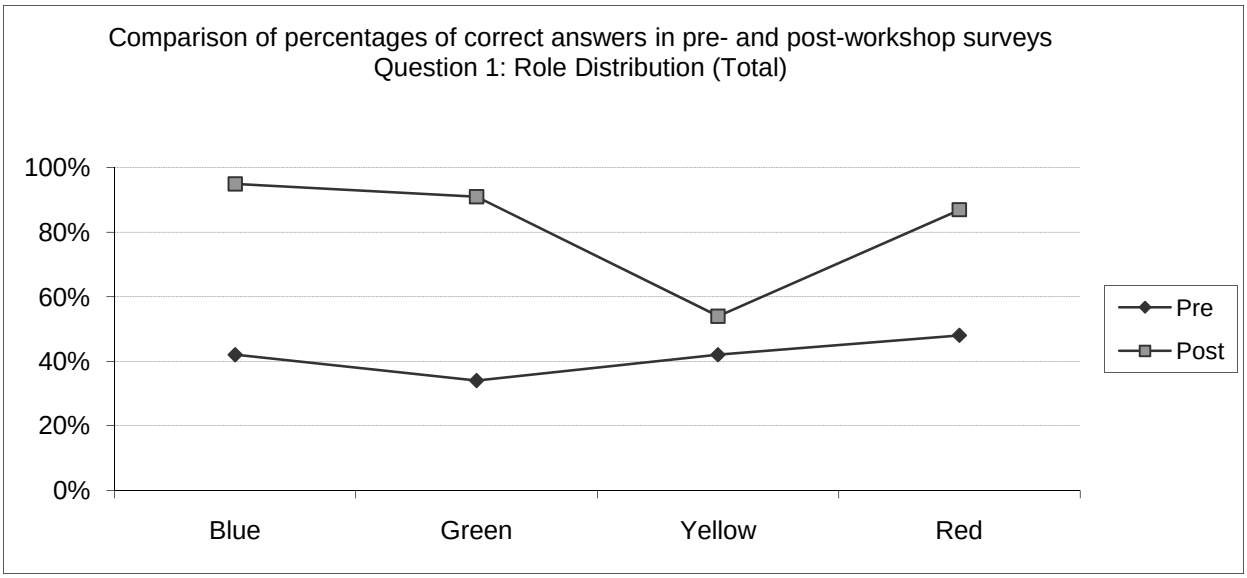


Figure 13. Comparison of percentages of correct answers in pre- and post-workshop surveys Question 1: Role Distribution

Question 2: Process Requirements. The second question asked learners to indicate which business activities were required to be completed prior to the events under analysis (prerequisites), and which ones were required to be performed during those events. Fifteen business activities, such as manufacturability review, gap assessment, and risk assessment were offered for coding.

The average percentage of correct answers in this category ranged between 57% (Group Red) and 67% (Group Green). As with the previous question, the post-workshop survey responses to the question about process requirements demonstrated an increase in the number of correct answers across all four groups (Figure 14). Groups Red and Blue had the largest increase of correct scores (31%), followed by Group Green (28%). Group Yellow again demonstrated the least progress in their learning of the strategic process requirements in comparison to managers

from other groups. This group had the lowest increase in percentages of correct answers from pre-workshop to post-workshop survey (9%).

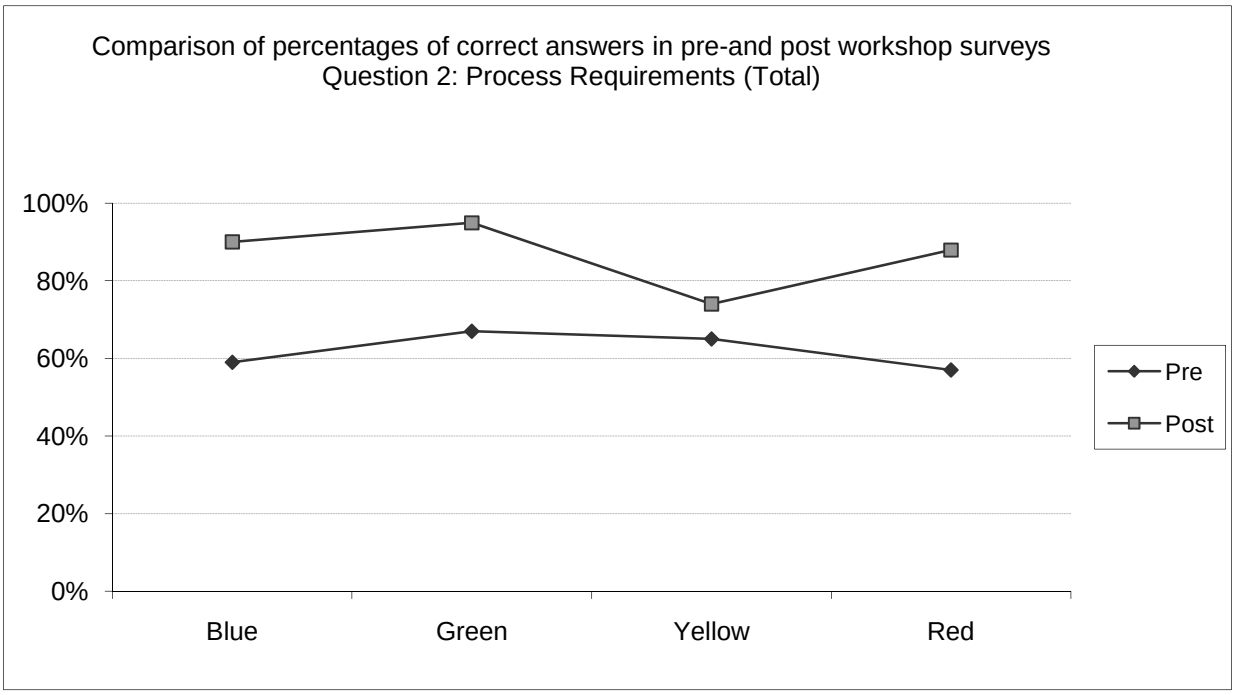


Figure 14. Comparison of percentages of correct answers in pre- and post-workshop surveys Question 2: Process Requirements

Question 3: Documentation Requirements. The third question asked learners to indicate which technical documents were required to be produced before the critical manufacturing events, and what documents were required to be delivered in the course those events. Twenty documents, such as the Development History Report, User Requirements, and Standard Operating Procedures were offered for coding.

In the pre-workshop surveys, the percentage of correct answers across groups ranged between 64% (Group Blue) and 72% (Group Green). This question elicited the highest number of correct scores obtained before the workshop.

Similar to the responses related to role distribution and process requirements, managers from all four groups demonstrated an advancement of their knowledge of strategic documents

after they attended the workshop (Figure 15). However, Group Yellow's progress was again notably minimal in comparison to the results of other three groups (7%). Group Blue demonstrated the highest increase in their percentages of correct answers (31%), followed by Group Red (24%) and Group Green (22%).

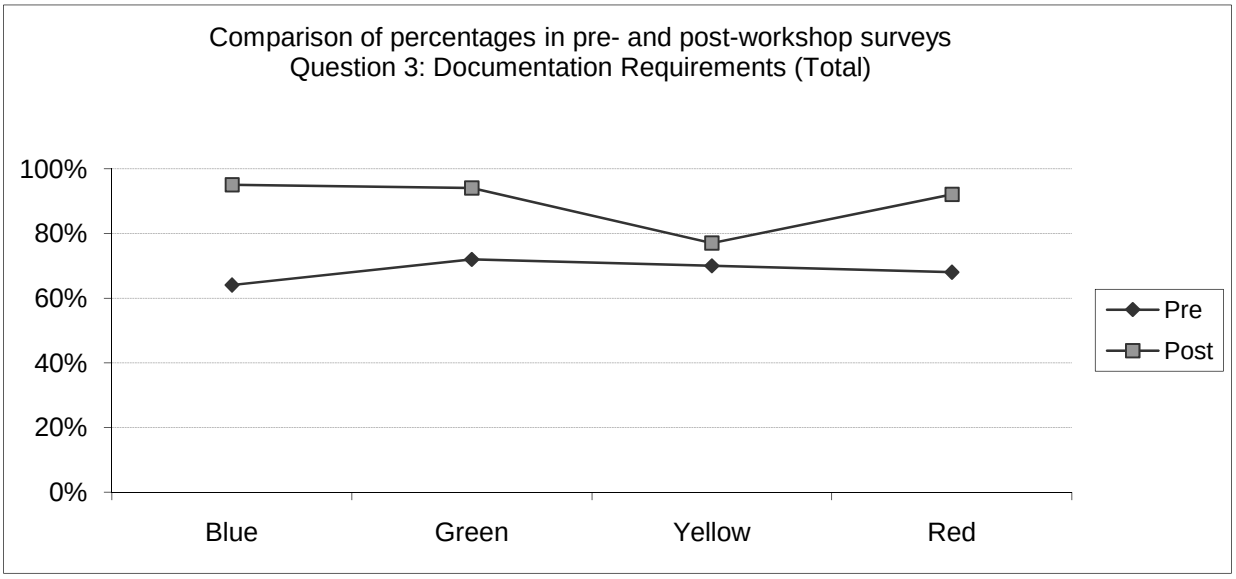


Figure 15. Comparison of percentages of correct answers in pre- and post-workshop surveys Question 3: Documentation Requirements

Comparison of the pre-workshop and post-workshop survey results in the *Strategic Concepts and Processes* category revealed the advancement of managerial understanding of role distribution and process and documentation requirements related to four critical MTS events, Process Validation, Technology Transfer, Acceptance from Development and Deviation Management that were under analysis during the workshop. Three out of four groups demonstrated an increase in number of correct answers ranging from 22% to 57%. Group Blue was the highest performing group in this survey category, while Group Yellow consistently demonstrated least increase in the percentage of correct scores across all the questions in this section of the survey.

Appendices M, N and O provide the detailed statistical analysis of the pre- and post-workshop survey responses and comparison of the results organized by questions included in this section.

Additional analysis was conducted on the data obtained from Group Yellow, as their performance on the test was notably different from other groups. An interesting result was obtained when the increase in percentage of correct answers related to the event group Yellow worked on during the workshop, Acceptance from Development, was compared to the increase in percentage of correct answers related to other events. In two out of three questions, Role Distribution and Process Requirements, Group Yellow demonstrated less progress on the Acceptance from Development event than on the other events. In other words, managers from Group Yellow appeared to learn more about the events presented by other groups than about the event they worked on during the workshop.

Strategic Problem Solving

Lack of a systematic, strategic approach to solving complex problems arising during the change agenda implementation was another challenge mentioned by the MTS vice-president and the members of the strategic planning group during the interviews:

> *"My major concern that we still have a culture of 'fire-fighting', instead of being analytical, proactive and address problems from scientific perspective. Any training initiative we plan must address this issue. We need to help people learn how to look at the problem holistically and efficiently since the complexity of our processes will be increasing all the time. We need to actively discuss ways to simplify and speed-up decision-making, especially when dealing with deviations that affect safety."* (Vice-President, MTS)

> *Solving problems it's what we're about. And it's not only deviations, it's issues we deal with every day. Take, for instance, aged equipment that we have to qualify for validation. We know it wouldn't be in compliance with new standards, but we have to qualify it anyway. How?! What decisions will be made by the site MTS? The solution cannot compromise our quality commitments. How will it affect our processes now and down the road? All tough questions…"* (Senior Research Advisor, MTS strategic planning group)

In order to address the question of managerial strategic problem-solving, the surveys included two scenarios based on Medex-specific business situations. Managers were expected to analyze the issue contained in the scenario and answer the following questions by selecting correct answers (Appendices B and H):

- What factors may have caused this issue?
- What processes are directly affected by this issue?
- What functional units are directly involved in the situation?
- What action(s) are required for addressing this issue?

The goal of this survey section was to obtain the data on managerial strategic problem-solving based on whether or not the questions were answered correctly. The respondents could mark all the answers they considered correct from the lists of five potential answers to each questions.

The range of correct answers in each group was between 45% and 60% in Scenario 1. Group Red demonstrated the highest scores: 60% of total correct answers (average percentage of correct answers for four questions). Group Green demonstrated lowest performance: 50% of total correct answers (average percentage of correct answers for four questions). In Scenario 2, the percentage of correct answers in the pre-workshop survey ranged between 51% and 69%. Group Blue demonstrated the highest average percentage of correct answers: 65%, while Group Green demonstrated 59%, the lowest average percentage of correct answers among four groups.

Appendix M provides the statistical summary of the pre-workshop survey responses to the problem solving section.

In the post-workshop survey, all four groups demonstrated an increase in percentage of correct answers. Thus, the average percentage of correct answers provided by Group Green in

Scenario 1 was 90%, which is a 40% increase from the original responses to the pre-workshop survey (50%). Groups Blue and Red also demonstrated considerable improvement of their scores: their increase of the average percentage of correct answers in the post-workshop survey was 38% and 24%, respectively. Group Yellow's performance in Scenario 1 improved the least: 13%. Figure 16 summarizes the results for Scenario 1.

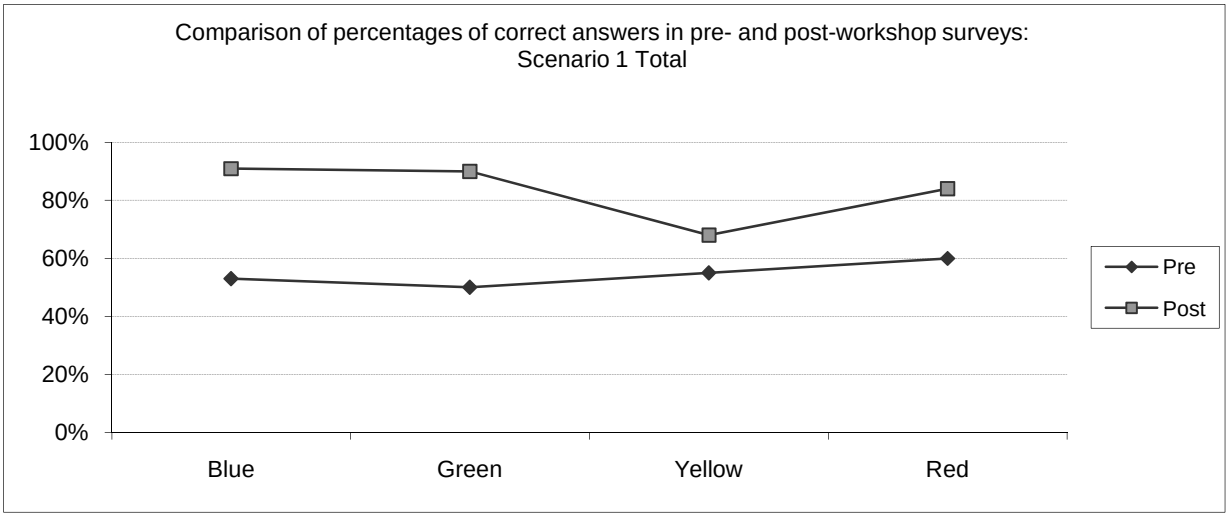


Figure 16. Comparison of percentages of correct answers in pre- and post-workshop surveys: Scenario 1

In Scenario 2, Group Green again demonstrated the highest increase of correct answers: 29% of total correct answers (average percentage of correct answers for four questions). Groups Blue and Red increase their correct scores by 28% and 26%, respectively. Group Yellow was again standing apart from other groups: its percentage of correct answers in Scenario 2 increased only by 10%. Figure 17 summarizes the results for Scenario 2.

Appendix N provides the statistical summary of the post-workshop survey responses to the problem solving section.

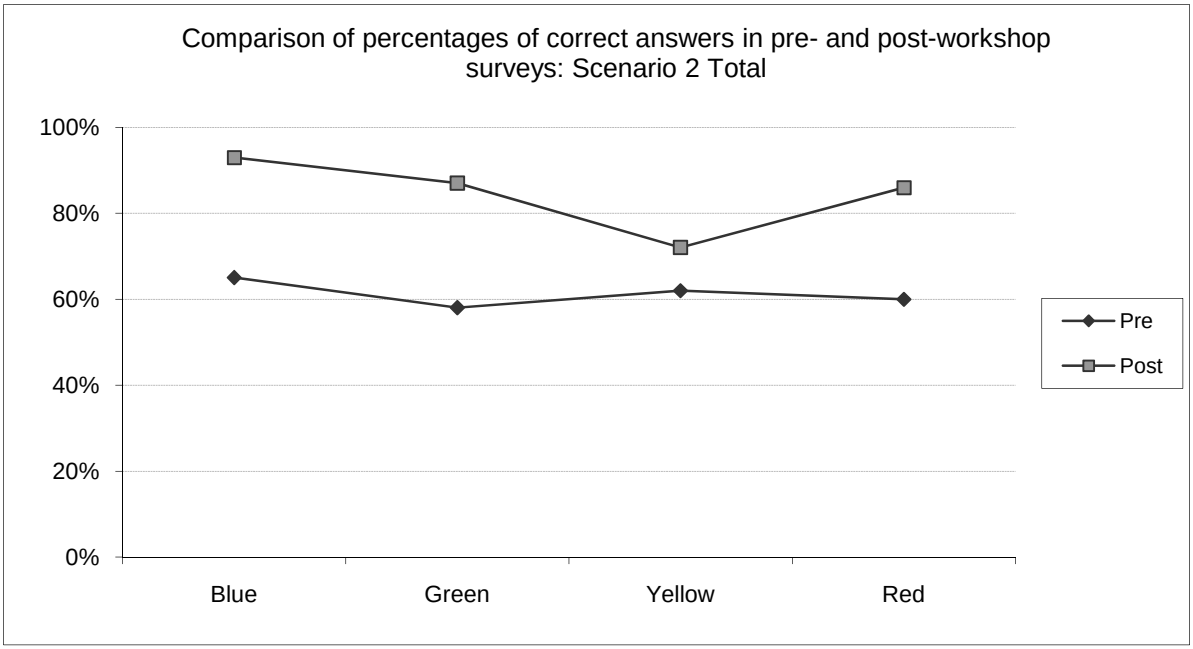


Figure 17. Comparison of percentages of correct answers in pre- and post-workshop surveys: Scenario 2

Overall, all four groups demonstrated the advancement of their strategic problem solving skills after participating in the workshop. Group Green increased its performance the most: 34.5%, followed by Group Blue (33%) and Group Red (25%). Group Yellow showed the least improvement of their strategic problem solving skills - 11.5% - three times less than the highest performing Group Green.

Appendix O provides a comparison between the pre-workshop and post-workshop survey results organized by the questions related to each problem scenario.

Self-Assessment of Strategic Competencies

Both surveys included a self-assessment section asking managers to evaluate their strategic competencies in the following categories:

- assigning roles and tasks in change-related activities (Category 1)
- planning and managing change-related activities (Category 2)

- evaluating the impact of change on external organizational environment (Category 3)
- evaluating the impact of change on internal organizational environment (Category 4)
- identifying and managing organizational aspects supporting change (Category 5)
- identifying and managing barriers to change implementation (Category 6)

In order to use the self-assessment data to make a comparison between the pre-workshop and post-workshop results, several analytical steps were taken first to evaluate construct validity and internal consistency of the self-assessment instrument.

The data was subjected to AMOS 6 confirmatory factor analysis using maximum likelihood estimation (MLE) method to test the predetermined factor model specifying the number and composition of the factors. Six factors and fifteen observed variables were included in the data set. The goodness of fit statistics was checked in order to see if the six theoretical factors matched the actual data. The results provided in Table 10 show that the model fit the data well. χ^2/DF was less than 5 for an acceptable fit, and other relative fit indices (CFI, IFI, and TLI) are all above .90, which support the good fit for the data to model.

Table 10

Goodness of fit statistics for confirmatory factor analysis

	Default model
Npar*	50
χ^2	241.13***
Df	70
χ^2/DF	3.45
CFI	.93
TLI	.90
IFI	.93

Note. Npar refers to number of distinct parameters
*** $p < .001$

Next, the factor loading of items was checked (Table 11). All the standardized factor loadings are above .70, which indicates high correlation of the items with the factors.

Table 11

Factor loadings for confirmatory factor analysis

	Unstandardized	Standardized	P
Role definition			
Q1	1.00	0.95	NA
Q2	0.89 (0.04)	0.93	.001
Managing change			
Q3	1.34 (0.11)	0.81	.001
Q4	1.00	0.79	NA
Q8	0.83 (0.06)	0.74	.001
Q15	0.85 (0.08)	0.75	.001
External impact			
Q5	1.00	0.76	NA
Q6	0.74 (0.07)	0.74	.001
Internal impact			
Q9	1.00	0.73	NA
Q7	0.78 (0.08)	0.73	.001
Supporting factors			
Q11	1.00	0.97	NA
Q12	1.04 (0.04)	0.95	.001
Hindering factors			
Q10	1.02 (0.08)	0.73	.001
Q13	1.00	0.96	NA
Q14	0.89 (0.05)	0.88	.001

Next, the reliability test was performed to test internal consistency of the self-assessment section of the survey. The Cronbach's Alpha of the pre-workshop survey was .893 indicating high reliability of the survey (Table 12).

Table 12

Descriptive statistics of pre-workshop self-assessment of strategic competencies

	N	Minimum	Maximum	Mean	Standard Deviation
Blue	21	1.87	3.87	2.46	.47
Green	23	1.80	3.60	2.43	.52
Yellow	22	1.60	3.53	2.27	.61
Red	20	1.67	3.53	2.51	.52

5= Strongly Agree; 1= Strongly Disagree
Scale reliability: Cronbach's alpha = .893

The one-way ANOVA test was run to find out if there was significant difference between the responses to the pre-workshop self-assessment questions provided by four groups. As shown in Table 13, there was no significant difference between the means of four groups in pre-workshop survey at the level of .05.

Table 13

ANOVA test results for pre-workshop self-assessment of strategic competencies

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.68	3	.23	.81	.493
Within Groups	23.14	82	.28		
Total	23.82	85			

The Cronbach's Alpha of the post-workshop survey was .94 indicating high reliability of the survey (Table 14).

Table 14

Descriptive statistics of post-workshop self-assessment of strategic competencies

	N	Minimum	Maximum	Mean	Standard Deviation
Blue	20	3.67	4.80	4.27	.26
Green	22	3.53	4.80	4.24	.32
Yellow	18	2.27	3.20	2.80	.25
Red	19	3.40	4.73	4.12	.35

5= Strongly Agree; 1= Strongly Disagree
Scale reliability: Cronbach's alpha = .94

A one-way ANOVA test revealed a significant difference between the four groups in the post-workshop survey with an F-test score of 104.49 (Table 15). Tukey's post hoc analysis was run to obtain information on which groups were different from others. The result of the analysis indicated statistically significant difference between Group Yellow and the other three groups in the post-survey. Group Yellow has significantly lower mean than the other three groups. The Blue, Green, and Red groups were not significantly different from each other.

Table 15

ANOVA test results for post-workshop self-assessment of strategic competencies

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	27.67	3	9.22	104.49	.000
Within Groups	6.62	75	.09		
Total	34.29	78			

Category 1: Assigning roles and tasks in change-related activities. The means of the Blue, Green, and Red groups more than doubled from the pre-workshop survey to the post-workshop survey (Figure 18). Effect sizes between 0 and .2 are considered a small effect size, between 0.2 and .8 a medium effect size, and above .8 a large effect size. As seen in the t-test and Cohen's effect size the increases in means of these three groups were both statistically and practically significant. The increase in the mean of Group Yellow was not significant.

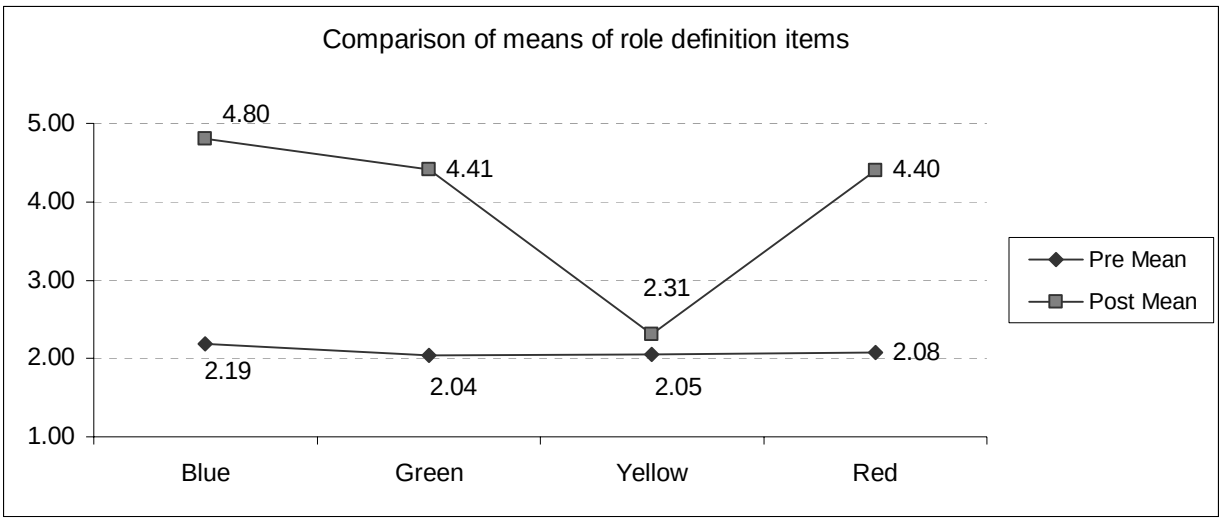


Figure 18. Comparisons of role definition in change process items in pre- and post-workshop surveys

Category 2: Planning and managing change-related activities. The increase in the means of Groups Blue, Green and Red from the pre-workshop survey to the post-workshop survey were statistically and practically significant at the level of .001 (Figure 19). The increase in the mean of group Yellow from the pre-workshop survey to the post-workshop survey was significant at the level of .01.

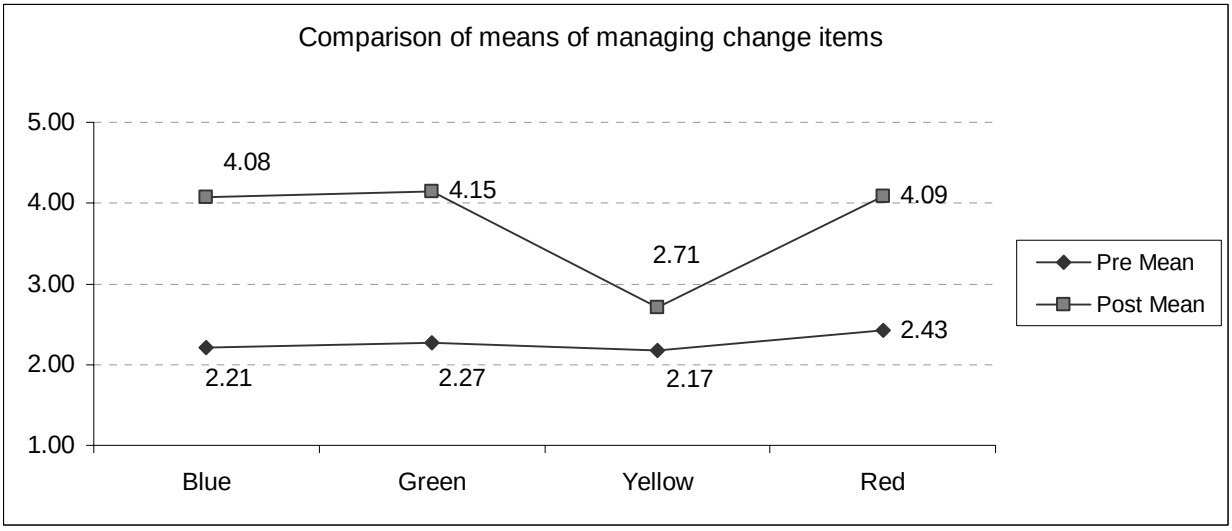


Figure 19. Comparisons of managing change items in pre- and post-workshop surveys

Category 3: Evaluating impact of change on external environment. The increases in the means of all groups from the pre-workshop survey to the post-workshop survey were statistically significant (Figure 20).

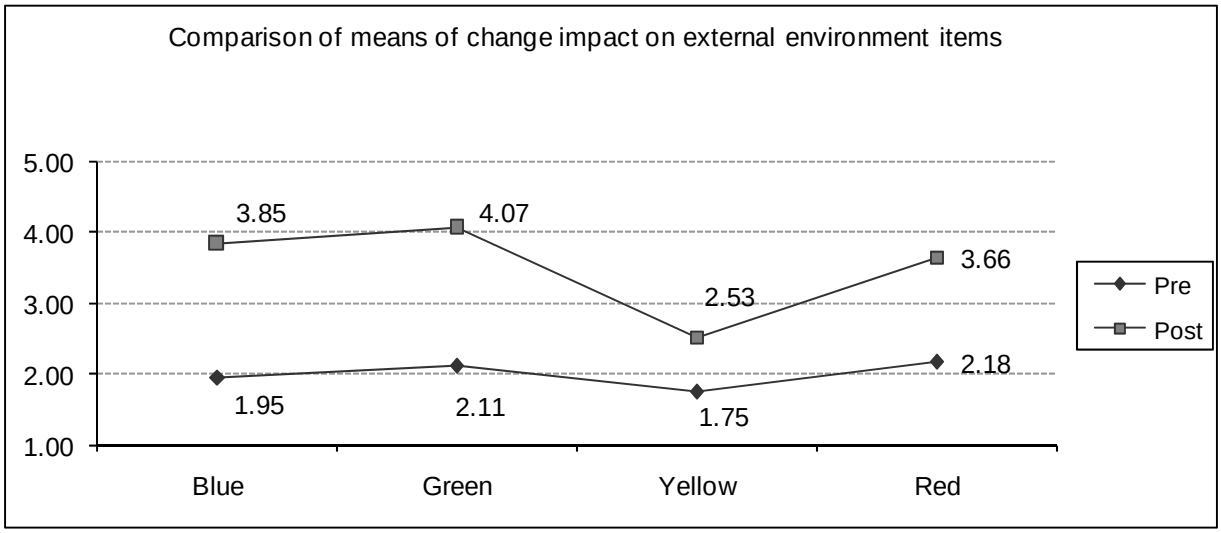


Figure 20. Comparisons of change impact on external environment items in pre- and post-workshop surveys

Category 4: Evaluating impact of change on internal environment. The increases in the means of the Blue, Green, and Red groups were statistically and practically significant at the level of 0.001. The increase in the mean of Group Yellow was not significant (Figure 21).

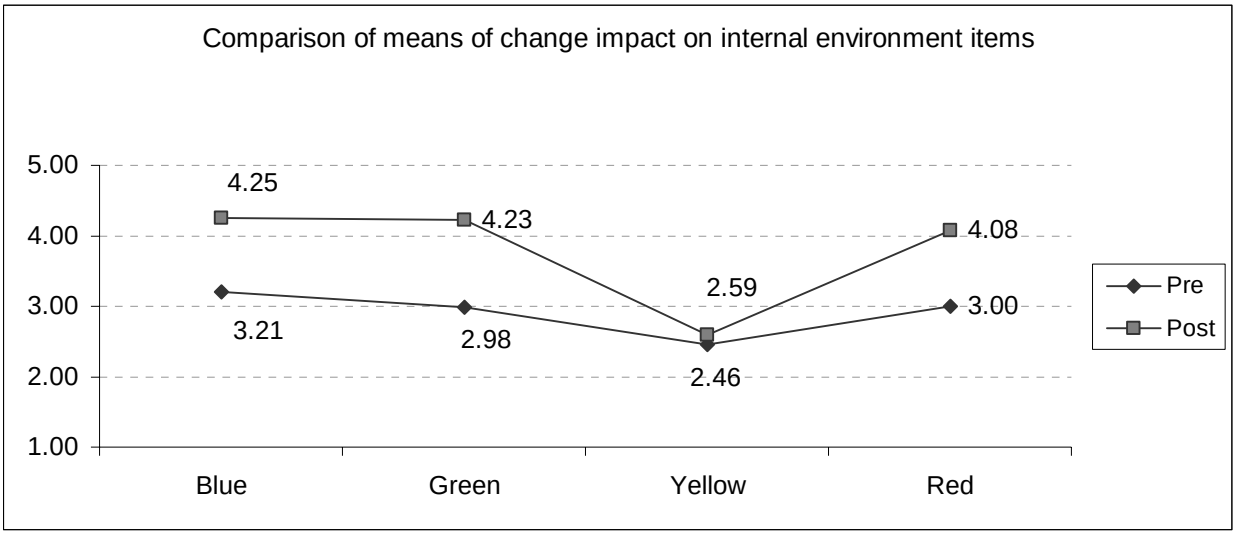


Figure 21. Comparisons of change impact on internal environment items in pre- and post-workshop surveys

Category 5: Identifying and managing strong organizational aspects supporting change. The increases in the means of all groups from the pre-workshop survey to the post-workshop survey were statistically significant (Figure 22).

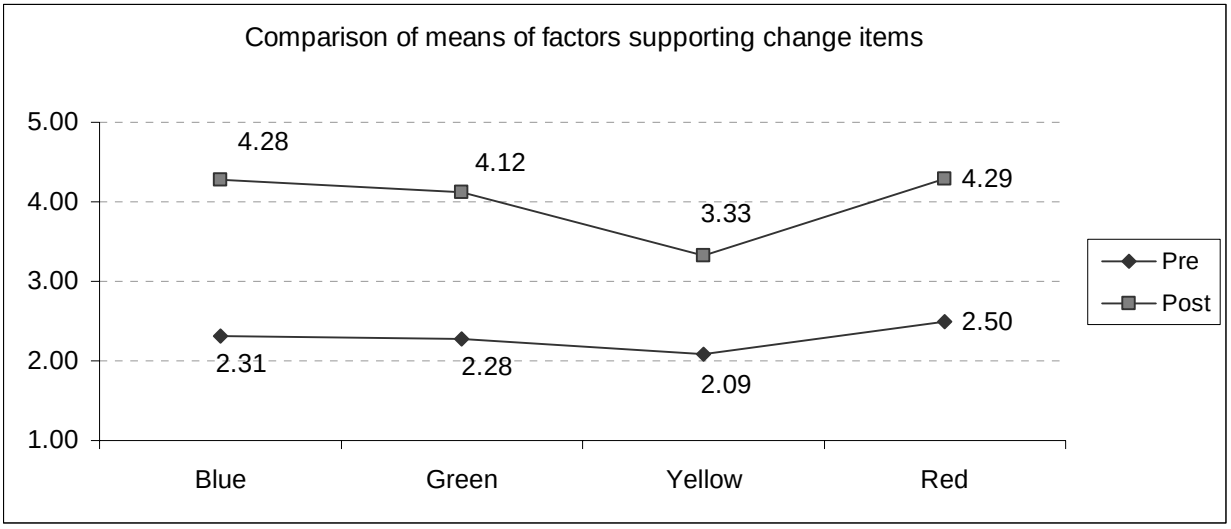


Figure 22. Comparisons of factors supporting change items in pre- and post-workshop surveys

Category 6: Identifying and managing barriers to change implementation. The increases in the means of the Blue, Green, and Red groups from the pre-workshop survey to the post-workshop survey were statistically and practically significant at the level of .001 (Figure 23). The increase in the mean of Group Yellow was significant at the level of .01.

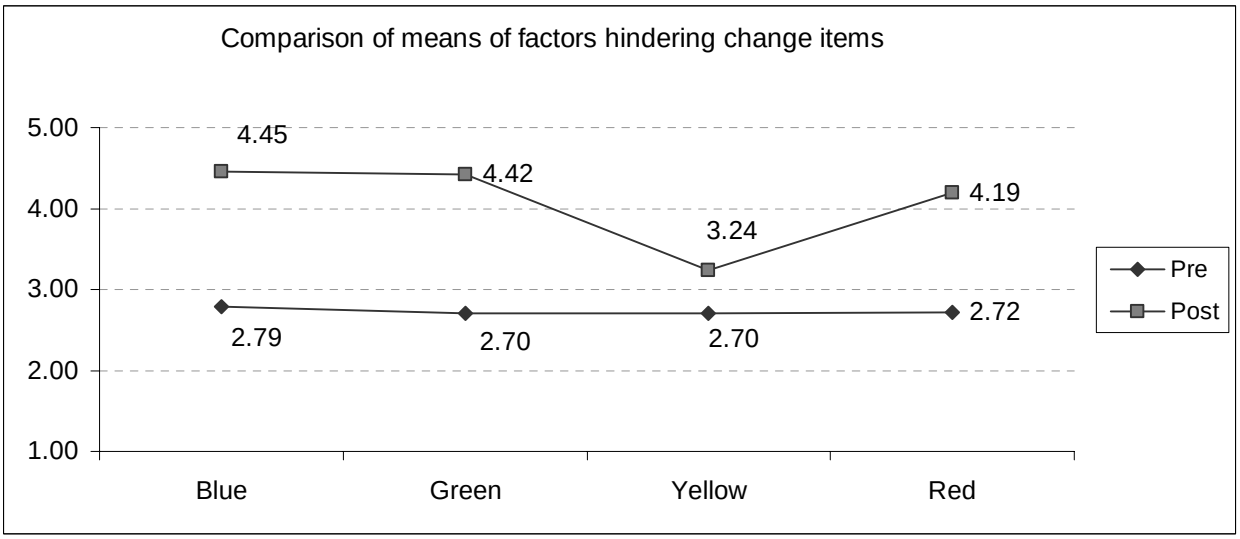


Figure 23. Comparisons of factors hindering change items in pre- and post-workshop surveys

While their pre-workshop strategic competencies were assessed by managers as average or slightly below and above average, the post-workshop survey results demonstrated a large increase of self-assessment scores in three out of four groups. Groups Blue, Red and Green assessed their strategic competencies as very high after attending the workshop. The scores of managers from Group Blue increased the most, especially in areas related to the knowledge of role distribution among functional units and identification and leveraging strong organizational factors supporting change. Group Yellow showed the least increase in self-assessment of strategizing abilities, especially when evaluating their knowledge of role distribution and the impact of changes on internal organizational processes.

The analysis of the scores based on six self-assessment categories revealed that after the workshop managers felt more confident in their understanding of role distribution among functional units involved in change implementation (Category 1), abilities for planning and managing change projects (Category 2) and identification and use of organizational factors that could support change initiatives (Category 5). They felt least confident in their ability to explain how the changes in their organization are aligned with regulatory requirements and the World-Class Commercialization framework and how they would impact partnering organizations and vendor networks. In other words, they still could not confidently explain why the changes were needed and what consequences MTS and the whole company would face if it failed to implement them.

Strategic Knowledge Transfer: Change Agenda Implementation Plans

Examination of the survey results was complemented by the analysis of the change agenda implementation plans submitted by the workshop participants within two months after attending the workshop. The research question formulated for this data was concerned with the

evidence of transfer of learning from the strategic episode to the workplace context. The study proposition related to analysis of the plans suggested that these documents would demonstrate the transfer of the strategic design approach learned during the strategic episode into business-specific actionable items.

Managers who participated in the workshop were asked by the MTS leadership to use the notes and design documents from the strategic episode when preparing the plans. The plans were submitted within two months from the workshop delivery. These documents were expected (a) to summarize the status of change agenda related projects at the plants and (b) to provide the schedule for concrete change activities. Each of the four manufacturing networks submitted a plan to the MTS strategic planning group who gave permission to use fragments of those documents in this research study. Since the plans were not a part of the study's initial data sources, they had certain limitations. Although they were prepared only by the managers who participated in the strategic episode, there was no information about the workshop group affiliation of those managers who authored the plans. Therefore, linking a particular group's design decisions from the strategic episode with the specific elements of the plans was not feasible. Another limitation was the free format of the plans. The documents were not required to follow the triangular design defined by the activity-based strategic tool, which made the analysis challenging and required the development of the following proxy measures:

- The plans will contain evidence of the identified seven component groups for each business process they outline, organized into categories consistent with the elements of the activity-based strategic tool: *People, Tasks, Outcome, Functions, Rules, Methods/Tools,* and *Context* (Criterion 1)

- The plans will contain evidence of identified strengths, gaps and contradictions related to each business process they outline (Criterion 2)

Despite their limitations, the plans provided some valuable information on how managers applied their learning from the strategizing exercise in the workplace context.

Networks A and D organized their plans around critical deliverables specified by the change agenda, such as Process Flow Documents, Development History Reports, or Validation Master Plans. Networks B and C took a more holistic approach to strategic planning, focusing on the current situation at the network and defining and prioritizing projects. Figures 24 - 27 below outline the structure of each plan. The fragments of the original plans are provided in Appendix P.

Change Agenda-Required Process/Document		
CURRENT STATE:		
Key Best Practices	Key Enablers & Opportunities	Key Issues
IMPLEMENTATION PLAN:		
Action Items	Owner/Contributor/Reviewer	2004-2005 Deliverables & Delivery Dates

Figure 24. Structure of change implementation plan: Network A

1. Critical projects for 2004-2005
2. Project owners and contributors*
3. Project action items and deliverables*
4. Required documents and other prerequisites*
5. Issues to address*
6. Available resources*
7. Timeline*

** - for each individual project listed under #1*

Figure 25. Structure of change implementation plan: Network B

Current Tasks	Priority Level	Execution Barriers	Solutions	Role Assignments	Deadlines

Figure 26. Structure of change implementation plan: Network C

Change Agenda-Required Process/Document				
Required Actions	Status	Resources	Deadlines	Responsibilities

Figure 27. Structure of change implementation plan: Network D

Although all network groups used different terminology, they demonstrated structural consistency and similar components. The authors approached the plans' design systematically, identifying key players and, in some cases, indicating their specific responsibilities (e.g., owner, contributor, or reviewer). They identified the tasks along with resources and timelines for their completion, and, in the majority of plans, managers included the barriers to implementing those tasks along with potential ways to address them. Based on the criteria developed in this study for evaluating strategic knowledge transfer to the workplace context, these documents provide evidence that the activity-based approach was partially utilized by the plans' authors:

Criterion 1. All four plans contained evidence of several categories consistent with the elements of the activity-based strategic tool:

- *People/Functions* (Network A: Owner/Contributor/Reviewer; Network B: Project Owners and Contributors; Network C: Role Assignments; Network D: Responsibilities);
- *Tasks* (Network A: Action Items; Network B: Project Action Items and Deliverables; Network C: Current Tasks; Network D: Required Actions);
- *Methods/Tools* (Network A: Key Best Practices; Network B: Available Resources; Network D: Resources);

- *Rules* (Network A: Delivery Dates; Network B: Required Documents and Other Prerequisites, Timeline; Network C: Priority Level, Deadlines; Network D: Deadlines);
- *Outcome* (Network A: specified product (e.g., Process Flow Document) and 2004-2005 Deliverables; Network B: Project Deliverables; Network C: Solutions; Network D: specified product (e.g., Validation Master Plan).

As we see from this list, all but the *Context* components of the business process consistent with the elements of the activity-based strategic tool were present in the change agenda implementation plans. Moreover, managers applied the exact same vocabulary used during the strategic episode when they mapped system elements onto the activity triangles (e.g., owner/contributor/reviewer, role assignments and responsibilities).

Criterion 2. Some plans contained evidence of identified strengths, gaps and contradictions related to each business process they addressed. Thus, managers from Network A listed the availability of the Development Process Flow Document (PFD) and new global standards among key enabling factors that would support them in the preparation of Manufacturing Process Flow Documents consistent across the network plants and structurally similar to the documentation prepared by the Product Development organization (see Appendix P). At the same time, managers pointed to the challenging aspects of PFD preparation by indicating that technical knowledge required for preparation of a PFD at sites was limited and there were gaps in understanding the PFD requirements depending on the level and specific areas of personnel involvement in manufacturing process. The plan submitted by Network C also contained information about certain aspects of the business ("execution barriers") that presented challenges to successful implementation of the change agenda related tasks. For instance,

preparation of the Development History Reports (DHR) required for each product being manufactured was found problematic for older products. Since DHRs were not previously required, historical data and lessons learned from daily manufacturing processes have not been captured and organized in a systematic way. Managers described the gap that existed between manufacturing process knowledge since the product went on the market (sometimes 15-20 years ago) and the present day as one of the major issues in preparation of DHRs for legacy drugs.

The analysis of the plans using this criterion demonstrated that three out of four plans listed gaps and contradictions that presented barriers to change agenda related activities, and one plan (Network A) also recognized strong business aspects that would support implementation of the planned tasks.

Summarizing the results of the plans' analysis conducted following the criteria developed for evaluating strategic knowledge transfer to the workplace context, we can suggest that managers at least partially utilized the strategizing approach guided by the activity-based strategic tool that they learned during the workshop. Certainly, we cannot claim that the evidence of strategic knowledge transfer demonstrated by the change implementation plans can be exclusively attributed to the managers' experiences during the strategic episode. Additional factors, such as other workshop activities, formal and informal discussions during the conference, or the previous experience of the managers who were in charge of preparing those plans could have contributed to the plans' design. Further investigation would be required to follow the linkages between the strategizing experience and the application of strategic knowledge in the real workplace context. Unfortunately, the limited time of this project did not allow for such a follow-up. Nevertheless, the available data provided by the plans suggest

applicability of the activity-based tool for guiding managerial strategic thinking in change-related context.

Managerial Reflection on Strategic Learning

Managers' comments on the advancement of strategic expertise collected during the post-workshop interviews provided additional insights into the role of the activity-based strategic tool in facilitating the process of strategic knowledge development. A series of semi-structured interviews and focus groups was conducted after the workshop in order to obtain the managers' perspective on learning from the collaborative strategizing exercise and integrating what they learned into their business practice (Appendix K).

The majority of the interview respondents noted that the strategic episode helped them to better prepare for the conference and identify priorities for the conference's topical discussions:

> *"I think talking about balancing MTS change agenda with local constraints before we actually began our conference was a very smart move. Structured discussions gave us a better idea what to focus on at the conference and formulate more specific questions.* (Director, MTS, Group Green)

When asked about how the activity-based strategizing experience was different from other training exercises, one of the MTS team leaders commented: *"We typically get content-based training, but content knowledge is not enough for solving our problems. It was very useful to talk to other people and look at the problems from different angles."* (Group Green)

Other interview respondents echoed this feedback by emphasizing the novelty of team-based problem solving and knowledge sharing that was very different from other training activities in which they had been involved:

> *"Usually our training is watching the slides or video broadcasts with leadership messages and some best practice examples. You do not have a chance to talk to other people or discuss what worries you at the moment. This exercise was incredible; we covered so much in one hour that we wouldn't for the whole year! The only thing that can*

> *be done for improvement is to give people more time for this exercise."* (Manager, Engineering, Group Red)

Cross-functional collaboration was perceived as the most valuable aspect of the strategic episode. It allowed managers, not only to clarify critical business issues and to compare their views, but, most importantly, to start moving towards resolution of those issues:

> *This activity showed us how to build a more cooperative environment between all functional areas…now it seems as if all areas: Engineering, Tech Services, QC* [Quality Control] *are laboring under a silo mentality…Everyone is worrying about their group at the expense of overall priorities.… This is most likely a survivalist response - people are swamped with work, they focus on immediate needs. The result is… more work because we are not coordinated. I believe, if we did this kind of activity more often, we could get more done without going crazy about amount of work we have to do every day.* (Team Leader, Engineering, Group Yellow)

> *"I don't know if I'm saying this correctly or not, but I think this form of teamwork helps us develop a true learning organization where all levels have a better understanding of what it takes for them to work together to come up with new ideas, with new solutions".* (Manager, MTS, Group Blue)

Another positive aspect frequently mentioned in the interviews was an opportunity for novice members of the MTS organization to learn from more experienced managers:

> *"I did not know anything about PFD* [Process Flow Document] *as we don't have it at our site. Now I have a very clear understanding of what needs to be done and how to do it. My group was incredible; I've never had a chance before to work side-to-side with a network director. It was a bit intimidating at first, but I learned a wealth from him."* (Sr. Associate, MTS, Group Green)

> *"It was a very… invigorating experience. I've never seen Dr. Smith so alive, she shared so many ideas in her design! Our group had several project associates, some from the affiliates, they definitely learned a lot of new things from her. I wish we did it earlier and more often."* (Team Leader, MTS, Group Blue)

The collaborative, problem-based format of the strategic episode helped middle managers learn important strategic concepts and processes and received almost unanimous accolades. However, some members of the upper management who did not feel that the strategizing activity was beneficial for them expressed reservations:

> *"I haven't learned much in this exercise. Maybe it was useful for the folks who are just joining MTS. I always think about a practical side of such exercises: Can we use them in real planning? I don't think so. There were some interesting discussions, though, at the end of the session when we talked about DPM's* [Development Project Management] *role in manufacturing process. DPM is a new concept and people indeed need more information about it."* (Director, MTS, Group Yellow)

> *"I prefer very concrete, data-driven presentations. This triangle provided a good structure, but can we devote so much time to discussions?! This approach is risky: people can slide into criticizing everything without accomplishing anything. What we really need is to clearly communicate what must be done and evaluate how it is done at the sites."* (Director, MTS, Group Yellow)

This comment may have its merit: accustomed to the instructor-centered information transmission methodology, some employees may not feel comfortable using a collaborative problem-solving approach that requires an active participation in the learning process and ability to deal constructively with different, sometimes antagonistic, ideas. Of particular interest here is the group affiliation – Group Yellow - of both directors who responded negatively to the format of the strategic episode and use of the activity-based tool. As we have seen from the post-workshop survey analysis, the performance of Group Yellow in all three categories of the survey (strategic concepts and processes, strategic problem solving, and self-assessment of strategic competencies) was significantly lower than the one of the other three groups. The analysis of the strategizing process of Group Yellow (presented in the next section) reveal that the number and quality of the design artifacts produced were lower than those of other groups, and that Group Yellow's conversations did not advance beyond simple identification of the system issues. The fact that negative comments came from the director level suggests that in the MTS hierarchical culture, upper management may believe that the collaborative format of a training activity threatens power relationships with their subordinates. Follow-up interviews, which are presented after the discussion of the strategizing process in the next section, explored the process dynamics

and the potential causes of the group's negative performance. Further research would be beneficial for examining the impact of power relationships on collaborative dynamics and performance of the groups that are represented by both upper and lower management.

Managers noted several "aha" moments that occurred when they used the tool. Thus, Group Blue's representative indicated that his understanding of the concept and role of both operational and 'integrated' validation master plans in guiding compliant validation processes at manufacturing plants significantly changed in the course of analysis of the Process Validation system:

> *"The VMP* [Validation Master Plan] *seemed to mean many different things to everyone I've talked to before the workshop. The need for having additional VMP, an integrated version was not well understood. We did not know why it was required, and how it was supposed to be different from the one we were using. My understanding was that iVMP* [integrated Validation Master Plan] *is a template for product-specific VMPs. I did not realize that the idea of iVMP is completely different. We talked a lot about it when we designed our validation triangle. iVMP is required for each type of manufacturing capability, and it includes more than just validation exercise, it sets criteria for integrated systems. This was a big new thing for me."* (Sr. Associate, MTS, Group Blue)

Another project associate from Group Yellow commented on his 'discovery' that the Development Process Flow Document should be used in conjunction with the Manufacturing Process Flow Document to ensure consistency during the transfer of drug production process from the laboratory to manufacturing environment and compliance with critical process parameters established during the product development.

The limited time of the strategic episode was mentioned as a factor that negatively affected managers' learning during the strategic episode. The design of the strategizing activity required a pace that challenged careful reflection on their design decisions and detailed discussion of alternative system changes:

> *"I wish we could have more time in this activity. When you hear other people in your group proposing something, you want to discuss it to be able to understand if their*

> *proposal makes sense. Also, it was such a great idea to put us in groups with folks from other areas! Of course, we wanted to talk as much as possible and learn how they deal with the same issues that we have. There was no time for that."* (Team Leader, MTS, Group Blue)

Unfortunately, in the context of this project, the decision about time allocation for the workshop did not belong to the researcher. For future studies that would consider replicating the design of the strategic episode implemented in this research, at least six to eight hours are recommended for completing all the steps:

- defining the elements of a business system and mapping them onto the activity-based tool.,
- analyzing interactions between all the elements and identifying strong linkages, gaps and contradictions,
- formulating system changes necessitated by identified gaps and contradictions; and
- integrating these changes into the system design.

When asked about the potential application of the strategizing approach used at the workshop in the workplace context, eleven out fourteen interviewed managers (79%) indicated that they would use the collaborative strategizing format and an activity-based tool in site-based training activities when analyzing issues related to business project implementation. A manager from Network B shared that the strategizing activity had been already successfully replicated at the network-based strategic meeting that took place in August 2004, two months after the MTS conference. Although the data from that network meeting are outside the scope of this study, the review of the design sketches provided by the manager demonstrated that network B personnel analyzed six critical change agenda-related projects using the activity-based strategic tool, listed problems identified as the result of the design, and outlined a program of action that addressed

those problems. This, although limited, evidence suggests that managers from Network B were able to successfully transfer their strategizing experience to the local, network-specific context and replicate it for addressing network-specific needs.

During the follow-up interviews, a participant estimation method (Phillips & Stone, 2002) was used to assess the extent to which a strategizing activity contributed to the advancement of managers' strategic knowledge. Interview respondents were asked to estimate their progress in developing strategic knowledge and skills before and after participation in the workshop and other conference activities. Nine respondents (64%) indicated that between 70 to 80 percent of their improvement could be attributed to their participation in the strategic design activity, and another 20 to 30 percent to participating in other workshop activities and conference sessions. Two respondents (14%) estimated the impact of the strategizing episode on the advancement of their strategic expertise as 50 to 60 percent, and three respondents (21%) – as 20 to 30 percent. The criteria for these estimations listed by the interview respondents included: (a) the collaborative format of the strategic episode, (b) the focus on real issues, (c) a systematic approach to addressing those issues, (d) the visual structure of the tool that helped analyze complex processes, and (e) the peer exchange of expertise and workplace experiences.

Assessment of Strategic Learning: Summary of Findings

The research question focused on the impact of the strategizing experience on managerial learning was addressed through the analysis of the surveys, change agenda implementation plans and, partially, through the follow-up interviews and focus groups.

Surveys. By comparing the results of the pre-workshop and post-workshop surveys, we looked at how the strategic competencies changed after the MTS managers participated in the strategic episode. The following study propositions were tested:

- The results of the post-workshop survey will demonstrate learning gains in relation to knowledge of the strategic concepts and their application in ill-structured problem solving contexts.
- The workshop participants' self-assessment of the strategic skills in the post-workshop survey will improve in comparison to the initial survey.

When answering the post-workshop survey questions, MTS managers demonstrated progress in all three survey categories: strategic concepts and processes, strategic problem solving, and self-assessment of strategic competencies. The scores of all four groups before the workshop were comparable, but after the workshop, Group Yellow consistently demonstrated the least progress across all categories of the survey, and its scores were significantly lower than those of the other three groups. The follow-up interviews and focus group with the members of Group Yellow were focused on investigating the potential causes for such discrepancy, and they are discussed further in this chapter.

Managers also demonstrated the increase in their self-assessment of strategic competencies after attending the workshop. The self-assessment scores of managers from Group Blue increased the most, especially in areas related to (a) knowledge of role distribution among functional units and (b) identification and leveraging strong organizational factors supporting change. Group Yellow showed the least increase in self-assessment of strategizing abilities, especially when evaluating their knowledge of role distribution and the impact of changes on internal organizational processes. Overall, after participating in the strategic episode, managers felt very confident (a) explaining role distribution among functional units involved in change implementation, (b) identifying organizational factors that could support change initiatives, and (c) assessing their ability to plan and manager change-related projects. They still needed support

in such areas as (a) alignment of change-related activities with external regulatory requirements and (b) assessment of the change projects impact on partnering organizations and other organizational networks.

The study propositions related to the survey were generally supported. The results of the survey analysis suggested that the strategizing experience using an activity-based strategic tool helped managers clarify critical aspects of the organizational process, such as role distribution, new process and document requirements, managing change-related activities and leveraging strong and weak organizational factors that may have an impact on change implementation.

Change agenda implementation plans. Analysis of the change agenda implementation plans was concerned with the strategic learning transfer to workplace context. The following research proposition was tested as the plans were examined:

- The change agenda implementation plans produced after the workshop will contain the evidence of the transfer of the strategic concepts and design approach learned during the strategic episode into specific actionable items.

Examination of the change agenda implementation plans submitted after managers' participation in the strategic episode provided some evidence of strategic knowledge transfer to the workplace context. When constructing the plans, managers utilized the systematic approach to business problems learned during the strategic episode. They (a) outlined the tasks associated with the change agenda requirements and defined the project outcomes, (b) identified best practices, enablers and opportunities as well as the issues that presented barriers to task completion, (c) assigned roles to the key organizational actors involved in the projects, and (d) identified methods, tools and resources for supporting project work. This approach was consistent with the strategizing process managers experienced during the workshop and met the

criteria for transfer assessment developed for this group of data. Although the plans varied in their presentation of the strategizing approach, mostly because they were not part of the planned study data, we believe that the proposition regarding the transfer of the approach learned during the strategic episode into specific actionable items was at least partially supported by the change agenda implementation plans.

Follow-up interviews and focus groups. The follow-up interviews and focus groups generally supported the results obtained from the analysis of surveys and plans. The majority of the interviewed managers expressed their satisfaction with the format, content and process of the strategic episode and emphasized the positive role of the activity-based tool in clarifying complex strategic issues. Seventy-nine percent of interviewees indicated their intention to use the tool in site-based training programs, and one manager shared information about successful replication of the strategic episode and use of the tool at the local strategic meeting.

More than half of the interviewees indicated that between 70 and 80 percent of their learning at the conference could be attributed to their participation in the strategic episode, and all interviewed managers recognized the impact of the episode on the advancement of their strategic expertise.

Considering the context of the strategic episode that included other workshop activities and conference sessions that immediately followed, we cannot claim that the evidence of the advancement of strategic knowledge and skills demonstrated by the workshop participants through the surveys, plans and interview responses can be exclusively attributed to the managers' experience during the strategic episode. As always in action research, many environmental factors may exert influence on learners and affect the results of the learning assessment. This exploratory study was design primarily for examining the affordances of a new activity-based

tool used for guiding the strategizing process. If the specific goal of a future study is an assessment of learning gains resulting from the use of this tool, a more structured, perhaps experimental, research context would be more effective for isolating the effects of training intervention on the learning outcomes of the study participants. However, regardless of the limitations associated with the study context, a conclusion can be made that the strategic episode guided by the activity-based strategic tool had contributed to the advancement of managers' strategic knowledge demonstrated through the tests and improvement of their self-assessment of strategic competencies.

As asserted earlier in this manuscript, evaluating effectiveness of strategic tools cannot be limited to the assessment of the outcomes of a strategic tool's use or user testimonials (Davis and Kottemann, 1994; Rosenhead and Mingers, 2001; Stenfors & Tanner, 2007). This study's design is grounded in a proposition that the effectiveness of a tool used for mediating a strategizing activity can be demonstrated not only through competency test results and through the accounts of participating individuals, but at the time when a strategic tool is actually used, that is, during a strategic episode. The evidence of advancement of managerial strategic expertise, or strategic knowledge construction, can be obtained through (a) examination of the artifacts produced during the strategizing activity and (b) evaluation of strategic discourse. Therefore, the next several sections focus on the analysis of the collaborative strategizing process and discuss the evidence of the strategic knowledge construction demonstrated through managers' conversations and their design decisions.

Strategizing Process

The research question focused on the specifics of the activity-based strategic tool use during a strategic episode was addressed through analysis of the (a) design artifacts produced by managers using the tool, and (b) conversation records made during a strategizing activity.

Observational notes, worksheets, and managers' reflection on the strategizing process provided additional insights into the dynamics of the strategic episode and clarified some of the tensions that have negative impact on group dynamics and individual performance of collaborating managers.

During the 60-minute strategic episode, the workshop participants were engaged in analysis and redesign of four business systems based on major MTS events: Acceptance from Development (Group Yellow), Process Validation (Group Blue), Technology Transfer (Group Green), and Deviation Management (Group Red). The process followed Mwanza's methodology for analyzing activity systems (Mwanza, 2001) adapted to the context of a strategic episode and involved the following steps:

- defining elements of a business system and mapping them onto the activity-based tool,
- analyzing interactions between all the elements and identifying strong linkages, gaps and contradictions,
- formulating system changes necessitated by identified gaps and contradictions, and
- integrating these changes into the system design.

For presentation purposes, these steps are discussed here as three categories:

- Modeling business systems

- Analyzing business systems and identifying contradictions
- Redesigning business systems

These three task categories correspond to the assignments that managers received during the strategic episode at the workshop.

Although strategic design and managers' discussions naturally took place at the same time, they are presented here in two separate sections to make the discussion of results more structured and help the reader navigate through the evidence of strategic knowledge construction present in both design outputs and managerial conversations.

Before I present the results of the strategic design and associated discourse, I refer the reader to the technical glossary provided in Chapter Two: Organizational Context. The content of both design artifacts and discourse is very technical and company-specific; therefore, the reader will benefit from reviewing key technical terms used in the following sections prior to examining the dynamics and outcomes of the strategizing process.

Strategic Design

The goal of the analysis of the design artifacts produced by managers during the strategic episode was to look at how the activity-based strategic tool assisted with identification, analysis, and resolution of organizational issues. The study propositions related to this data category suggested that

- the strategic design documents produced by the workshop participants will exhibit evidence of identified components of the business systems,
- the strategic design documents will exhibit evidence of identified strong linkages between the system components,

- the strategic design documents will exhibit evidence of identified contradictions (gaps and/or tensions) between the system components, and
- the strategic design documents will evolve during the strategic episode thus demonstrating change in business system structures and component relationships.

Modeling Business Systems

The system modeling step was concerned with identifying elements of a business system and mapping them onto the activity-based tool. Managers began their work with identifying and grouping the system elements and recording them on posters that contained an activity-based triangular template. Adaptation of Mwanza's 8-step model was used to guide identification of *Outcome, Tasks, People, Functions, Tasks, Rules, Methods/Tools and Context* and for each system:

1. Outcome (*Result)*: What is the outcome of the event?
2. Tasks *(Problem Space)*: What is the goal? What problems are being solved?
3. People *(Key Players)*: Who is directly involved and responsible?
4. Functions *(Roles Distribution, Level of Involvement)*: How are the roles distributed? What functions are performed?
5. Rules *(Controls, Standards, Expectations)*: What internal and external standards regulate the event?
6. Methods/Tools *(Documents, Procedures, Technologies)*: How are procedures performed? What tools and methods are used?
7. Context *(Product lifetime context)*: What organizational structures and WCC stages are impacted?

The duration of the modeling step varied among groups. Thus, Group Blue mapped the components of the Process Validation system within ten minutes, while it took almost half an hour to reproduce the current Acceptance from Development process for Group Yellow. All four groups were able to identify at least one system component under each category of the triangle. Appendix J contains the initial design produced by the groups.

The modeling step involved not only deconstructing the current business systems and mapping their components onto the triangular template; the groups also identified several issues within and between the categories that corresponded to Engeström's primary and secondary level contradictions. These contradictions are discussed under each category below.

Outcome. Outcomes of the systems were identified first in all four groups. These were major document deliverables, such as a deviation report (Group Red) or the formal approval of a new process (Groups Blue: validated manufacturing process; Group Yellow: manufacturing process readiness after transferring from Development organization; Group Green: transferred validated process).

Groups Blue, Yellow, and Green debated whether the outcome of the system should be a process or a specific document:

> *"Are we talking about a validation report or approved validation? There are several outcomes that can be listed here: qualification reports, validation reports, stability reports, testing lots… They all are critical. What do we pick?"* (Group Blue)

The decision in all three groups was made to indicate the major process-based outcome, and to list all interim deliverables, both process- and document-based under *Tasks*.

Tasks. Components listed under the *Tasks* category were identified successfully in all workshop groups. The only observed issue was the dilemma between the *Tasks* components versus the *Outcome* components discussed above. All four initial system designs contained a

balanced combination of processes and documentation deliverables that the key players listed under the *People* category had to complete in order to achieve the expected *Outcome*.

People. All four groups presented components under the *People* category as a multifunctional set that included not only representatives of the MTS organization, but their major technical partners: Engineering, Quality, Operations, and Development, as well as corporate and local auditing units, such as the Regulatory group and the Global Post-Launch Optimization Team. Groups Red and Green especially struggled through deciding who would be included in this category as key players. The two groups debated whether only the people who were immediately involved in managing business events should be part of the *People* category, or whether local and corporate control units who were auditing the process and approving its outcome should also be included:

> *"Why is GPLOT* [Global Post-Launch Optimization Team] *listed here? Sure, it's the main player, but they don't run the transfer on a daily basis, they just oversee it, authorize it. Basically, we can list anyone under this section; the transfer involves everybody at both sites. We probably need to have two sub-groups here: local folks and corporate functions.*
>
> *I think, we just list everyone here, and then explain their roles when we fill in the Functions part."* (Group Green)

Group Green made the decision to include all functional units, either corporate- or plant-based, who were involved in preparing documentation, or managing, executing, authorizing and evaluating the technology transfer process. Similar designs were produced by the other three groups.

Functions. Although several key players were listed under the *People* category, managers did not elaborate fully on their roles and responsibilities in the initial designs and simply listed MTS as a managing body. There were two examples, however, that indicated an attempt to differentiate between the MTS roles and the contributions of other functional units involved in

the business systems under analysis. Thus, Group Red recorded shared ownership over the deviation investigation process between MTS, the Regulatory, and the Quality units:

> *"MTS orchestrates all activities; MTS, Regulatory and Quality co-own the process and all sign report."* (Group Red: record made on the design of current Deviation Management system)

Group Yellow, however, could not resolve the process ownership tension between MTS and the Development Project Management (DPM) and decide which functional unit – DPM or MTS – was responsible for managing and overseeing the product transfer from Development organization to Manufacturing organization:

> *"DPM/MTS – review if development is done and manage transfer."* (Group Yellow: record made on the design of current Acceptance from Development system)

This difficulty is not surprising considering the fact that both Development organization and MTS are equally involved in transferring the drug production process from the laboratory environment into the large manufacturing context. Group Yellow could not resolve this tension in the subsequent design stages, and their interpretation of the MTS vs. DPM functions remained contradictory in the final design.

Rules. Components under the *Rules* category were successfully identified in the initial designs. For example, Group Blue proposed a comprehensive set of internal and external controls, such as FDA validation guidelines, corporate quality policies, standard operating procedures, and product-specific controls, such as Critical Process Parameters and Criteria for Forward Processing, which are used in manufacturing operations as process quality control tools.

Of particular interest here is the correct understanding of the external versus internal regulating factors that was demonstrated by all four groups in their initial sketches. Thus, Groups Yellow, Green, and Red integrated a variety of corporate and local standards and procedures regulating their business systems under analysis, such as Standard Operating Procedures or

Notification to Management, but they did not include any industry requirements for their systems. The FDA regulations do not specify the performance criteria and process requirements for such events as Acceptance from Development or Technology Transfer and leave it to pharmaceutical companies to regulate these events internally. Group Blue, on the other hand, listed FDA validation guidelines under the *Rules* category as this process is tightly controlled by government agencies.

The major issue observed during the development of the *Rules* category, was the managers' confusion between the components comprising *Rules* and *Methods/Tools*:

> *"Wait a second… Are we listing SOPs* [Standard Operating Procedures] *here or under Methods? We cannot do both!*
>
> *Well, I don't know what to do… SOPs have the requirements for process, so they're rules, I guess…. But they're tools, too: they help structure the process."* (Group Green)

Similar exchanges were recorded regarding several components that were listed under both the *Rules* and the *Methods/Tools* categories: Process Specifications (Group Blue), Process Flow Document (Groups Green and Yellow), and Standard Operating Procedures (Groups Red and Blue). As the design progressed, more redundant components were added under both categories, such as 2-page guidelines for conducting Manufacturability Review required for Process Validation (Group Blue) or Medex global quality standards (Group Red) (see Appendix J). It is important to note that, despite this redundancy, managers insisted on the particular designs confirming the dichotomous nature of these components in the context of their work:

> *"I think, PFD should be under Rules and under Tools. It is a guidance document and it should be a template at every site. There is value in creating a master PFD for a particular molecule, so it can guide performance across the sites. It would help to see the individual site differences and provide better governance of the process. It will also give a nice template to the site folks so all our PFDs are consistent."* (Group Green)

Methods/Tools. When identifying components for the *Methods/Tools* category, Group Red distinguished specific methodologies and instruments used for guiding business processes and placed them into two separate sub-categories:

> *"Methods: MR reviews, audits, batch records reviews. Tools: PFD, PPQA, PQE, SOPs, change controls."* (Group Red: record made on the design of current Deviation Management system)

Other groups combined methods and tools in one list that included both procedures, such as Control Strategy that establishes general criteria for manufacturing process across several sites (Group Green) and technologies, such as PICAR, a comprehensive data management system.

Contradictions were evident in this category as well. For example, managers from Group Blue spent some time debating whether a process validation protocol is a method or a tool:

> *"Can anyone tell me the difference between the two? Protocol prescribes what to do, step-by-step, during a validation exercise. Can we say it's a methodology?*
>
> *Isn't it a tool? I am not sure I remember correctly, but Steve's Validation Guide has it as one of the critical documents we need to produce before we get to validation exercise."* (Group Blue)

This ambiguity very well may be the reason why some of the workshop groups did not provide any components that would be clearly identified as methods or tools. For example, all the components listed by Groups Blue and Yellow were technical documents, such Development History Reports, Standard Operating Procedures, or Process Flow Documents. Some of those documents were technical references (e.g., Development History Reports), while others possessed process-oriented methodological features and were used as instruments (e.g., templates or rubrics).

Context. *Context* replaced the *Community* category of Engeström's original activity model during the pilot study. The reasons for this change were: (a) perceived redundancy of the *People* and *Community* categories, and (b) need for a category to address time and scope aspects

during system analysis. Since the World-Class Commercialization (WCC) framework (see Figure 1) was included in the triangle as part of the question identifying *Context* ("What organizational structures and WCC stages are impacted?"), it was expected that the groups would include the WCC reference under this category. Groups Blue, Green and Yellow indicated the WCC stages related to their systems. This, Group Green recorded under the *Context* category: "WCC: 7 – involves transferring and receiving sites." Groups Blue and Yellow simply provided the numbers of WCC stages. Group Red, however, chose to determine the context through the set of open-ended questions that, from their perspective, would better characterize the ill-structured nature of the system they analyzed (Deviation Management): *"What is the scope of the problem? What are time considerations? What is priority level?"* Certainly, this choice appears to be logical, as we understand that deviations may occur at any point of the product lifecycle, and one cannot predict at which WCC stage it can take place. Questions also seem to better address the contingencies of the complex environment in which any of those events take place.

Conclusions about Modeling Business Systems

The outputs of the first phase of strategic design –Modeling Business Systems – demonstrate that all workshop groups were able to identify system components and group them in categories using the activity-based template. This analysis supports the study proposition about the activity-based design documents containing evidence of identified system components and internal system contradictions within and between those components.

Table 16 summarizes the number of system elements identified by the groups for each category of the activity triangle during the modeling step.

Table 16

System analysis summary: Modeling step

Group: System Analyzed	People	Rules	Methods/Tools	Functions	Tasks	Context
Blue: Process Validation	7	5	4	1	4	1
Green: Technology Transfer	5	2	4	1	5	1
Red: Deviation Management	7	6	8	2	6	3
Yellow: Acceptance from Development	7	4	5	1	5	1

Several primary and secondary contradictions were discovered during the modeling step. Primary contradictions, according to Engeström (Engeström, 1993a), occur within a component of a system, when a certain element of the system contradicts itself. Secondary contradictions occur between different elements of a system when either existing elements change their intrinsic or extrinsic value, or, as it was in our case, the elements under different categories had identical values. Primary contradictions were identified within:

- the *Outcome* category: either a process or a product can be regarded as the system outcome (e.g., transferred process versus process transfer report)
- the *Tasks* category: either a process or a product can be regarded as the system task (e.g., validated process versus process validation report)

- the *People* category: direct involvement versus peripheral involvement of certain functional groups make the decision about their inclusion under this category challenging (e.g., inclusion of the Global Post-Launch Optimization Team which is not involved in manufacturing operation in any management capacity but which approves any major business decision in Manufacturing, such as technology transfer)
- the *Functions* category: the ownership over some manufacturing events is not established, resulting either in shared ownership or tensions between functional units (e.g., ownership conflict between the MTS and Development Project management teams in the event of Acceptance from Development)
- the *Method/Tools* category: the same documents can provide technical guidance, or 'methods', and serve as instruments, or 'tools' (e.g., Standard Operating Procedure, or Process Flow Document)

Secondary contradictions identified between the system categories to some extent are related to the primary contradictions described above. Thus, a fact that the same documents can be viewed as tasks or as outcomes of the business process (e.g., validation report) formed a secondary contradiction between the *Outcome* and *Tasks* categories. The characteristics of the documents that contain process performance criteria, and thus can be considered 'rules', and, at the same time serve as templates, and therefore can be considered 'tools' (e.g., quality standards) created a secondary level contradiction between the *Rules* and *Methods/Tools* categories.

Once managers mapped their system components onto the activity triangles, they were asked to analyze the relationships between the system components and identify (a) strong aspects

of those relationships that were driving system performance, and (b) gaps and tensions that negatively impacted those relationships and caused system performance problems.

Analyzing Business Systems

During this step, six interactional schemata conceptualized by Mwanza (Mwanza, 2001) were used for guiding system analysis. Managers were asked to respond to the following open-ended questions developed for each interaction:

Interaction 1: *People – Methods/Tools – Tasks*. How do technical documents, procedures, and technologies help the key players perform their tasks?

Interaction 2: *People – Rules – Tasks*. What impact do external and internal regulations and performance expectations have on task completion?

Interaction 3: *People – Functions – Tasks*. How does role distribution among key players help to achieve the event's goals?

Interaction 4: *Methods/Tools – Context – Tasks*. What is the impact of the context in which the event takes place on the technical documents, procedures, and technologies used for completing the tasks?

Interaction 5: *Rules – Context – Tasks*. How does the context of the event determine the rules regulating task completion?

Interaction 6: *Functions – Context – Tasks*. How does the context of the event affect the distribution of responsibilities among the functional areas involved in execution of the tasks?

Guided by these questions, managers were expected to analyze interactions between the system components listed under each category of the triangular template and identify strong and problematic relationships between them. The following paragraphs present each interactional

schema in a graphical format and discuss the results of managers' analysis as they went through every interactional schema. Poster sketches, worksheet notes and discussion records were used in the following presentation of the design results.

Interaction 1: People – Methods/Tools – Tasks. Analysis of this interaction was concerned with identifying the impact of documents, technologies, and guiding procedures on the ways Key Players performed Tasks in order to achieve the expected results (Figure 28).

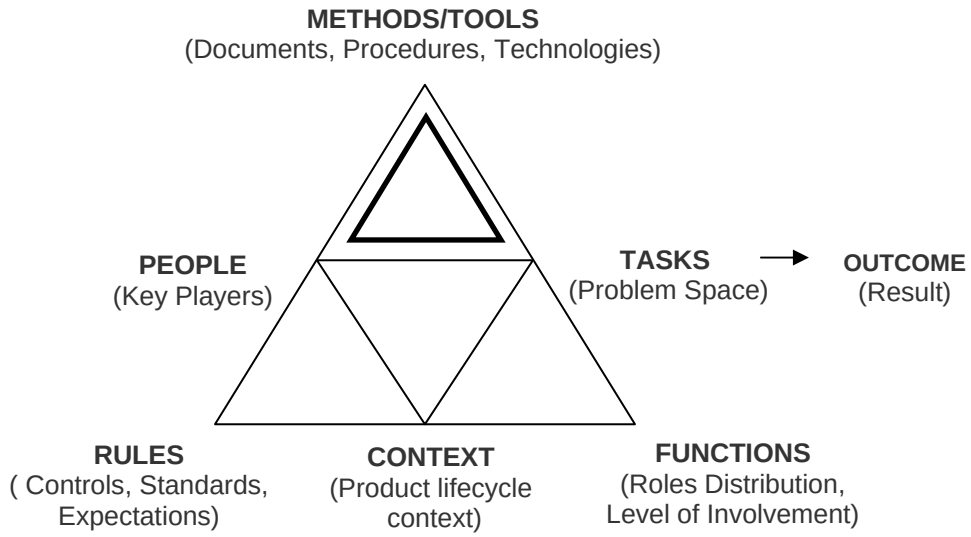


Figure 28. Interaction 1: People – Methods/Tools - Tasks

The examples of the strong aspects of this interaction that supported system performance and ensured successful completion of the tasks managers included:

- Availability of technical documentation containing process specifications that provide step-by-step guidance to manufacturing operators, such as Standard Operating Procedures, Criteria for Forward Processing and Critical Process Parameters (Group Blue)

- Integrated data management systems, such as PICAR, which provide access to current and historical technical documentation that can be referenced by anyone involved in a specific manufacturing process (Group Green)
- Manufacturability Reviews, process evaluation activities the goal of which is to assess the organization's readiness to proceed to the next step in the product lifecycle (Group Red)
- Integrated Validation Master Plans, comprehensive documents that outline requirements for every aspect of the manufacturing process in the facility which is accepting a new drug from development organization (Group Yellow)

Managers identified several gaps in the system that impaired its performance and made the task completion challenging. Examples of the identified gaps included:

- Lack or ineffective use of historical documentation such as Development History Reports that can help manufacturing employees understand the product's evolution during its laboratory 'life' and to avoid unnecessary modifications of the drug production process since they were already tested in the past (Groups Blue, Green, Red)
- Lack of Process Flow Documents at many manufacturing facilities; these documents ensure consistent implementation of manufacturing steps across the plants producing the same drugs based on unified performance criteria (Group Blue)
- Absence of gap analysis tools and methodologies (evaluation of equipment, facilities, documentation, etc. conducted in order to assess the difference between

the transferring and receiving plants and make necessary adjustments to the process) at the receiving plant prior to transferring a process (Group Green)

Among the tensions between the system components that presented significant challenges to task completion, managers identified the following:

- Difference in operator training at the transferring and receiving plants that often results in failures to follow the required procedures at the receiving plant (Group Green)
- Inadequate involvement of third party vendors in deviation analysis and decision making as well as different issue analysis procedures employed at principal and vendor plants that made deviation investigation difficult (Group Red)

Based on the results of the manager's examination of the first interactional schema, a conclusion can be made that technical artifacts representing a mediating category, *Methods/Tools*, may demonstrate either enabling or constraining characteristics based on their availability, quality and use by the MTS employees.

Interaction 2: People – Rules – Tasks. Analysis of this interaction was concerned with identifying the role of internal and external standards and requirements in the process of performing the tasks. It examined the relationships between People, Rules and Tasks (Figure 29).

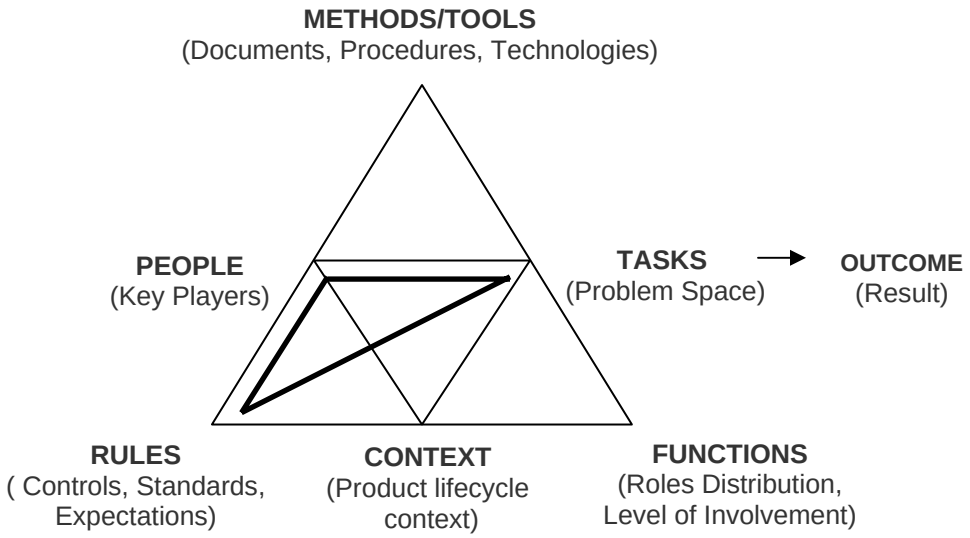


Figure 29. Interaction 2: People – Rules - Tasks

Among the strong aspects of this interaction, managers identified the following:

- FDA guidelines providing high-level directions for planning and conducting process validation procedures and insights into inspectional expectations regarding validation (Group Blue)
- Regular and systematic safety evaluations that were instituted in Medex Manufacturing in the past several years in response to some FDA concerns resulting in issuance of warning letters were named by Group Red as a major company-based regulation helping all the sites consistently monitor the process and attend to the safety-related issues in timely manner and using a variety of methodologies and tools
- Group Yellow members emphasized the role of Good Manufacturing Practices (GMP) in guiding the product transition from laboratory to manufacturing environment. GMPs are FDA requirements for manufacturers to have a quality system for any aspect of medical products manufacturing intended for commercial

distribution in the United States. Although Group Yellow recognized that GMPs do not provide step-by-step guidance for product transfer from Development to Manufacturing, and it is left to the manufacturer to determine the best methods to attain quality objectives, they recognized GMPs as a driving force in achieving the change agenda goals.

Several gaps were identified when examining the relationships between People, Rules and Tasks, the most critical among them being a lack of guidance documents for conducting manufacturability reviews, the assessments of system readiness for beginning critical events in the drug lifecycle, specifically for initiating validation activities (Group Blue).

Discussions of this interaction revealed quite a few conflicts both inside the same categories of the triangle and between the elements under different categories. Among the most critical examples were the following:

- Old quality policies, still in effect at Medex at the time of the workshop, did not adequately address the needs of those involved in planning and implementing validation procedures. Managers also mentioned the conflict between the quality policies they had to follow and newly developed quality standards that supposedly would include all up-to-date guidance and criteria for validation. Although the standards still were in development, employees were expected somehow to follow the requirements of both documents: old policies and new standards (Group Blue)
- Group Red recorded discrepancies between the operational requirements, policies and procedures at Medex's principal sites and at the vendor facilities producing the same drugs. Managers expressed concerns that a mismatch between methodologies and tools for guiding deviation investigations that occur at the

vendor plants may delay investigations, cause tensions between the Medex and vendor employees involved in investigation, and ultimately jeopardize the company's reputation of an enterprise committed to the highest quality and safety of its products.

- Intrinsic conflict between the regulatory commitment documents submitted at the time of registering the drug with the FDA (some of them more than thirty years ago) and current guidance for operations (Group Yellow). Since most of the documentation required today was not required in the past decades when legacy products were made, there have been a significant number of discrepancies in process parameters, equipment or production 'recipes' recorded in the initial and current technical documents.

Based on the results of the managers' examination of the second interactional schema, a conclusion can be made that the mediating category, *Rules*, may demonstrate either enabling or constraining characteristics based on the level of alignment between (a) company-based and industry-based regulating documents, (b) company-based and vendor-based regulating documents, and (c) consistency between the company documents regulating the same manufacturing processes (e.g., validation).

Interaction 3: People – Functions – Tasks. Analysis of this interaction was focused on identifying the impact of distribution of roles and responsibilities on the ways Key Players performed the Tasks in order to achieve the expected results (Figure 30).

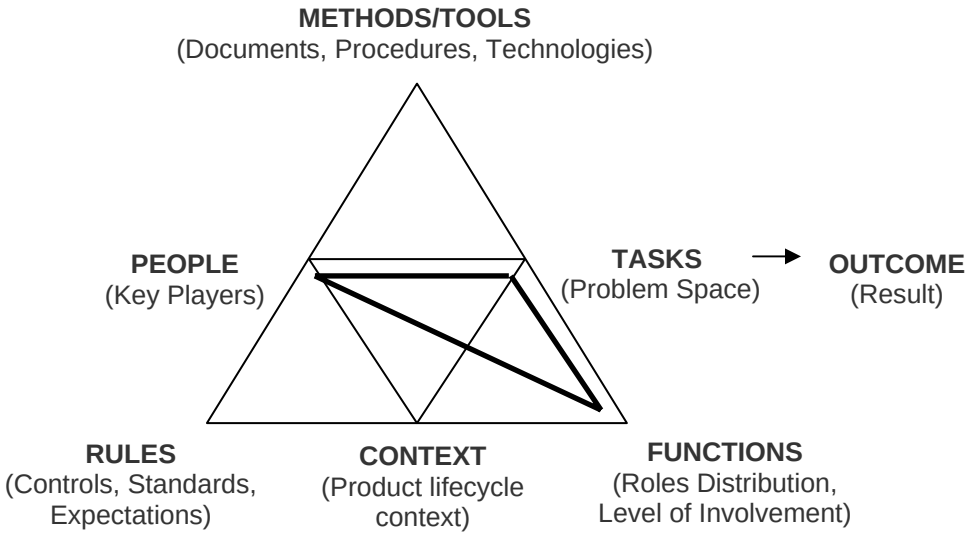


Figure 30. Interaction 3: People – Functions - Tasks

The analysis of this interaction revealed only problematic relationships between the key actors, their roles and responsibilities and task performance characterized by ambiguity of the roles of owner, contributor, and reviewer/approver resulting in redundant actions, delays with deliverables, and 'turf wars' (Groups Blue, Green, Yellow). Group Red was the only one among the four workshop groups that provided some indication of the role assignment among the functional units:

> *"MTS orchestrates all activities; MTS, Regulatory and Quality co-own the process and all sign report."* (Group Red: record made in the worksheet for Deviation Management system)

According to the managers' worksheet notes and discussion records (presented further in the Strategic Discourse section), a mediating category in this interaction, *Functions*, can either enable system performance or practically paralyze it depending on how the relationships between various functional units are structured and how the project roles and tasks are distributed.

Ownership conflict and lack of clear guidance for all functional units on their responsibilities in each manufacturing event were two most notable themes brought up by all the workshop groups.

Interaction 4: Methods/Tools - Context – Tasks. Analysis of this interaction was concerned with identifying the role of organizational context as well as methods and tools in performing business tasks aimed at achieving the desired outcome (Figure 31).

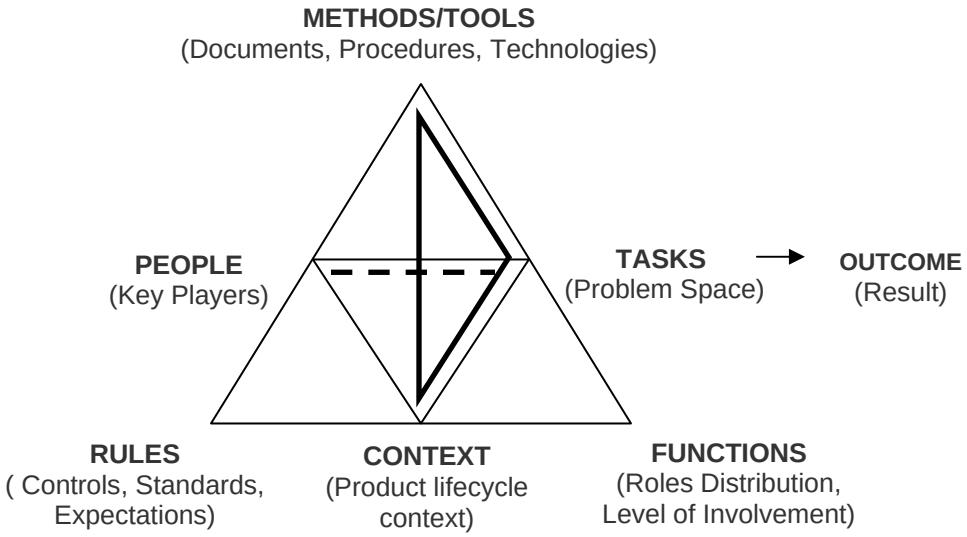


Figure 31. Interaction 4: Methods/Tools – Context – Tasks

In this schema, there are two mediating categories, *Methods/Tools* and *Context*, that can affect the completion of Tasks by the Key Players and can impact each other. I had some initial reservations regarding offering this interaction for analysis since the original meaning of the *Context* category, a *Community*, did not have mediating characteristics. The relationships between the *Methods/Tools* and the *Community* in the initial Mwanza's model would be explored with the *Community* being an actor, not as a mediator (Mwanza, 2001). Due to the modifications to the model made during the pilot study, *Community* was converted to *Context*, and it was not a simple word change meant to address corporate vocabulary. The *Context* category acquired

mediating attributes thus changing the system design and dynamics through forming relationships with other mediating categories: *Methods/Tools* (Interaction 4), *Rules* (Interaction 5), and *Functions* (Interaction 6).

The dual mediating dynamics, such as *Context - Methods/Tools* in this interactional schema, however, made sense to Medex managers. Thus, Group Red conducted a brief impact analysis and indicated that the lack of global quality standards (they were still in preparation at the time of the workshop) affected all business levels (site, network, the whole Manufacturing organization and vendor plants), since it caused an inconsistent approach to managing investigations of process deviations in the facilities making the same products. On the other hand, Group Red emphasized that once the unified standards are approved, they would become a strong supporting force in change agenda-related projects:

> *"Standards are still in a state of flux. Site structures are often different from [central Medex manufacturing location], but corporate MTS does not seem willing or able to recognize this. They must push the development of global standards so we have requirements for every site, not just best practices, which are nice, but optional.*
>
> *You're right. It appears that some sites sign SOPs* [Standard Operating Procedures] *as standards and other sites consider them optional. Do we treat SOPs as standards since standards are not available? And how do we do that considering that site structures and processes are so different?!*
>
> *In our network, some sites have implemented PQEs* [Periodic Quality Evaluations] *for equipment per SOP and other sites continue to operate without PQEs. If there are no global standards, this situation becomes common across all manufacturing* [sites]. *Our actions are sending the message to FDA that either the SOPs are optional or that some sites are exempt from compliance and audit.* (Group Red)

Group Green made similar notes about the availability of Process Flow Documents (PFDs) at both transferring and receiving plants when a manufacturing process is moved to a different location. PFDs, when available, provide clear guidance and criteria for manufacturing process irrespective of the manufacturing location. If PFDs are not available or differ

significantly from site to site, it creates a negative impact on both transferring and receiving plants.

Analysis of the managers' notes and discussions of relationships between *Methods/Tools, Context* and *Tasks* suggests that not only the dynamics between the two mediating categories, *Methods/Tools* and *Context* affect the way the tasks are performed, but also that one mediating category may have an impact on another mediating category. Thus, the availability and quality of certain technical tools and guidance documents (e.g., PFDs, global standards) belonging to *Methods/Tools* category creates either positive or negative impact on the context where they are used and, therefore, either support or impair task performance.

Interaction 5: Rules - Context – Tasks. Analysis of this interaction was focused on identifying the impact of rules and context on task performance in the systems under analysis (Figure 32). This is another example with two mediating categories, *Rules* and *Context*, affecting system performance and having mutual impact.

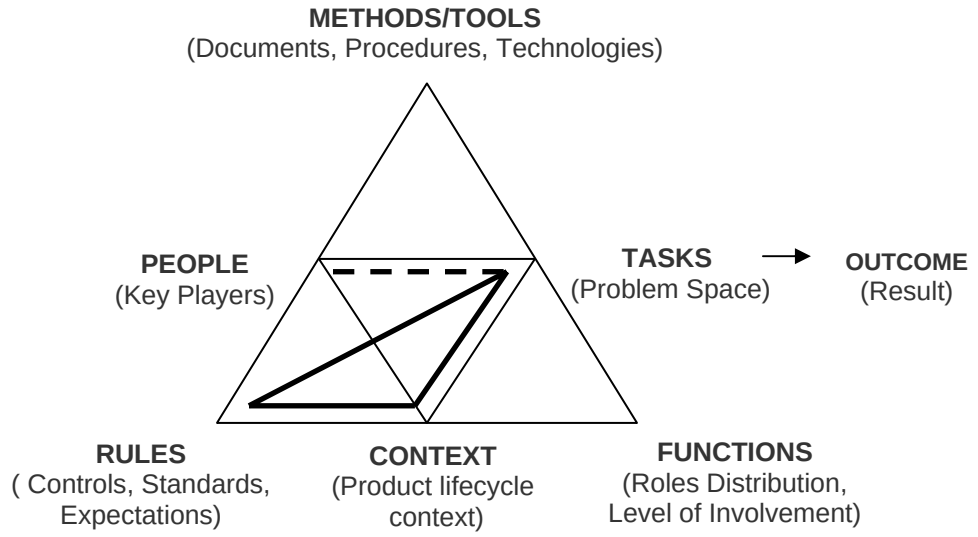


Figure 32. Interaction 5: Rules – Context - Tasks

Of a particular interest here were managers' accounts of contradictions between the Rules and Context categories. Thus, Group Red's analysis of the requirement to notify management about process deviation revealed that while this requirement undoubtedly provides a very structured way to approach a process error or failure, the escalation of the issue to the upper management creates cultural tension within the functional unit where deviation occurred. On one hand, the unit is obligated to report a deviation to upper management and partnering organizations in order to initiate an investigation; on the other hand, by revealing the issue, the unit opens itself to various institutional reprimands.

Group Green noted that a mismatch between the documents that regulate processes at the principal and vendor facilities not only creates tension between the two sites, but also has a negative impact at the network and the company levels. Medex products manufactured by third parties represent the company's name and reputation among consumers and other stakeholders who expect products of the same quality and safety regardless of where they are produced. If corporate requirements are not followed completely at the vendor facilities, or if vendor's internal requirements differ from corporate requirements, collaboration between principal and vendor facilities becomes challenging and may require additional procedures for ensuring the quality of the product manufactured at vendor facilities.

The managers' examination of this interactional schema suggests that the mediating categories, *Rules* and *Context*, may have either enabling or constraining qualities based on alignment of specific regulating documents used by various functional and business units.

Interaction 6: Functions - Context – Tasks. Analysis of this interaction was focused on identifying the impact of role distribution and the context in which business processes took place on task performance in the systems under analysis (Figure 33).

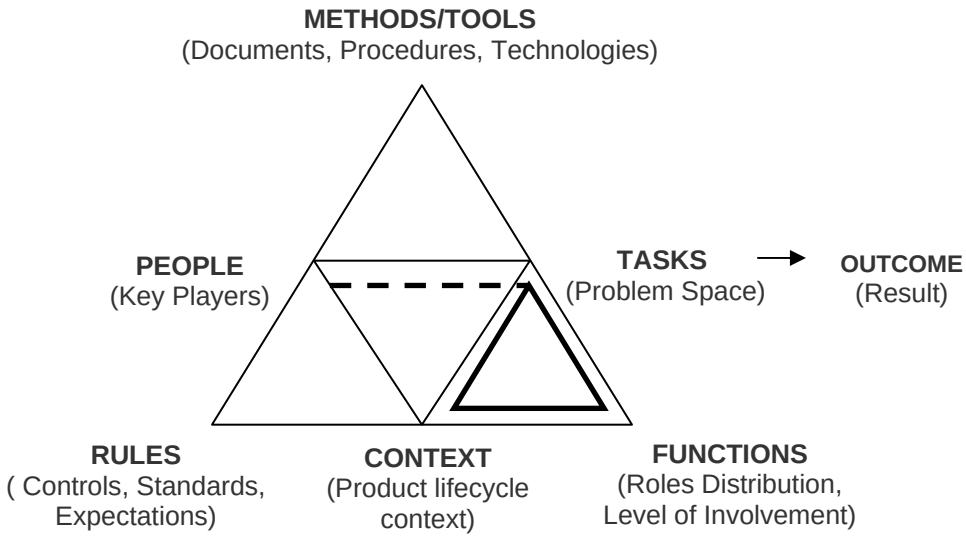


Figure 33. Interaction 6: Context – Functions - Tasks

Similarly to the previous interaction, two mediating categories here, *Functions* and *Context*, were perceived by managers as both enabling and constraining, depending on the clarity of roles and responsibilities of people involved in completing the tasks. Groups Blue, Green and Red emphasized the criticality of defining the roles of owners, contributors and reviewers in the tasks related to the systems they analyzed. Role distribution was perhaps the most prominent aspect in the whole analysis activity affecting directly both the task performance and relationships between functional units. The records made here echo the ones produced during the analysis of Interaction 3. Managers noted multiple document review loops, delays with deliverables, redundant activities and ownership conflicts that put strain on collaboration between functional units and clearly affected task performance. This is another example in which one mediating category, *Functions,* exerts impact on another mediating category, *Context*, and they both produce either positive or negative impact on task performance depending on how the roles and responsibilities are distributed and agreed upon among all key players involved.

Emergent Interactions

Two additional interactional schemata that were not included in the original Mwanza's framework emerged from the discussion of strategizing managers.

Interaction 7: Rules – Methods/Tools – Tasks. In several instances, managers discussed the linkages between the *Rules* and the *Methods/Tools* categories. It appeared that almost all regulating documents had an associate instrument (a template, a graphic) that could be used as a tool supporting execution of business tasks. For example, the relationship between these two mediating categories (Figure 34) was discussed by Group Blue in the context of Manufacturability Reviews (MR).

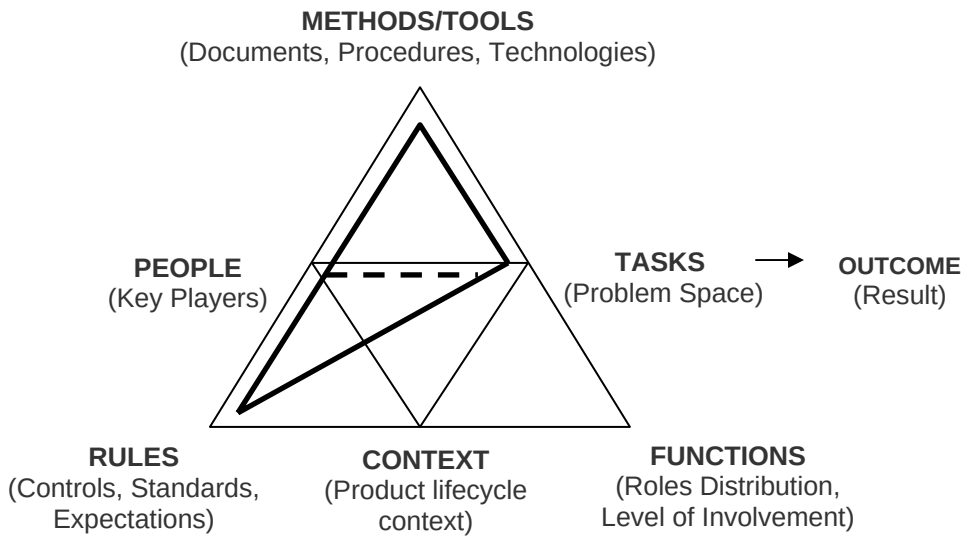


Figure 34. Interaction 7: Rules – Methods/Tools – tasks

MRs are concerned with process assessment performed several times during the product lifecycle. In essence, MRs are the 'gates' through which manufacturing employees take a product. They are critical milestones in the life of a product since they define the stages of the World-Class Commercialization, a strategic framework guiding the whole manufacturing

process. Despite the criticality of MRs, the guide on how to conduct them ("2-pager") or MR template were not available. Managers indicated that this situation created confusion among the plant leadership as, on one hand, the use of MRs was obligatory, but on the other hand, nobody knew how exactly to conduct them:

> *"I'm not sure I can articulate the expectation around the MRs. We need further clarification on the MR process overall. Everybody talks about these 2-pagers, but they are not ready yet. We need templates, we need training. It becomes very difficult to keep current with the most recent revisions, especially of C3 and C7"* [types of MR].

The discussions evolved around interactions between *Rules, Methods/Tools* and *Tasks* suggest that mediating effect of rules and tools on task performance may be negative if there is a misalignment between the rules containing task requirements and instruments and methods that are needed for execution of those tasks. The example of Group Blue clearly demonstrated that the introduction of the Manufacturability Review was in itself a positive step towards streamlining manufacturing performance; however, lack of specific guides or templates made the implementation of MRs very problematic. This contradiction created a lot of tension within the MTS organization as the top management required strict adherence to the MR requirements while regular employees struggled with the MR implementation.

Interaction 8: People – Methods/Tools – Functions. Another interactional schema emerged from the discussion of the dependency of the tools and methods on the roles that Key Players perform in the specific task (Figure 35).

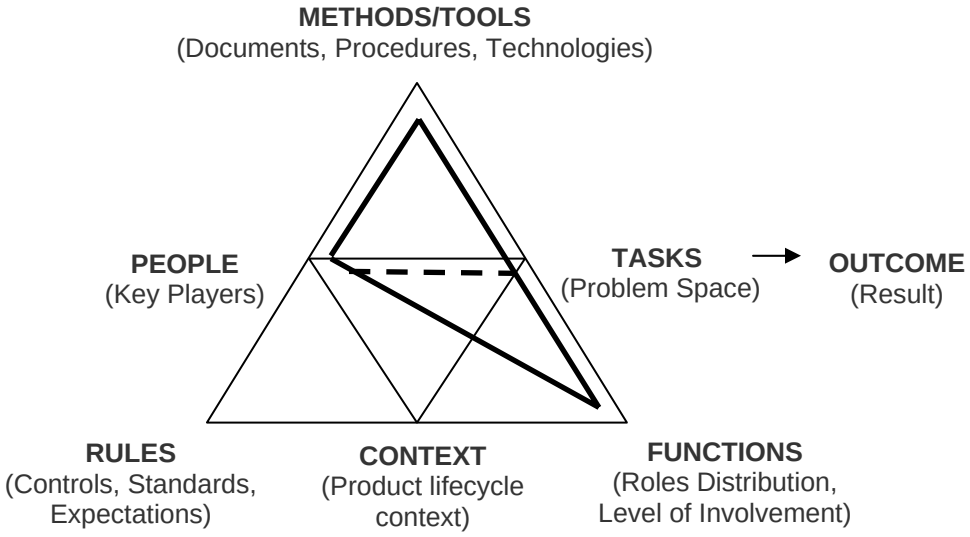


Figure 35. Interaction 8: People – Methods/Tools - Functions

The discussion of this interaction started in Group Red during the modeling step when one of the managers asked for clarification of the documents every functional unit was required to prepare when conducting deviation investigation. Discussion of this question resulted in a worksheet record that contained a list of roles, a brief description of the Key Players' activities, and the tools they were expected to use when involved in deviation investigation. For example, a Molecule Steward was responsible for obtaining historical records, such as a Development History Report and providing technical expertise based on the early studies that would help with the current issue. If deviation happened at a vendor plant, the local quality control unit was listed as responsible for sharing internal safety evaluation records. MTS representatives were charged with providing Process Flow Documents and updating the deviation investigation groups on process specifications.

This worksheet record demonstrated a systematic, strategic approach to managing organizational resources at the moment of crisis. It showed an appropriate division of responsibilities and created a feasible, simple plan that could be consistently implemented at

every plant across the network. At the same time, managers indicated that if responsibilities related to the preparation of critical documents are unclear between the functions, production of redundant and inconsistent documentation might result and, therefore, delay completion of the required tasks:

> *"There is definitely an ambiguity in our relationships with Quality. We're still deciding who prepares or approves a deviation report.*
>
> *I thought it was clear that MTS is driving investigation….*
>
> *That's true, but every time we have to negotiate responsibilities or we'll end up reviewing the same stuff again and again…. If a third party's involved, it adds another dimension to these negotiations."* (Group Red)

Conclusions about Analyzing Business Systems

The outputs of the second step of strategic design –Analyzing Business Systems – demonstrate that all workshop groups were able to identify (a) strong aspects of the systems under analysis that supported system performance, (b) gaps within the systems that impaired system performance, and (c) tensions (contradictions) within and between the system categories that negatively impacted the performance of required tasks in each system they analyzed.

Table 17 summarizes the results of managerial analysis of all six interactions when the system strengths, gaps and contradictions were identified.

The analysis of this step of managerial strategic design supports the study propositions about the activity-based design documents containing evidence of (a) identified strong linkages between the system components, and (b) identified contradictions (gaps and/or tensions) within and/or between the system components.

Table 17

Interaction analysis summary

Characteristic	Description	Identified characteristics (# per interaction)					
		I1	I2	I3	I4	I5	I6
Strengths	System elements or linkages between system elements that drive overall system performance and support implementation of change agenda-related projects	7	5	2	6	4	1
Gaps	Lack or inadequate presence of system elements or linkages between system elements that impair overall system performance and hinder implementation of change agenda-related projects	12	5	5	7	3	3
Contradictions	Tensions, or conflicts, between the system elements that impair overall system performance and hinder implementation of change agenda-related projects	8	12	19	12	6	7
Level 1	Primary contradictions that occur within a component of a system, when a certain element of the system contradicts itself	0	3	4	0	2	3
Level 2	Secondary contradictions that occur between different components of a system	0	3	5	5	0	2
Level 3	Tertiary contradictions that occur when a new objective, usually more technologically advanced, is introduced into the system, thus requiring new tasks and causing resistance of system components	3	1	1	0	0	0
Level 4	Quaternary contradictions that occur between neighboring systems that typically have the same objective but differ in strategies used for achieving this objective	5	5	9	8	4	3

Table 18 presents the system strengths, gaps and contradictions identified by each group.

Table 18

Interaction analysis results by group

Group/ System Analyzed	Interaction	Strengths	Gaps	Contradictions Level 1	Level 2	Level 3	Level 4
Blue/	I1	2	4	0	0	3	0
Process Validation	I2	3	2	1	1	1	0
	I3	0	1	1	2	1	3
	I4	4	4	0	2	0	0
	I5	1	2	1	0	0	0
	I6	0	1	0	2	0	0
Subtotal (Blue)		10	14	3	7	5	3
Green/	I1	1	2	0	0	0	1
Technology Transfer	I2	0	2	0	2	0	2
	I3	0	4	1	0	0	4
	I4	1	2	0	0	0	3
	I5	0	1	0	0	0	2
	I6	0	1	2	0	0	2
Subtotal (Green)		2	12	3	2	0	14
Red/	I1	3	6	0	0	0	4
Deviation	I2	1	1	2	0	0	3
Management	I3	2	0	1	0	0	2
	I4	0	1	0	3	0	2
	I5	3	0	1	0	0	2
	I6	0	1	0	0	0	0
Subtotal (Red)		9	9	4	3	0	13
Yellow/	I1	1	0	0	0	0	0
Acceptance from	I2	1	0	0	0	0	0
Development	I3	0	0	1	0	0	0
	I4	1	0	0	0	0	1
	I5	0	0	0	0	0	0
	I6	1	0	1	0	0	1
Subtotal (Yellow)		3	0	2	0	0	2
Total		22	35	12	12	5	32

As we can see from the above results, gaps and Level 4 contradictions were the leading categories identified by the managers. Level 4, or quaternary contradictions, characterize the tensions that occur between neighboring systems that typically have the same objective. Since all the critical processes under analysis require involvement of multiple functional units, the large number of quaternary contradictions would be expected in the organizational environment that experience performance challenges.

Of particular interest here is a small number of identified tertiary contradictions, which indicate tensions in the system when a new objective is introduced. Considering the number of new documents and processes required by the MTS change agenda, one would expect a substantial number of tertiary contradictions to be identified. Possible explanation for this finding could be that the change agenda had been introduced for two years before this study took place, and managers did not perceive the elements of the systems they analyzed as new. Their discussions during the strategic episode, therefore, were focused on the strategies of organizing multiple functional units and addressing the ambiguities in their collaboration, as opposed to challenging specific items of the change agenda.

Group Yellow's performance related to identification of the system strengths, gaps and contradictions differed significantly from the rest of the groups: only five characteristics of the Acceptance from Development system were identified in comparison to 42, 33 and 38 characteristics identified by Groups Blue, Green and Red, respectively.

Redesigning Business Systems

Once the interactions among the system components were examined, managers engaged in brainstorming the potential changes to their initial design that could address the identified gaps and contradictions. Some of the changes were renegotiated after the groups tested the new

models by applying them to business scenarios, and the final changes were integrated into the triangular models. The following examples in Table 19 illustrate how the identified gaps and contradictions in the interactional schemata were addressed through the system modifications:

Table 19

Examples of identified contradictions and proposed changes

Groups	Interaction	Identified gap or contradiction	Contradiction level	Proposed change
Blue Green Red	I1	Lack of Development History Reports (DHRs), especially for legacy products, that make the references to previous studies problematic	gap	Include DHR as required document for validation; develop schedule for DHR preparation at the sites
Blue Red	I2	Tension between outdated, but still required policies and newly developed standards that address the needs, but still not institutionalized	1	Retire policies and approve global standards as the only documents governing manufacturing processes
Blue Green Yellow	I3	No assignment of responsibilities across functions; redundancy in task completion; 'turf wars'	2	Assign project owners, technical contributors, supporting functions and reviewers
Green Yellow	I4	Process Flow Document (PFD) availability impacts the performance in transferring and receiving sites	4	Ensure that both Development and Manufacturing PFDs are prepared before the transfer process begins
Red	I5	Notification to management requirement during deviation detection causes tensions within the unit where deviation occurs	1	Develop strategies for conducting risk assessment; involve training experts to develop programs aimed at prevention of deviations; review best practices regarding data trends analysis

Blue Green Red	I6	Negative impact of conflicting project priorities on all levels of the organization	4	Develop technical agenda including project prioritization; review individual project assignments
Blue	I7	New Manufacturability Reviews (MRs) are the cornerstones of the World-Class Commercialization framework guiding all manufacturing processes, but there is not guidance or templates on how to conduct them	3	Make the development of MR 2-pagers and templates a priority for Q3-Q4; implement these documents across the entire manufacturing, including affiliates and vendors
Green Red	I8	No assignment of preparation of documentation during deviation investigation or technology transfer that impacts product quality and cause inspectional concerns	2	Identify documentation preparation responsibilities for all manufacturing functions

Figures 36 and 37 demonstrate modification of the Technology Transfer system made by Group Green. The reader is invited to explore the initial and redesigned systems created by all four workshop groups provided in Appendix J.

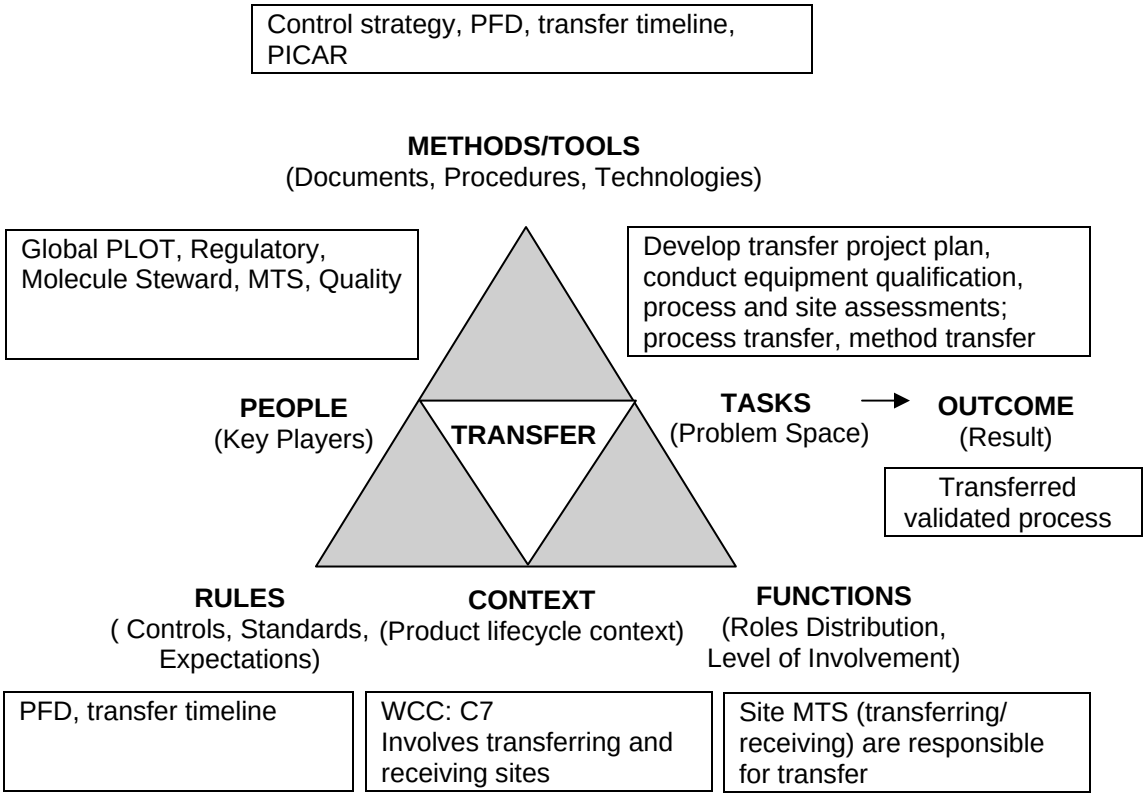


Figure 36. Initial system design (Group Green)

As the design in Figure 37 illustrates, there was some addition to the activity-based tool made by Group Green during the redesign step. Similar change was also made by Group Blue (see Appendix J). Both groups added a new element representing an extension of the Outcome category. This extension emphasizes the iterative nature of the system under analysis. Once the objective, such as a transferred validated process, is achieved, it triggers another round of changes within the system (e.g., updated in the Process Flow Document that reflects the specifics of the receiving plant environment, such as different equipment or different capacity of the plant), and becomes 'invested' in other systems (such as post-transfer validations or manufacturability reviews at the facility to which the process was transferred).

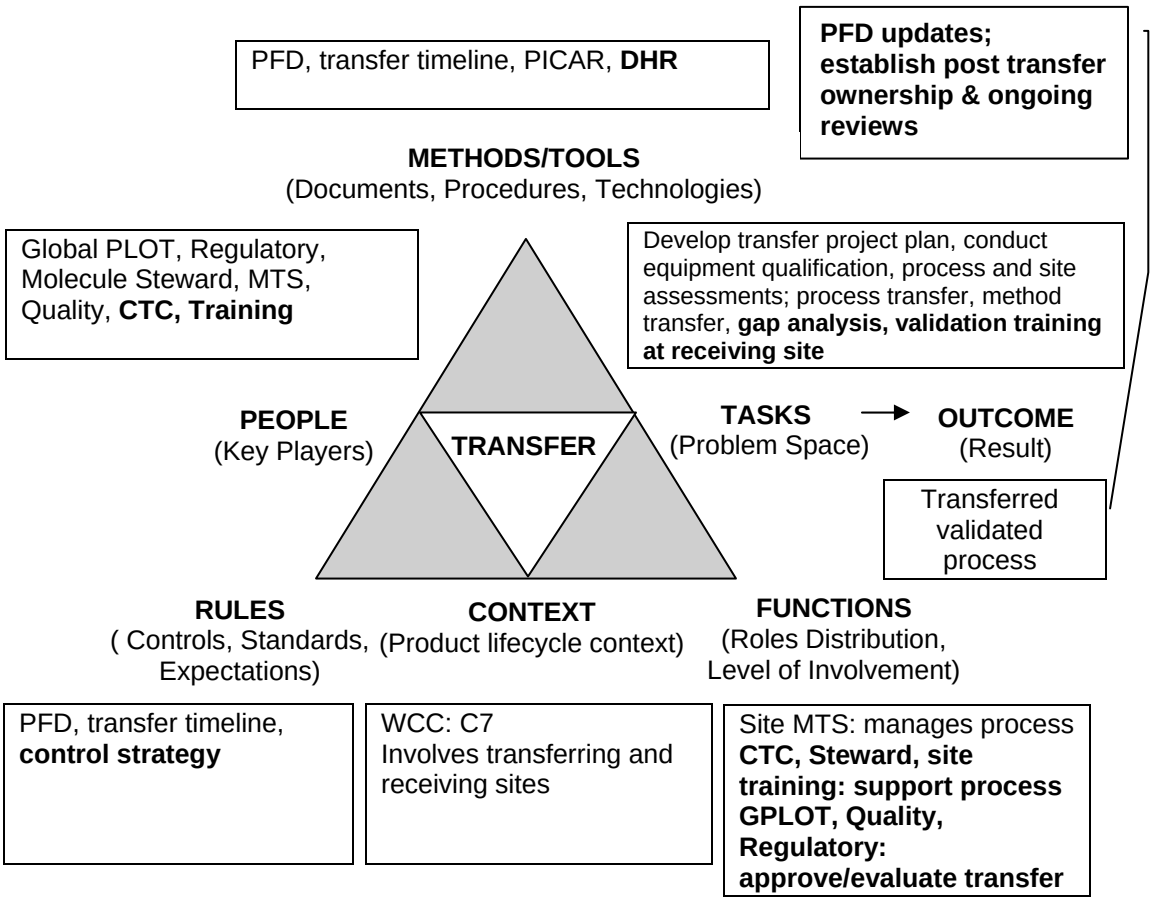


Figure 37. Redesigned system (Group Green)

Conclusions about Redesigning Business Systems

The analysis of this step of managerial strategic design supports the study proposition that the strategic design documents would evolve during the strategic episode thus demonstrating change in business system structures and component relationships.

The workshop participants not only demonstrated their ability to follow guidance for using an activity-based tool, but extended its use by proposing new interactional schemata and extensions of the system design through illustrating how the outcomes influence further system changes and get integrated into other systems (examples of system outcome applications created by Groups Blue and Green).

The least productive group in the redesign step was Group Yellow, which, despite identifying several some system contradictions in the previous step, was not able to generate any propositions regarding their resolution.

The next section is devoted to examination of managerial conversations that took place during the system modeling, analysis and redesign discussed in the previous paragraphs.

Strategic Discourse

The research question on the evidence of social construction of strategic knowledge was addressed through the analysis of discussions that took place during the strategic episode when managers utilized the activity-based strategic tool for analyzing and redesigning business systems: Acceptance from Development, Process Validation, Technology Transfer, and Deviation Management.

The framework of social construction of strategic knowledge was conceptualized and pilot-tested specifically for this study in order to measure the progression of strategic knowledge. This framework emanates from Engeström's expansive learning cycle (Engeström, 1999b) that interprets the process of social construction of knowledge as a sequence of seven epistemic actions, from questioning the existing practice to consolidating the outcomes of the learning process into a new form of practice (see Figure 3). The expansive learning cycle was applied during the pilot study for structuring the analysis of managerial discourse using dialogical sequences (Bakhtin, 1981) as units of analysis. The pilot study findings discussed in details in Chapter Four provided evidence of advancement of managerial discourse through five stages of strategic conversation comparable to the epistemic actions described by Engeström. These stages were conceptualized as a framework of social construction of strategic knowledge that indicates advancement of strategic decisions as managers analyze and redesign business systems:

- Stage 1: Modeling the current system
- Stage 2: Examining the current system and formulating problems
- Stage 3: Negotiating changes and modeling a new system
- Stage 4: Testing and modifying the new system
- Stage 5: Planning implementation of the new system

Sixteen types of dialogical sequences identified during the pilot study and formulated as coding categories for data analysis purposes were applied to analyze managerial conversations that occurred during the strategic episode.

The study propositions related to the discourse data suggested that (a) during the strategic episode, the discussions of collaborating managers would advance through five stages of the social construction of strategic knowledge, with a shift towards higher stages over time, and (b) managerial discourse would contain identification and analysis of strong relationships, gaps and contradictions between the system components as well as substantiated change propositions thus providing evidence of managerial strategizing activity.

On-task dialogical sequences accounted for 94% of all sequences identified by the coders (235 out of 250). Table 20 presents the frequency of the dialogical sequences related to each stage of the social construction of strategic knowledge.

Table 20

Strategic knowledge construction stages: Summary

Stage	Coding category	Number of sequences
Stage 1: Modeling current system and formulating problems	Provide/Seek explanation of current system	7
	Negotiate current system design	9
	Integrate components into the current system design	4
	Define problems in current system	20

		Stage 1 total	40 (17%)
Stage 2: Examining current system	Examine strong aspects of the system		17
	Examine gaps in the current system		44
	Examine contradictions in the current system		31
		Stage 2 total	92 (39%)
Stage 3: Negotiating changes and modeling new system	Propose and justify change		25
	Criticize proposed change		4
	Negotiate change/consider alternatives		16
	Integrate change into initial redesign		11
		Stage 3 total	56 (24%)
Stage 4: Testing and modifying new system	Use specific business examples for testing changed system		3
	Negotiate components/ relationships of the changed system		17
	Integrate change into final redesign		13
		Stage 4 total	33 (14%)
Stage 5: Planning new system implementation	Discuss change implications for internal environment		6
	Discuss change implications for external environment (new)		3
	Discuss change implementation steps		5
		Stage 5 total	14 (6%)
		Total dialogical sequences	235

The discussions of two groups, Blue and Green, moved through all five stages of social construction of strategic knowledge. It is important to note that the designs produced by these two groups, which were presented earlier in this chapter, contained the highest number of suggested changes to the systems they worked with. These two groups contributed 78% of the total number of dialogical sequences exchanged by all four groups (Table 21).

Table 21

Strategic knowledge construction stages: Dialogical sequence frequencies

	Stage 1		Stage 2		Stage 3		Stage 4		Stage 5		Total	
	N	%	N	%	N	%	N	%	N	%	N	%
Blue	15	6	34	15	26	11	19	8	7	3	101	43
Green	12	5	33	14	18	8	14	6	5	2	82	35
Red	7	3	11	5	15	6	0	0	3	1	36	15
Yellow	7	3	9	4	0	0	0	0	0	0	16	7
Total	40	17	92	39	56	24	33	14	14	6	235	100

Group Red reached Stage 3, negotiating changes and modeling new system, however, they skipped Stage 4 - testing a new design in a specific business context - and proceeded to discussing the implications of the proposed system changes (Stage 5).

Group Yellow spent time exclusively in stages 1 and 2 mapping and analyzing problems of the current system. This group's members identified a certain number of gaps and contradictions, but they did not suggest any changes for addressing those problems.

The time spent on each stage also varied among the four groups. Table 22 presents the stage-based time allocation for each group. Every group spent 60 minutes on the design task.

Table 22

Strategic knowledge construction stages: Time distribution

	Stage 1		Stage 2		Stage 3		Stage 4		Stage 5	
	min	%	Min	%	min	%	min	%	min	%
Blue	10	17	14	23	18	30	12	20	6	10
Green	15	25	13	22	20	33	7	12	5	8
Red	15	25	14	23	21	35	0	0	10	17
Yellow	26	43	34	57	0	0	0	0	0	0

The average time spent in each strategic knowledge construction stage by each group is, of course, equal (m=12). However, the distribution of time spent is different in each group and stage. Time spent by Group Blue is the closest to normal distribution across five stages. This group spent the most time in Stages 2 and 3. Group Green spent the most time in Stage 3, but they spent considerable time in Stages 1 and 2 as well (44%), which in total is higher than the total of Stages 4 and 5 (20%). Group Red has a higher standard deviation than the Blue and Green groups because they did not spent any time in Stage 4. Group Yellow group has the highest standard deviation (SD of %: 28%) as they did not spend any time in Stages 3, 4, and 5.

Stage 1: Modeling Current System and Formulating Problems

Seventeen percent of the dialogical sequences were coded as the first stage of the social construction of strategic knowledge. As managers engaged in mapping business systems onto the activity triangles, it became obvious that some of them needed clarification of the systems' purpose, structure and context of use. Thus, Group Green spent almost five minute clarifying the technology transfer requirements while members of Group Blue extensively debated the inclusion of the specific validation-related activities in the system they modeled:

> *"I have a question of purpose and scope of the tech transfer plan – is this an inspection review document or more for internal use?*
>
> *No, FDA does not provide specific requirements for tech transfers; it is completely our own process."* (Group Green)
>
> *"Do we include VMP [Validation Master Plan] here or we just focus on a specific project that involves validation? Is it a rule or a tool to help prepare a validation project? The VMP seems to mean many different things to everyone I've talked to."* (Group Blue)

In part, this situation can be explained by some ambiguity in terminology used for newly established MTS processes, as it was explained later in one of the follow-up focus groups reflected on the strategic episode:

> *"For some folks, juggling PPQEs, PQEs, QPPAs was just plainly confusing. Many sites still do not have a process for transitioning from old tech reviews to the new requirements. I guess, we need to sort these things out first, and then we can get some planning done."* (Manager, MTS)

> *"What's the difference between QPPA, APR, PPQE, PQE? Are we standardizing the terms with industry or making unique Medex acronyms? We need to simplify concepts for people to understand and retain."* (Sr. Associate, MTS)

Challenges during the initial triangular design can be also attributed to the characteristics of the MTS system elements that made them consistent with several triangle categories. The most tension was observed between the *Rules* and *Methods/Tools* categories:

> *"I don't know….SOPs can be under Rules and under Tools as well… You follow SOP to make sure the process is right.*
>
> *Yeah… we use it as a recipe and as a checklist, so to speak…"* (Group Red)

None of the four groups could resolve this dilemma until the very end of the exercise and included the same system elements under both *Rules* and *Methods/Tools* categories: Standard Operating Procedure and Process Specifications (Group Blue), Process Flow Document (Groups Green and Yellow), and Standard Operating Procedure and change controls (Group Red).

Identifying problems within the current system was the most frequent focus of managerial conversations; it accounted for 50% of the total number of sequences exchanged during this stage. Some primary and secondary contradictions were identified during this stage:

> *"We are missing process for cascade review: what all groups need to see, in what order, and for what reason."* (Group Yellow)

> *"What about third party vendors? If they follow our procedures and carry our brand, they need to be included as well."* (Group Red)

> *"Who actually signs off the transfer – Development or us? I'll put both DPM and MTS here, but this needs to be clarified."* (Group Yellow)

These issues were either included into the designs or stated verbally and recorded in the activity worksheets with the purpose of addressing them during the redesign step. At this point, managers did not examine the causes or consequences of identified problems. Some of the problem statements were substantiated in the next stage, but some of them remained subjective opinions without any supporting evidence and did not make their way to the redesigned systems.

Of particular interest at this stage was the self-regulating nature of the discussions, consistent with the pilot findings. In three groups, Blue, Green and Yellow, managers attempted to propose the change to the system immediately after the issue was identified. Yet, their peers suggested mapping the system first and then conducting thorough analysis before making any change-related decisions:

> *A revalidation assessment tool is a current gap. We're are developing our own tool at Brownville. It should be under the Tools.*
>
> *Yeah, that's a good one. Let's map what we have now, and then we'll get back to the problems and see what changes we need."* (Group Blue)

Stage 2: Examining Current System

The second stage accounted for thirty-nine percent of the total number of dialogical sequences. Examination of identified gaps and tensions between system components were the most frequent sequences used by participants to examine the discrepancies from the historical perspective and evaluate their current impact on the system:

> *"Development work hasn't been done in Bayford for years; we are a pure manufacturing facility. I am not sure that we need to include DHR* [Development History Reports] *– it is simply unknown within our group and won't be used.*
>
> *Tom, we're not mapping it just for your site; DHRs have data from early studies, from campaigns, analytical stuff. It really doesn't matter if you are not doing any lab work –*

> *you should look at them as sources that may help with your investigations tomorrow."* (Group Red)

One of the most frequently discussed issues, coded as 'Examine Contradictions' in the current system, was the ambiguity of roles and responsibilities assigned to people directly involved in managing the analyzed systems. Managers talked about tensions between different functional groups that could not reach consensus regarding preparation of critical documents, milestone reviews, and final approvals:

> *"Perhaps we need to re-look at overall governance process. We have lots of turf wars at our site; some reports go in circles because nobody assumes responsibility."* (Group Blue)

These tensions certainly negatively impacted business processes by causing delays with deliverables and redundant documentation reviews.

Certain contradictions were observed in the Rules category. Group Yellow, for example, delved into impasses between the Regulatory Commitment Document (RCD) that was filed when the project was ready to be manufactured and the Process Flow Document, which is used to guide current manufacturing operations. Both documents contained certain criteria for manufacturing operations, but for some products, RCDs were filed more than 25 years previously, and many process parameters and much equipment had changed during the intervening years. Quality control was continued through an abundance of regulating documentation, standard operating procedures and so forth, but the question raised by Group Yellow was whether both historical and current documents could be included under the same category and used in the same way, although they obviously had some contradictory points.

Another series of interesting debates was around the *Context* category. In the MTS strategic episode, Context transformed from being a singular mediating factor to a multidimensional domain encompassing time, scope, and internal/external impact. The best way

to explain this phenomenon is to refer the reader to the Group Red's design of Deviation Management system (Appendix J):

> *"What is the scope of the problem? What are the time considerations? What is the priority level? What is the impact on business? Multi-site? Local? Network-wide? How significant is the issue in the supply chain network? What is the impact on the customer? How is the third party affected?"* (Group Red: record made on redesigned Deviation Management system)

Managers could not (and were not planning to) come up with any definite items for Context category because of the nature of the system they were reconstructing: Deviation Management. Deviation from the prescribed process steps in pharmaceutical manufacturing is a serious problem, but it is an unpredictable problem as well. Nobody knows when it occurs and what structures and processes it will to affect. The approach to analyzing the Context dimensions of a deviation suggested by Group Red was very much aligned with the change agenda expectations as it demonstrated a proactive, strategic approach to dealing with process deviations and failures.

According to the underlying theory, Stage 2 interactions are critical to the concept of social knowledge construction because they provoke critical discussions and facilitate inquiry into the problem domains (Engeström, 1999b). Collaborating learners are challenged by contrasting points of view experiencing cognitive dissonance and gradually work towards finding consensus that allows them to negotiate problem solutions in the subsequent stage. The high intensity of Stage 2 discussions observed in this study is consistent with Engeström's case studies in manufacturing context (1999b) which revealed extensive use of actual-empirical analysis of business issues.

Stage 3: Negotiating Changes and Modeling New System

Twenty-four percent of the dialogical sequences were coded as the third stage of the social construction of strategic knowledge during which changes in system designs were negotiated and integrated into the initial sketches. The largest number of dialogical sequences coded as 'Propose and justify change' and 'Negotiate change/consider alternatives':

> *"I need to know where to point people for examples of best practices and process. Global validation standard should be under Rules.*
>
> *How do we qualify older equipment to the current standard? Standards are being developed as we speak, and we don't have any mechanism yet to apply them to old facilities and equipment. We might include quality policies instead; they've been around for a while."* (Group Blue)

Of particular interest here is the very small number of sequences recorded at this stage that contained criticism towards the proposed changes (4; 2%). Managers were extending their colleagues' propositions rather than challenging them:

> *"PQEs* [Periodic Quality Evaluations] *are largely conducted outside MTS. What is the role of MTS in these processes? We can influence the process, but we need buy-in and resources from the other functions to make real progress in this area.*
>
> *That's an excellent point! I'd also add that such buy-in is necessary for other projects, APR* [Annual Product Review] *or tech transfer, for example.*
>
> *Basically, what we're all saying is that we need somehow integrate the links between all functions, right?"* (Group Red)

This finding can be explained by the shared experience of participating managers. They all were facing a challenge of balancing their daily job responsibilities with efforts focused on implementing the change agenda directives and they viewed a strategizing activity as an opportunity to learn from each other.

Not all the groups were engaged in constructing new solutions for addressing the issues they previously indentified. Group Yellow remained at Stage 2, and, in fact, never progressed to

the later stages. Their discussions for the remainder of the session focused on two primary issues from Stage 2: a primary contradiction within the Rules category (RCD vs. PFD) and another primary contradiction within the Functions category (DPM vs. MTS). The first contradiction was discussed in the previous section. The tension within the Rules category was related to the shared ownership between Development and MTS divisions due to the nature of the event: the transfer of the drug production process from Development to Manufacturing. Group Yellow continued to examine these conflicts and did not suggest any changes to their initial design.

Stage 4: Testing and Modifying New System

Only two groups, Blue and Green, reached Stage 4, and their discussions examining the redesigned system models contributed 14% of all dialogical sequences. The examination process involved the model's application in a real workplace context:

> *"Let's test it now. We're transferring the process to* [name of the affiliate site]. *They're a third party vendor who are going to manufacture bulk and ship it to us for filling. First, we'll do gap assessment to see if the facilities and equipment can be qualified."* (Group Green)

In the course of testing, several components were transferred to different category. Thus, control strategy was moved from the Methods/Tools category to the Rules category (Group Green) and the Development History Report and the Process Flow Document were moved from Rules to Methods/Tools (Group Blue). These changes were consistent with design dilemmas of Stage 1 when managers could not decide if some of the technical artifacts belonged to one or another category.

Of particular interest at this stage was the question raised by both groups about the further application of the system outcome. Group Blue contemplated the use of the data obtained from the validation exercise in revalidation activities and in integration into the foundational MTS documents, such as the integrated Validation Master Plan and the Process Flow Document:

> *"There's no place on this diagram for showing how we can use validation results for updating PFDs* [Process Flow Documents]. *We need to show the loop, how the results are feeded* [sic] *back into the system, how they inform revalidation process and so forth."* (Group Blue)

Group Green discussed activities that immediately follow technology transfer focusing on ensuring a sustainable manufacturing process at the site to which the process was transferred:

> *"Tracy, make sure we record post-transfer activities at the receiving site. The PFD needs to be updated. They actually need their own PFD now. Some post-transfer training still needs to be done, and the site plan – we probably need to facilitate that."* (Group Green)

Both groups integrated these ideas into their redesigns (Appendix J).

Stage 5: Planning New System Implementation

Only 6% of the dialogical sequences fell into the last stage: planning new system implementation. The low number of dialogical sequences is not surprising for several reasons. First, there were no explicit instructions in the workshop guides for learners and facilitators to plan implementation activities since this was the objective of the next workshop exercise. Second, research on social construction of knowledge suggests that the latter phases rarely occur in the data (Engeström, 1999b; Garrison, Anderson and Archer, 2001; Osman and Herring, 2007; Paulus, 2003).

Although brief, this stage revealed interesting contributions of Group Red that resulted in the addition of a new dialogical sequence category to the coding scheme. As the group engaged in brainstorming change actions, the discussion centered around three issues: impact of deviation on the customer, on the organization in general, and on the Medex vendors:

> *"There're so many parameters. Cost, for example. How much will it cost to the company? Of course, we need to fix the problem soon, but we need to investigate it as well. So, we have a conflict here: we need to move on quickly because it costs a fortune, but we have to investigate appropriately so it does not happen again."* (Group Red)

> *"Every problem hits us hard. You need to stop the process, sometimes for a week or longer, check all affected batches. If it happens often, how can we ever meet the market demands?"* (Group Red)

Group Red at this stage not only deepens their analysis of the issues extending the notion of impact to external environment, their discussions revealed a fundamental contradiction in the Context category between the interests of the company and external actors: patients, vendors, and organizational customers, such as Marketing and Sales.

Groups Blue and Green also spent some time contemplating specific steps towards implementing their ideas:

> *"I think, at this point we should be very specific. Let's take PFDs. Do all our sites have ones? If not, how soon can we take care of this gap, and what needs to be done? Maybe it's better to have at least drafts so we can compare them and see what the discrepancies are."* (Group Red)

Conclusions about Strategic Discourse

The findings from the analysis of conversations of strategizing managers generally support the study proposition that during the strategic episode, the discussions of collaborating managers would advance through five stages of the social construction of strategic knowledge, with a shift towards higher stages over time.

Similar to the findings of Engeström (1999b), as well as of those scholars who applied various models of social construction of knowledge to technology-supported discourse (e.g., Garrison, Anderson and Archer, 2001; Gunawardena, Lowe and Anderson, 1997; Pawan, Paulus, Yalcin and Chang, 2003; Paulus, 2003), the managerial discussions during the strategic episode centered on Stage 2 (Examining Current System; 39%) and Stage 3 (Negotiating Changes and Modeling New System; 24%), with moderate presence of Stage 1 (Modeling Current System and Formulating Problems; 17%) and Stage 4 (Testing and Modifying New System; 14%) and minimal presence of Stage 5 (Planning New System Implementation; 6%).

Two groups, Blue and Green, moved through all five stages of social construction of strategic knowledge, and were able not only to model, analyze and modify the systems, but also advance the concept of the activity system triangle by offering extensions in the form of a feedback loop and the investment of system outcomes in other business systems. Group Red reached Stage 3, where changes to the system were outlined; however, it did not test a new design in a specific business context and proceeded to discussing the implications of the proposed system changes (Stage 5).

Managers from Group Yellow did not advance beyond stage 2. They were able to outline the current system design and identify several contradictions within it, however, they did not suggest any changes for addressing these contradictions and failed to identify their impact on the system's and overall organization's performance. Group Yellow consistently demonstrated the lowest performance during the workshop, and it demonstrated the least progress in the post-workshop survey. Therefore, special emphasis in conducting and analyzing the follow-up interviews was made on examining the issues surrounding the performance of this group.

Managerial Reflection on Strategizing Process

In addition to the questions related to strategic learning that were explored in the previous section, several follow-up interview items were designed for soliciting managerial feedback on the activity-based strategic tool. Most interviewees commented positively on the simplicity of the tool design, which helped them to clarify certain aspects of the business systems under analysis:

> *"We always talk about problems but they've never been laid out in front of you so clearly and so organized! When I looked at engineers under People group and drew a line from it to different corners of the triangle, I knew almost instantly what documents I would be responsible for, and what standards I need to follow. I am not sure how it works, but the triangle makes you think about certain elements of the process that you haven't considered before."* (Manager, Engineering)

Another favorable aspect of the activity-based tool mentioned by interviewees was its potential for systematic guidance of their thinking about the issues:

> *"In my previous training, I felt that the courses on PFDs* [Process Flow Documents] *or VMPs* [Validation Master Plans] *given by MTS were not detailed enough to be useful. The main objective seemed to be to tell people why they need a PFD rather than what the expectations, or issues, or actual examples to spark discussions. Here we dissected every task, every problem and worked on them step-by-step. It will be probably difficult to instill such a different practice without follow up. The sites will need help, but I'd say this approach is much more useful that anything we've ever had before."* (Sr. Associate, MTS, Group Red)

Among less useful, or challenging, aspects of the strategizing activity were mentioned (a) the limited affordances of the activity-based tool for recording the dynamics between the elements of the business system mapped onto the triangle, and (b) the too structured design of the tool that would not allow capture of a system in all its complexity:

> *"I wish we could have some visual way to show how the things we listed under one corner of the triangle work with things listed under other corners. Simple lines between the corners can't translate the whole complexity of these interactions."* (Process Consultant, MTS)

> *"In our team, we struggled with the concept of the outcome not going anywhere. Once the transfer is completed, the results are used to inform many manufacturing activities at both sites, the work does not stop with the process transfer. We added another box and linked it to the Outcome to show how it's used after the transfer."* (Team Leader, MTS)

Another major goal of the follow-up interviews was an examination of issues surrounding the poor performance of Group Yellow. As discussed in the previous sections, Group Yellow demonstrated the least progress among all the groups in responding the post-workshop assessment of strategic competencies and failed to move through the stages of social construction of knowledge.

One of the reasons that could contribute to this situation was the lack of representatives from the Development division who would almost certainly drive the discussions and contribute

their expertise to formulating and resolving the issues related to the event being analyzed by Group Yellow: Acceptance of the process from Development organization into Manufacturing organization.

Another issue that was shared at the focus group was a tension between two network directors and the rest of the group:

> *"I don't think we had productive time together. Steve was mostly on his cell, which rang every five minutes and we had to stop and wait for him. John was skeptical about the whole exercise; for him, it is a pure waste of time, he did not see any value in working with subordinates."* (Sr. Associate, MTS)

Several members of Group Yellow mentioned the power issues that arose between the upper-level managers (directors) and their subordinates. One of the directors clearly dominated the conversations and defined the agenda for discussions, and the team to which he was assigned had to follow his lead. This issue was compounded by the fact that almost thirty percent of Group Yellow members were representatives of the overseas affiliate divisions. Cultural and language differences between the US and foreign members of the group could also impair the group's interactions:

> *"I prefer to listen. My English is not very good. It does not mean I have nothing to say, but during the exercise it was obvious that we had to talk about what corporate people wanted us to talk about. I have much learning to do, so it was all right."* (Manager, MTS, European branch)

Since the goal of this research was the examination of the potential application of Activity Theory in the strategizing process, the study design and scope did not permit in-depth investigation of cultural factors that affected Group Yellow's performance. Further research is needed to explore the impact of group composition on collaborative managerial strategizing.

Despite the above issues, the strategizing experience was perceived by managers as a valuable, engaging, and enjoyable experience. Eleven interviewees (78%) indicated that they

would like to participate in such an experience again and plan to introduce this activity at their sites.

Strategizing Process: Summary of Findings

The research question focused on the use of the activity-based strategic tool in the strategizing process was addressed through the analysis of the design artifacts produced by managers and examination of their conversations that took place during their work on the strategic design tasks.

Strategic designs. During examination of the strategic design documents produced by managers during the strategic episode, the following study propositions were tested:

- The strategic design documents produced by the workshop participants will exhibit evidence of identified components of the business systems as well as linkages, gaps and contradictions between those components.
- The strategic design documents will evolve during the strategic episode thus demonstrating change in business system structures and component relationships.

The outputs of the first step of strategic design –Modeling Business Systems – demonstrated that all groups were able to use the activity-based tool for identifying system components and group them in categories. Several primary and secondary contradictions were identified during this step within and between the *People, Tasks, Methods/Tools, Outcome*, and *Functions* categories.

The outputs of the second step of strategic design –Analyzing Business Systems – demonstrated that all workshop groups were able to identify

- strong aspects of the systems under analysis that supported system performance,
- gaps within the systems that impaired system performance, and

- tensions (contradictions) within and between the system categories that negatively impacted the performance of required tasks in each system they analyzed.

Twenty-two strong system aspects, thirty-five gaps and sixty-one contradictions were identified by four groups. Primary contradictions accounted for 20% of all contradictions identified (12 out of 61); secondary contradictions – also for 20% (12 out of 61); five tertiary contradictions represented 8% of all contradictions, and quaternary contradictions accounted for 52% (32 out of 61).

The analysis of the third step of strategic design – Redesigning Business Systems – partially supported the study proposition that the strategic design documents would evolve during the strategic episode. Three out of four groups made changes to their initial system design based on gaps and contradictions that were identified in the Analysis step.

Two groups, Blue and Red, proposed new interactional schemata for more comprehensive translation of intra-system dynamics. Group Blue and Green also proposed extensions of the system design through illustrating how the system outcomes influence further system changes and are integrated into other systems.

The study propositions related to the strategic design documents were generally supported. The results of the analysis suggested that the strategizing experience using an activity-based strategic tool helped managers (a) critically evaluate the current state of critical MTS business systems, (b) identify strong aspects that support system performance and analyze gaps and contradictions that impair it, and (c) systematically address gaps and contradictions through making justified modifications to the system design.

Strategic discourse. Analysis of the strategic discourse was focused on examining the evidence of progressive construction of strategic knowledge during the strategic episode. The following study propositions were tested during discourse analysis:

- During the strategic episode, the discussions of collaborating managers will advance through five stages of the social construction of strategic knowledge, with a shift towards higher stages over time.
- The managerial discourse will contain identification and analysis of strong relationships, gaps and contradictions between the system components, as well as substantiated change propositions, thus providing evidence of managerial strategizing activity.

The new model of social construction of strategic knowledge inspired by Engeström's expansive learning cycle (Engeström, 1999b) was tested in this study, and the results demonstrate its potential for application and further examination in future research on the discourse of managers participating in organizational strategizing activities.

Three out of four groups moved through all five stages of social construction of strategic knowledge, modeling and examining current systems, identifying problems and strategies for addressing them, testing changes in applying business scenarios, and discussing change implications of external and internal organizational environments. One of those groups did not test a new design in a specific business context. The fourth group, Yellow, did not advance beyond stage 2. Its members were able to outline the current system design and identify several contradictions within it; however, they did not suggest any changes for addressing these contradictions and failed to identify their impact on system's and overall organizational performance. This group consistently demonstrated the lowest performance during the workshop,

and it showed least progress in the post-workshop survey. The analysis of the follow-up interviews and a focus group with managers from Group Yellow suggested that such factors as power relationships between upper-management and lower-management group members and cross-cultural dynamics (including differences in English language proficiency) between the American and foreign members of the group could have contributed to the low performance of Group Yellow. Further studies are needed to explore the impact of group composition on collaborative managerial strategizing.

The strategizing experience using an activity-based tool was generally perceived by managers as a valuable experience. 78% of the managers participated in the follow-up interviews indicated that they would like to participate in such activity again and plan to introduce this approach to management training at their sites.

The study propositions related to the strategic discourse were generally supported. The results of the discourse analysis suggested that the strategic episode using an activity-based strategic tool created an engaging learning environment in which managers could collaboratively build their strategic expertise through systematic analysis of the system, problem identification, and design of solutions for improving system performance.

CHAPTER SIX: CONCLUSIONS

The purpose of this study was to examine the use of Activity Theory as a design framework guiding collaborative strategizing activities of middle managers in the context of an organizational learning event. The main research goals were (a) evaluating the effectiveness of the activity-based strategic tool conceptualized specifically for guiding the strategizing process and (b) examining the impact of the strategizing experience on collaborative learning of participating managers. This chapter summarizes the findings related to the study research questions and discusses theoretical and practical contributions of this research project. It suggests implications of the use of Activity Theory in the context of organizational development and learning, acknowledges limitations to the study and points to directions for further research.

Research Questions Addressed

Two primary research questions, or themes, guided this study:

- How was the activity-based strategic tool used in the strategizing process of middle managers?
- What was the impact of the strategizing experience on managerial learning?

These questions were focused on two aspects of a strategizing activity: (a) the process of strategizing that involved analysis and redesign of the business systems and associated managerial discourse, and (b) the learning outcomes of the strategizing activity. Four additional questions were formulated for examining both the strategizing process and its outcomes:

- How did the use of the activity-based strategic tool affect identification, analysis, and resolution of organizational issues?
- What was the evidence of the social construction of strategic knowledge during the strategic episode that utilized the activity-based strategic tool?

- How did the use of the activity-based strategic tool contribute to the advancement of managerial strategic competencies?
- What was the evidence of transfer of learning from the strategic episode to the workplace context?

The summary of the findings presented here is organized around each of these four research questions.

Research Question 1: *How did the use of the activity-based strategic tool affect identification, analysis, and resolution of organizational issues?*

An activity-based design tool was developed specifically for this study in order to capture the results of managerial analysis of current business systems and to facilitate the system redesign process with the goal of improving system performance. Based on Engeström's triangular model of activity, this tool was used in conjunction with an adaptation of Mwanza's 8-step model and her framework of system interactions (Mwanza, 2001). All four groups successfully captured the structure and individual components of the current systems they analyzed, and identified problematic aspects that needed to be addressed. Four levels of system contradictions were identified by the managers during system analysis and design. Three out of four groups were able to integrate specific changes into their initial design and justify their inclusion. Two groups also conducted testing of the redesigned models by applying them to the Medex-specific business scenarios. Three out of four groups reviewed the potential impact of the suggested system changes on external and internal organizational environments.

The findings partially confirmed the research propositions developed in regards to strategic design:

1. The activity-based design documents produced by the workshop participants exhibited evidence of identified components of the business systems as well as strong linkages, gaps and contradictions between those components.
2. The activity-based design documents evolved during the strategic episode, thus demonstrating change in business system structures and component relationships.

Research Question 2: *What was the evidence of the social construction of strategic knowledge during the strategic episode that utilized the activity-based strategic tool?*

A five-stage framework of social construction of strategic knowledge and the coding scheme for strategic dialogical sequences were developed specifically for this study to be able to capture and analyze interactions of strategizing managers. The framework was grounded in the concept of the expansive learning cycle proposed by Engeström (1999b). The coding scheme was developed based on the concept of dialogical sequences (Bakhtin, 1981), units of conversation linked to a single theme or addressing a single problem. Two out of four groups, Blue and Green, advanced through all five stages of social knowledge construction, demonstrating competencies in identifying and analyzing system problems, generating and justifying solutions, and evaluating the potential impact of the proposed changes. The third group, Red, advanced through the first three stages, being able to determine system problems and generate potential solutions. The fourth group, Yellow, demonstrated the least progress in the collaborative strategizing activity due to some internal group dynamics that were examined and interpreted after the workshop.

Dialogical sequences related to Stages 2 and 3 (Examining Current System and Negotiating Changes and Modeling new System) were the most common in managerial discourse and accounted for 63% of all dialogical sequences present in five stages.

Groups that exchanged the highest percentage of dialogical sequences (Blue and Green) were also high performing groups. They identified the highest number of system characteristics that support or hinder system performance and proposed the highest number of changes to the systems they analyzed.

The findings partially confirmed the research propositions developed with regard to the social construction of strategic knowledge:

1. During the strategic episode, the discussions of collaborating managers advanced through five stages of the social construction of strategic knowledge, with a shift towards higher stages over time.
2. The managerial discourse contained identification and analysis of gaps and contradictions between the system components, as well as substantiated change propositions thus providing evidence of managerial strategizing activity.

Research Question 3: *How did the use of the Activity Theory framework contribute to the advancement of managers' strategic knowledge and their ability to plan organizational change actions?*

Several approaches were used to capture and analyze learning which resulted from the strategizing experience of the workshop participants:

1. Comparison of the selected sections from the pre- and post-workshop surveys, which measured a learner's knowledge of strategic concepts and processes and their ability to independently analyze and resolve critical business problems, and provided a self-assessment of their strategic competencies. All groups demonstrated an advancement of strategic knowledge and an increase in their self-assessment of strategic competencies related to role and task assignments,

including management of change-related activities, leveraging strong organizational aspects supporting strategic processes, and recognizing and addressing barriers to strategy implementation.

2. Evaluation of learning transfer to the workplace through analysis of the change agenda implementation plans submitted by managers after the workshop delivery. Several criteria were used to check for evidence of strategizing techniques used during the workshop. All four plans produced by representatives of four manufacturing networks contained selected components of the activities system (e.g., Tasks, People, Methods, Tools) as well as key enablers and barriers to implementation of change-related activities.
3. Collecting managers' reflections on the collaborative learning process through interviews and focus groups. The findings revealed a high level of satisfaction with the strategizing experience. Approximately 75% of managers who participated in the strategic episode indicated their interest in repeating the experience and introducing the new technique at their local learning events.

The findings partially confirmed the research propositions developed with regard to strategic learning:

- The results of the post-workshop survey demonstrated learning gains in relation to knowledge of the strategic concepts and their application in ill-structured problem solving contexts.
- The workshop participants' self-assessment of their strategic skills in the post-workshop survey improved in comparison to the initial survey.

- The change implementation plans produced after the workshop contained evidence of the transfer of the strategic concepts and design approach learned during the strategic episode into specific actionable items.

Based on the analysis results, the conclusion can be made that the use of an activity-based strategic tool in a collaborative strategizing activity creates a structured, yet very engaging environment that enables managers to systematically analyze current business processes, identify performance barriers and develop strategies for addressing those barriers. It also serves as a vehicle for peer knowledge exchange and collaborative decision making of complex organizational problems thus promoting shared ownership over strategic decisions and organizational change propositions.

The evidence from the case discussed here suggests that the application of Activity Theory for development of managerial strategic competencies led to new insights into how middle managers can actively contribute their expertise and experience to the company's strategic development. Further, it provided the company with a framework for approaching organizational issues systematically and promoting strategic collaboration between executives and 'practical strategists' (Jarzabkowski, 2005). The activity-based strategic tool's successful, independent application by managers again after the initial strategic episode demonstrates a potential for the tool being adapted by Medex and other organizations willing to engage their middle management in the strategizing process, thus helping them acquire strategic expertise and building a shared sense of ownership over organizational critical decisions.

Certainly, we need to acknowledge the specifics and limitations of this research before discussing its theoretical and practical implications. The most important factor here is the concept of strategizing defined specifically for addressing the organizational context under

analysis, the concrete needs of the organization, and the purpose and scope of the research project. The strategizing process in this study was conceptualized as a sequence of managerial actions that occurred during a time-limited strategic episode and focused on (a) reflection on current organizational systems and their components, as well as interactions between the system components, (b) identification of the strengths and weaknesses of the current business systems and their potential impact on organizational performance, and (c) formulation and justification of system changes required for improving organizational performance. Such operational definition of a strategizing process emanates from the goal of this study to develop a greater understanding of strategizing activities of ordinary organizational actors rather than focusing on a set of change events from a firm level of analysis. We recognize that any strategizing event has its unique goals and content to deal with, and the readers will have to make decision regarding the relevance of this particular notion of managerial strategizing activity to the context of their inquiry. The following section summarizes limitations related to implementation of this research project.

Study Limitations

This study was limited in a number of ways due to my role as an external consultant with limited time and access to informational resources. The most significant limitations are outlined below.

Role Limitations

In this study, I played an active role in shaping the learning environment in which the strategic knowledge construction took place. I conducted the initial analysis of the organization, developed conclusions and recommendations for intervention, designed workshop activities, including a strategic episode, and developed assessment instruments to evaluate the impact of

this activity on learning and transfer. At the same time, I came to this project as an external consultant who did not have access to all pertinent organizational data that could provide additional insights into the problems being studied. As an outsider, I influenced neither the selection of study participants nor group assignments, had quite limited input to the design and content of the pre-workshop survey, and did not decide the length of the strategic episode.

Time Limitations

The time devoted to this study was not sufficient to observe the impact of the strategic episode on changes in organizational processes. The study was limited to researching specific organizational issues and developing recommendations for the MTS leadership regarding future communication and learning initiatives related to organizational strategic development. Thus, no immediate change of the official change agenda was observed during the period the study was conducted. However, the data collected from the managers after the workshop delivery (e.g., action plans) and the evidence provided by managers from Network B about replicating a strategic episode at the network meeting two months after the study suggested that some of the concepts formulated during the collaborative strategizing activity were integrated into the network strategic planning, which makes me feel optimistic about the potential impact of this project on advancement of the MTS strategizing practices.

Context Limitations

I had no face-to-face access to the study participants located overseas. The most critical issues experienced by the organization were identified by the organization's overseas branches, and an opportunity to have focus groups with representatives of these branches would provide additional valuable data. Another issue was the limited information about group composition in terms of percentage of representatives of foreign affiliate plants in each group. As the study

results suggested, the group performance may had been significantly affected by the power relationships and cross-cultural dynamics, as it was in the case of Group Yellow; however, limited demographic information did not permit extended analysis of this aspect of the study.

Study Implications

Theoretical Implications

Several interesting theoretical ramifications for Activity Theory were raised by this study.

Reconceptualization of the triangular model. The changes in the initial vocabulary used to identify the activity elements (e.g., Community, Division of Labor) were necessitated by the need for more suitable ways to communicate the vocabulary's meaning to corporate learners accustomed to distinct, company-specific professional language. However, this change resulted in more than a convenient and easy-to-understand facilitation tool for guiding a strategizing exercise. Conversion of the *Community* into *Context*, for example, brought several new dimensions to the activity model. It revealed not only time-related factors - in the case of this study, they were the phases of World-Class Commercialization process - but also such critical dimensions as scope, priority, and position of the system under analysis in the supply chain. Time dimension is typically discussed in AT studies as an overall historical context in which a system is grounded, and interactions of system components are relatively independent of this context. This study demonstrated that the system dynamics are conditioned by the business cycle, which determines the context of activity, as well as the choice of mediating artifacts. Further research is needed to examine and validate this dependency.

The scope and priority dimensions link the activity system under analysis to a wider business context. In a large corporation with dozens of manufacturing plants producing a large variety of principally different products, every project that involves the systems that were

analyzed (Validation, Technology Transfer, Deviation Management, and Acceptance from Development) is unique. It can be dependent on the product characteristics (solid or liquid form), needs for specific equipment, and equipment characteristics, size of the plant where an activity takes place, human resources availability (some small plants employ specialists who have combined roles), and many other important factors that shape the makeup of the activity system. Activity-based analysis of process validation system in a large US-based facility would most likely be different from the one conducted at a small plant in one of the foreign branches. The value of this study was to help managers to identify commonalities among those differences, and approach system analysis and design from more global perspective, capitalizing on shared strategies and practices as opposed to emphasizing on inevitable differences.

The *Context* element also revealed the multi-dimensional impact of system interactions on several organizational 'layers': organizational (business, regulatory, manufacturing), functional within manufacturing organization (Engineering, MTS, Quality, Operations), local vs. global (one-site, multi-site, network-wide, domestic, foreign), and impact-specific (impact on customer, supplier, vendor). Each of these layers could form a separate activity system with its distinct dynamics and unique elements. This finding is similar to the one discussed by Marken (2006) as "nested Activity Systems" in relation to the *Rules* category. By recognizing the multi-dimensional, complex nature of the activity system, we are grounding the analysis and reconstruction of the systems into wider contexts, and, although by doing this we inevitably increase the complexity of a strategizing activity, we also avoid trivializing the context in which organizations operate and make decisions. Further studies are needed for exploring the ways of using the activity-based tool for addressing the multiple contextual dimensions identified by this study.

Dual mediation effect. Managerial analysis of business systems in this study revealed an interesting phenomenon that may have theoretical implications for both the activity system design and the ways interactions between the activity elements are analyzed. Quite a substantial number of activity elements identified by managers exhibited double mediating characteristics, for example, performing both as tools and as rules. Among those were mentioned the Process Flow Document, critical process parameters, Standards Operating Procedure, and several other elements. Most of them finally were listed under both *Rules* and *Methods/Tools* categories. This fact cannot be attributed to the contradictory nature of these elements; rather, one should recognize that the specifics of organizational context where these artifacts are conceived define the activity system composition. It is critical to avoid imposing a tool and making managerial decisions to be limited by its design. Instead, a designer or a researcher who introduces this tool should allow organizational actors themselves to fill in the details on the activity triangle that make sense in the context where they operate.

In addition, the role of the *Context* category (Interactions 4, 5, 6) has some interesting theoretical ramifications. Managers suggested that selection of specific tools or methodologies, assignment of responsibilities, or compliance with the external and internal regulations are determined largely by the *Context* category of the system, which, as discussed in the above paragraphs, may significantly change the whole makeup of the system and its dynamics. In such interactions, Context has a double mediating effect: first, it impacts another mediator, *Rule*, *Tool*, or *Function*, and then indirectly affects the completion of *Tasks*. The current design of the activity tool did not allow managers to illustrate such double impact, and further research would be needed to explore the complex relationships between two mediators acting simultaneously and task performance.

Gaps vs. contradictions. Another interesting question raised by this study was the applicability of the term "contradiction" to the system gaps. The concept of contradiction implied tension, or a conflict, within or between the activity system components and between activity systems. It typically involves two system elements that act or are acted upon. A gap, such as lack of a specific guidance document, can impair a system's performance but what kind of contradiction it creates remains unclear. As Marken (2006) asserts, currently there is no established typology of contradictions, and more systematic inquiry into micro-strategizing processes is needed in order to capture various impasses in organizational systems. System gaps, certainly, is one example of such impasses that are waiting to be qualified.

Activity system extensions. Another potential theoretical implication was revealed during the analysis of strategic designs created by Groups Blue and Green and their discussion records. Both groups attempted to demonstrate visually how the system's outcomes are reinvested back into the same system or are contributed to the design and dynamics of other systems. Managers were concerned with limited affordances of the activity tool, as they wanted to show that the *Outcome* element of the system is not a final goal; once it is achieved, it is appropriated by other, perhaps larger systems, or returns to its own system triggering iterative revisions of its components and relationships. The example from Group Green was especially telling: once the process is transferred from one location to another, formal technical data collected during the transfer, as well as specific approaches, tools and lessons learned, are used by the receiving plant for establishing post-transfer systems that include systematic processes and product assessments, validations, and manufacturability reviews. At the same time, the outputs of the transfer are used to make updates and modifications of the initial system components. Examples include making updates to the Process Flow Document at the transferring site or adjusting a transfer timeline and

making it more realistic based on the lessons learned from the transfer. This important finding demonstrate that managers do not perceive business systems in isolation, but in the larger organizational context, and their need for illustrating system position within this context and its ultimately iterative nature should be addressed by future studies.

Practical Implications

The following paragraphs provide suggestions derived from the key findings and lessons learned in this action research. These recommendations, although grounded in the specific context of this study, aim at assisting organizational strategists and instructional designers in their change management and performance improvement efforts.

Create collaborative learning opportunities for employees. Shifting focus from individual acquisition of knowledge to a socially distributed activity enhances collaborative knowledge exchange within organizations (Brown and Duguid, 2001). Continuous cultivation of collective learning practices within organizations is critical not only for creating a sustainable competitive advantage but also for developing core competencies for maintaining organizational life. The value of the collaborative strategizing experience for Medex managers was not only in clarifying pressing issues and enjoying a chance to make their contributions to the organization's decision-making, but most of all, in the rare opportunity to learn together with people from different organizational units, different geographical locations, and different management levels. One of the workshop participants summarized this experience in his follow-up interview:

> *"You know, this was actually the very first time we worked like that, in groups. I even did not care about the topic – what was important that I finally could meet the folks from Puerto Rico who work with us on a daily basis but we never meet and never have a chance to chat about things that bother us so much. What was really good that the workshop gave us some structure, so we could actually put our brains together and come up with some real plans."* (Process Consultant, MTS)

A learning environment that engages representatives from different organizational divisions and networks results not only in establishing a trusting, collaborative atmosphere, but provides the structure necessary for systematic problem solving, aligning business priorities across functional units, clarifying tensions, and developing feasible action plans.

Secure leadership commitment. The strategizing workshop and this study would not be possible without support of the MTS executives and their willingness to explore new avenues of organizational learning. The role of executive sponsors goes beyond initiating change; their support legitimizes the change process, and provides opportunities for innovative organizational learning practices (Malopinsky and Osman, 2006). Organizational literature also suggests that the level of resistance to change within organizations is inversely proportional to the level of support of executive sponsorship (Schermerhorn, Hunt, and Osborn, 2003).

Conduct facilitator training. The role of facilitator is essential for providing instructional scaffolding and sharing technical expertise to a diverse learning group that most likely has varying technical knowledge and experience working in the company. Although I was reminded several times that the workshop facilitators have high-ranking positions, in-depth expertise in their areas, and long tenure at Medex, my persistence in working with them on developing specific facilitation strategies related to the use of a theoretical strategic tool, Activity Theory, paid off well. First, Activity Theory was virtually unknown to the Medex employees and leadership (and I dare to suggest, it is not much known in other companies, either), therefore even those facilitators formally educated in business strategy and change management benefited from training on using the tool. Second, meeting before the strategizing session helps facilitators develop a consistent strategic message and a method to deliver it consistently to all participating groups.

Be flexible and welcome new ideas. Although maintaining structure during the strategizing session helps to promote the analysis of problems and the development of concrete solutions, facilitators should be open to any constructive ideas proposed by strategizing managers. It is critical to maintain an atmosphere of trust and unconstrained thinking to allow issues to surface and to be analyzed. Several new interactional schemata were identified by the managers that both revealed important organizational issues and presented new theoretical opportunities to be explored in future studies.

Use advantages of diversity. Group composition matters in collaborative strategizing. The experience of the Medex managers during the workshop was filled with debates, idea clashes, decision negotiations, and constant exchanges of experience and technical expertise. Since groups contained representatives of corporate and affiliate divisions, many of which were representing overseas manufacturing plants, managers had an opportunity to compare their practices as well as to evaluate differences in technologies and equipment used to produce the same product at different locations. Managers discovered that many of the issues that were perceived as insurmountable literally for months were easily resolved as they and their partners from different plants together mapped the processes. However, those who organize such learning events and facilitate them should be aware of the cultural and language differences that may hinder interaction and have a negative impact on managerial learning. Observational data and interviews confirm that participants who represented overseas branches, especially those with limited English language skills, contributed significantly less to the strategic conversations and ceded power to make change decisions to their corporate peers. This presents a question of how beneficial this strategizing experience was for the foreign managers and to what extent their suggestions were integrated into new system designs. My recommendation for future studies

would be to examine the cultural dynamics of strategizing activities, as well as to compare how this methodology works in cross-cultural versus homogenous groups.

Manage power issues in collaborating groups. Group composition also matters in terms of hierarchical relationships between managers in their real working context. The idea of this workshop was to give an opportunity to novices and experts to exchange ideas and to learn from each other. Perhaps I was too naïve in my egalitarian view of social learning, but the idea of a group that would include both plant directors and project associates (they all are considered managers in the company and in this study) was enthusiastically supported by the MTS strategic planning group, so the workshop was designed accordingly. Again, the observations of Group Yellow's performance suggest that inviting people who are several administrative levels apart to participate in one strategizing group can have a negative effect on the outcomes of both the collaborative activity and the individual learning of participating managers. Further research is needed to advance our understanding of the power dynamics within strategizing teams and examine the impact of power relationships on collaborative construction of strategic knowledge.

Study Contributions and Ideas for Further Research

This study made some theoretical and practical contributions and raised several questions that deserve to be examined in the future.

Activity Theory Use in Managerial Strategizing Process

According to strategic management research, there is a concern over the relevance of current management education for practicing managers and rather limited use of theoretical tools and techniques that may contribute to the advancement of managerial strategic knowledge and skills (Jarzabkowski, Balogun, & Seidl, 2007; Stenfors & Tanner, 2007). The unique contribution of this research is application of the Activity Theory framework for strategic design

purposes – an approach that has not yet been utilized in the context of organizational change. This dissertation study introduced a strategic tool that holds potential for facilitating collaborative construction of managerial strategic knowledge and formulation of strategic decisions that are highly relevant in the real workplace context.

The need for developing greater understanding of how middle managers contribute to organizational strategic development, negotiate strategic decisions, and which conceptual tools they use in strategy-making process has been extensively discussed in the most recent literature (e.g., Jarzabkowski, Balogun, & Seidl, 2007; Jarzabkowski, Laine & Vaara, 2007; Paroutis & Pettigrew, 2007; Stenfors & Tanner, 2007). While the need is largely recognized, the organizational research still has very limited empirical data on the dynamics of the strategizing process, strategic discourse, and, most relevant to this study, effectiveness of strategic tools that are used for facilitating managerial strategizing activities. The contribution of this research is marrying the concepts and theoretical models from social sciences with the domains of strategic management and organizational development.

Application of Activity Theory offers some interesting strategy-as-practice research opportunities. Most of the strategy-as-practice empirical work (e.g., Ikävalko, 2005) is focused on identifying and describing typologies of managerial strategic interactions that take place in daily business activities as opposed to in structured learning events where a specific strategic tool is used for facilitating strategizing activity. Although some authors (e.g., Paroutis & Pettigrew, 2007) include collaborative strategizing as a designed event among other strategic practices that involve middle managers, they neither elaborate on the dynamics of strategizing nor discuss the learning outcomes or effectiveness of the methods and tools used during such an event. This study complements this research by offering a framework for approaching not only analysis of

strategic issues but also helping managers acquire strategic planning and management competencies. The managerial contributions collected from systematic investigations of strategic issues using activity-based approach could be saved and shared within the company thus helping it leverage organizational learning over time.

While this approach demonstrated strong potential to be used for managerial strategizing, it would be interesting to compare it with other strategic tools, such as SWOT or Force-Field Analysis. Would the use of other tools for analyzing the same strategic issues result in comparable learning outcomes? Would other tools help managers identify the same system performance drivers and barriers and prompt them to consider the same system changes? Another interesting research avenue would be examining the use of Activity Theory in unstructured strategizing contexts, when managers are not constrained by the time allocated for a strategic episode and not expected to form a group with other managers. How the dynamics of strategic conversations would differ from those observed during the strategic episode in this study? What type of changes would be proposed? Would any strategic design artifacts produced? The findings from such a study could be then compared with the ones obtained during the workshop-based, more formal strategizing exercise to develop greater understanding of different strategizing environments and formats and their effectiveness.

As our knowledge of the strategic tool effectiveness in terms of enhancing managerial learning and improving organizational performance is still limited (Stenfors & Tanner, 2007), another interesting research possibility would be examining the extent to which the use of tools, including the activity-based tool, enable or restrict development of managerial strategic propositions. Medex managers indicated that although the tool was helping them organize their discussions in a more systematic way than it happened before, its design imposed certain

restrictions on presentation of their ideas, specifically visually demonstrating the impact of the system outcome on a larger organizational environment or translating complex relationships between system components. Was the theoretical framework perceived too simplistically and interpreted too literally as a triangle? Would the same issue be encountered if other conceptual tools were used for analysis and redesign of problematic aspects of complex business systems? The concerns of managers may be interpreted differently. We may speculate that Activity Theory itself does not work well as a tool for dissecting complex organizational issues and that it should be used as a broad philosophical framework for guiding strategic thinking. Alternatively, managerial challenges to present complex processes adequately using a tool could be attributed to insufficient scaffolding on the part of a facilitator. More studies will be able to address these questions.

Social Construction of Strategic Knowledge

As Yin (2003) proposes, a case study can "confirm, challenge, or extend the theory" (p.40). This study contributed to advancing our understanding of the dynamics of the strategizing process and associated discourse. Although the literature is prolific on taxonomies of social construction of knowledge in various learning contexts, especially in technology-mediated environments (e.g., Garrison *et al*, 2001; Gunawardena *et al*, 1997), there is not much reference to phases of collaborative strategizing, especially when a specific theoretical tool is used to frame strategic conversations. Despite the increasing interest in interactions and discursive practices of strategizing managers in the past few years (e.g., Regner, 2005), organizational research has yet to offer a framework for evaluating the discourse of managers participating in the collaborative strategizing process.

Lack of a theoretical model and previous studies that could be used for guiding evaluation of managerial strategic discourse prompted development of an original approach for capturing and analyzing managerial strategic conversations. Engeström's expansive learning framework was used for conceptualizing and testing a five-stage framework of social construction of strategic knowledge and Bakhtin's theory of dialogism was applied for creating a typology of dialogical sequences used as unit of analysis. This approach for analyzing managerial strategic conversations needs to be further tested in strategizing activities when managers use different methods and tools for guiding their knowledge construction process. The questions that would guide such examination may include the following: Would strategic discourse be different if managers used another strategic tool, for example, 7-S McKinsey model or SWOT analysis, or did not use any tool at all? Would the strategic discourse had a different pattern if managers had more time for strategizing or used computer technology for exchanging their strategic ideas? Is the use of Bakhtin's concept of dialogical sequences an appropriate way for capturing and analyzing strategic discourse? Addressing these questions would help us establish more rigorous, concrete and testable criteria for evaluating exchanges between strategizing managers in different settings. Although the results of the study suggested that this approach has a potential for guiding further studies on managerial strategic discourse, an alternative model of social construction of strategic knowledge may be needed as the research on managerial strategizing, and specifically on strategic discourse, advances.

Managerial Strategizing and Organizational Change

This dissertation research only tentatively identified a connection between managerial decision making during a strategic episode and the ways those decisions were transferred to the workplace context. More work needs to be done in this area. Future research could examine how

the changes to organizational processes suggested by managers during the strategic episode are integrated into 'official' organizational strategy and how they affect organizational performance. If only selected managerial propositions are integrated into organizational practice, future studies could focus on the rationale for selecting certain propositions and rejecting others.

Yet another potentially interesting area for further research involves attempting to obtain a better sense of how long it takes a company to internalize an activity-based tool and what variables would affect this process. Would they adopt the approach in its entirety or use the Activity Theory vocabulary alone since they found the design too constricting? Would other Medex organizations, such as marketing or financial, be able to use it in training their managers?

Perhaps as the first step towards answering these questions could be a follow-up research at Medex. It would be interesting to see whether Medex Manufacturing continues to use the Activity Theory approach in any recognizable form. If it is not there, what approaches, if any, do they utilize for bringing expertise of middle managers to organizational strategic development?

Socio-Cultural Aspects of Activity-Based Strategizing

This study provided some insights into the impact of cultural aspects of strategizing on group performance. Thus, power relationships between managers at the director level and their subordinates who became teammates during the workshop created certain tensions and arguably impaired their collaboration. Presence of representative of foreign affiliate plants also seemed to impact the group performance: varying language proficiency levels and different approaches to dealing with problems and participating in team-based activities most likely shaped the group dynamics, especially on those groups with the larger representation of managers from the overseas Medex branches. Further investigation of cultural aspects of strategizing could help us develop greater understanding of how the strategizing process that involves organizational

practitioners can be organized. The following research questions could guide examination of the socio-cultural aspects of managerial strategizing: How do social structures and cultural dynamics within strategizing teams impact their strategic decisions? How does the group makeup affect interactions of strategizing managers? The goals of such studies would evolve around (a) developing criteria for selecting group members to ensure that collaboration is the most beneficial for both the participating managers and their organization, and (b) creating scaffolds for supporting managers who are novices to the strategizing process or experience challenges when expressing their strategic ideas in a foreign language. The overall philosophy that should guide further studies on cultural aspects of managerial strategizing is that the voice of every organizational practitioner must be heard regardless of their affiliation or rank as soon as their expertise and experience can support peer learning and enhance organizational strategic capabilities.

Practical Contributions

The practical value of this study is in providing organizational leadership and performance improvement specialists with a detailed, systematic approach allowing active involvement of practitioners in analysis and resolution of organizational performance issues. I hope that organizational learning curricula would benefit from the advantages of collaborative problem-solving and from managers' resultant systematic reflections on organizational performance.

Evidence of successful replication of the strategizing activity at one of the Network B plants two months after the initial strategic episode took place suggests that managers were able to successfully transfer their strategizing experience to the local, network-specific context and use it for addressing their local business needs. Since I was not involved in preparation or

facilitation of that activity, I believe that the design of the activity tool and accompanying learner and facilitator guidance provided sufficient support to managers and allowed them to conduct independently a network-specific strategic episode.

This example suggests that instructional designers and human performance technologists, even without having a specific knowledge of a particular organization's strategy, can offer effective tools for supporting organizational efforts focused on adapting the strategy-as-practice approach in management training. The research here provides instructional design methodology that can be applied in a variety of organizational settings. By giving managers a powerful tool for deconstructing and critically analyzing their company's strategic content, designers enable them to make strategic decisions that are highly relevant to the context of their daily work. This approach also helps mangers develop a sense of ownership over strategic decisions, thus ensuring commitment to implementation of necessary organizational changes.

This study opens infinite possibilities for applying an activity-based strategic tool to the investigation of organizational issues and planning of changes in different organizational contexts and for addressing various goals, such as streamlining operations that involve vendors, examining bottlenecks that affect performance in affiliate organizations, coordinating training and organizational development efforts across the sites and networks, or use of the tool when conducting risk and gap analyses during major organizational transformations.

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APPENDICES

Appendix A: Catalogue of the MTS Strategic Documents

Number	Title	Date	Category
001	Manufacturing Technology & Science Change Agenda	04/17/2003	Change agenda
002	MTS Essential Elements of Technical Governance	12/04/2003	Strategic summary
003	Essential Elements of Manufacturability Reviews: New Chemical Entities, Line Extensions, and Post-Launch Network Technical Projects	11/13/2003	Strategic summary
004	Essential Elements of an Integrated Validation Master Plan	10/27/2003	Strategic summary
005	Essential Elements of a Process Flow Document	09/15/2003	Strategic summary
006	Essential Elements of an Annual Product Review	11/14/2003	Strategic summary
007	Essential Elements of a Quarterly Product and Process Assessment	12/16/2003	Strategic summary
008	WCC Technical Governance: Commercial Development Plan Approval for New Chemical Entity and Line Extension Projects	01/16/2004	Strategic summary
009	WCC Technical Governance: Process Definition for New Chemical Entity and Line Extension Projects	01/16/2004	Strategic summary
010	WCC Technical Governance: Process Definition for Post-Launch Network Technical Projects	01/16/2004	Strategic summary
011	WCC Technical Governance: Process Optimization for New Chemical Entity and Line Extension Projects	01/16/2004	Strategic summary
012	WCC Technical Governance: Process Optimization for Post-Launch Network Technical Projects	01/16/2004	Strategic summary
013	WCC Technical Governance: Process Completed/Ready to Validate for New Chemical Entity and Line Extension Projects	01/20/2004	Strategic summary
014	WCC Technical Governance: Process Completed/Ready to Validate for Post-Launch Network Technical Projects	01/20/2004	Strategic summary
015	WCC Technical Governance: Validation Complete/Launch Preparation for New Chemical Entity and Line Extension Projects	01/20/2004	Strategic summary
016	WCC Technical Governance: Validation		Strategic summary

	Complete/Launch Readiness for Post-Launch Network Technical Projects		
017	WCC Technical Governance: Commercial Development Plan Approval for Post-Launch Network Technical Projects	01/16/2004	Strategic summary
018	WCC Technical Governance: Annual Product Review for New Chemical Entity and Line Extension Projects	01/20/2004	Strategic Summary
019	WCC Technical Governance: Technology Transfer Assessment for Post-Launch Network Technical Projects	01/20/2004	Strategic Summary
020	Process Flow Documents Preparation, Approval, Distribution, & Maintenance	12/10/2003	Technical Guidance
021	Generation, Review, Approval and Maintenance of a Validation Master Plan	11/17/2003	Technical Guidance
022	The Integrated Validation Master Plan	11/24/2003	Technical Guidance
023	Common Questions Regarding Quarterly Product & Process Assessments	01/23/2004	Technical Guidance
024	Documentation KRA for Manufacturing Technology & Science Leaders	11/19/2003	Technical Guidance
025	Annual Product Review	11/17/2003	Technical Guidance
026	Problems in Technology Strategy Implementation	12/16/2003	Technical Guidance
027	Development Technology Transfer	11/19/2003	Technical Guidance
028	Critical Success Factors for Technology Transfers	11/19/2003	Technical Guidance
029	Process Validation: General Concepts	01/12/2004	Technical Guidance
030	Validation Practices	01/15/2004	Technical Guidance
031	Commissioning & Qualification Procedure: Workshop Report	12/16/2003	Technical Report
032	World-Class Commercialization and Technology Transfer: Network A	01/09/2004	Technical Report
033	World-Class Commercialization and Technology Transfer: Network B	01/09/2004	Technical Report
034	World-Class Commercialization and Technology Transfer: Network C	01/09/2004	Technical Report
035	World-Class Commercialization and Technology Transfer: Network D	01/09/2004	Technical Report
036	Validation of Manufacturing Processes	10/22/2003	Quality Policy
037	Qualification of Manufacturing Facilities, Utilities, and Equipment	10/22/2003	Quality Policy
038	General Principles for Qualification and Validation of Facilities, Equipment, Utilities, and Processes	10/08/2003	Quality Policy
039	Driving to World-Class Commercialization	01/14/2004	Presentation
040	Process Control & Capability Cycle	12/16/2003	Presentation

041	In Control & Capable	10/02/2003	Presentation
042	Define-Demonstrate-Document-Maintain: Principles of Manufacturing Validation	11/10/2003	Presentation
043	Manufacturability Reviews	01/07/2004	Presentation
044	Risk Assessment & Mitigation Through Process Characterization	01/20/2004	Presentation
045	Quality by Design	01/14/2004	Presentation
046	Managing Risk: The Driver for Improving Process Understanding, Quality Consistency, & Manufacturing Performance	01/16/2004	Presentation
047	Discussion of Process Flow Documents	09/04/2003	Presentation
048	Critical Process Parameters: Tools for Advocacy and Assurance	08/12/2003	Presentation
049	PCCC Global Validation Support: Roles & Deliverables	10/15/2003	Presentation
050	MTS Roadshow	09/16/2003	Presentation
051	Manufacturing Environment is Changing – You Can Sense It	05/09/2002	Presentation
052	MTS: Demanding Regulatory Context/Challenging Scientific & Technical Context	10/16/2002	Presentation
053	Process Analytical Technology (PAT): What's in a Name?	12/10/2003	Presentation
054	PAT Inspections/Submissions: Issues & Challenges	12/16/2003	Presentation
055	What To Do When Things Go Wrong	04/16/2002	Presentation
056	PAT to Critical Path: Challenging Opportunities	12/10/2003	Presentation
057	Commissioning & Qualification Procedures: Overview	09/14/2003	Presentation
058	Total Quality Management and Organizational Development		Presentation
059	Applying Risk-Based Strategy in Manufacturing	01/16/2004	Presentation
060	MTS Strategy: Food for Thought	06/10/2002	Presentation
061	MTS Manufacturing Project Management		Presentation
062	Validation Architecture: Fitting It All Together	12/09/2003	Presentation
063	MTS Mission & Vision: How Do We Achieve These?	11/06/2002	Presentation
064	Product Development and MTS Expectations for Conducting Manufacturability and Technical Reviews	01/28/2004	Presentation
065	Changing Manufacturing Environment: End in Mind	11/20/2003	Video broadcast

066	Driving World-Class Commercialization	01/12/2004	Video broadcast
067	New Directions of the MTS Organization	12/10/2003	Video broadcast
068	From Compliance to Capability and Control	10/14/2003	Video broadcast
069	Risk Based GMP: The Role of Manufacturing, Technology, and Science	01/12/2004	Video broadcast
070	Principle Activities Supporting Validation	09/30/2003	Tutorial
071	Best Practice Guide for Equipment Flowcharts	10/07/2003	Tutorial
072	Traceability Matrix	10/21/2003	Tutorial
073	User Requirements	08/26/2003	Tutorial
074	Laboratory Inspections	09/15/2003	Tutorial
075	Process Validation Checklists	08/04/2003	Tutorial
076	Role Description: Molecule Technical Steward	11/10/2003	Tutorial
077	Process Flow Document Template	09/15/2003	Tutorial
078	Annual Product Review Guidelines	01/22/2004	Tutorial
079	Integrated Process Validation Plan Template	10/27/2003	Tutorial
080	MTS Group Overview	06/17/2002	Tutorial
081	Quarterly Product and Process Assessment Training	01/23/2004	Tutorial
082	Six Sigma Overview	01/16/2004	Tutorial
083	Implementation of the Process Control and Capability Cycle	11/17/2003	Tutorial

Appendix B: Need Analysis Survey

MTS STRATEGY SURVEY

Thank you for taking the time to complete this survey. Your answers will provide valuable insight into the understanding of your professional goals and learning needs related to the MTS strategic change agenda implementation. Please answer each question in the following six sections to the best of your ability and provide comments, if necessary. Your responses will be kept completely confidential, and you will not be identified in any reports generated based on the results of this survey.

Expected survey completion time: 30 minutes.

I. GENERAL INFORMATION

This section asks general questions about your position at Medex.

1. Please indicate your level within the organization (*check one*):
   ___Associate/Sr. Associate
   ___Team Leader
   ___Process Consultant
   ___Manager
   ___Director

2. Your tenure at Medex (*in years*): _____

3. Your manufacturing network affiliation (*check one*):
   ___A
   ___B
   ___C
   ___D
   ___Central
   ___Partner organization *(provide name):* _____

II. CHANGE AGENDA CONCEPTS AND PROCESSES

The purpose of this section is to ask you to share your knowledge of the change agenda main concepts and processes and obtain information about your learning needs.

1. Indicate the roles of the specific functional units listed in the left column in managing the WCC/PCCC-determined manufacturing events. Use the following role codes:

"O" = Owner
"C" = Contributor

Functional Units		*Manufacturing Events*						
		Initial Process Transfer from Development	Node-to-Node Technology Transfer	Qualification	Validation	Deviation Management	Technical Evaluation (APR)	Quality Evaluation (PQE)
1	MTS							
2	Development							
3	Quality Control							
4	Engineering							
5	Operations							
6	IT/Automation							
7	Analytical Control							
8	Environmental Monitoring							

2. Indicate the processes required for the WCC/PCCC-determined manufacturing events. Use the following codes:

"P" = Prerequisite
"R" = Required during the event

Processes		*Manufacturing Events*						
		Initial Process Transfer from Development	Node-to-Node Technology Transfer	Qualification	Validation	Deviation Management	Technical Evaluation (APR)	Quality Evaluation (PQE)
1	Manufacturability Review							
2	Quarterly Process & Product Assessment							
3	Design Qualification							
4	Classification							
5	Installation Qualification							
6	Commissioning							
7	Operational Qualification							
8	Risk Assessment							
9	Computer System Validation							
10	Gap Assessment							
11	Measurement Uncertainty Analysis							
12	Change Control							
13	Site Acceptance Testing							
14	Technical Approval							
15	Quality Approval							

3. Indicate the required technical documentation for the WCC/PCCC-determined manufacturing events. Use the following codes:

   "I" = Key Input
   "O" = Key Output

Technical Documents		*Manufacturing Events*						
		Initial Process Transfer from Development	Node-to-Node Technology Transfer	Qualification	Validation	Deviation Management	Technical Evaluation (APR)	Quality Evaluation (PQE)
1	Development History Report							
2	Development Process Flow Document							
3	Manufacturing Process Flow Document							
4	Site Validation Master Plan							
5	Commissioning Documentation							
6	Commercial Development Plan							
7	Product Technical Agenda							
8	Approved Technical Reports							
9	Regulatory Commitment Documentation							
10	APR Report							
11	User Requirements							
12	Deviation Report							

13	Gap Assessment Report							
14	Performance Qualification Documentation							
15	In-Process Controls							
16	Standard Operating Procedures							
17	Risk Assessment Grids							
18	CSF Checklist							
19	System Classification Documentation							
20	Computer System Validation Plan							

4. Please specify your learning needs related to the change agenda topics using the following rating scale:

   1= Do not need clarification
   2= Need some clarification
   3= All aspects need to be clarified

   If you rate the topic as "2", please check those aspects of the topic that need further clarification. Use the textbox to provide additional comments, if needed.

   1) Development History (DHR):
   ___1 (*Do not need clarification*)
   ___2 (*Need some clarification*)
   ___3 (*All aspects need to be clarified*)

   I need more information about (*check ALL that apply*):
   ___ DHR deliverables
   ___ Criteria for writing DHR
   ___ Essential elements of DHR
   ___ Accountability
   ___ Information sources for DHR
   ___ Importance of DHR for Process Control and Capability Cycle
   ___ Leveraging DHR for improving manufacturing processes

Comments:

2) Validation Master Plan (VMP):

___1 (*Do not need clarification*)
___2 (*Need some clarification*)
___3 (*All aspects need to be clarified*)

I need more information about (*check ALL that apply*):

a. General Aspects:
___ Purpose and scope
___ Rationale for creating VMP
___ Definition of "capabilities" for which VMP is created
___ Advantages of VMP
___ Recommended implementation strategy
___ Sequence of activities in the process of creating VMP
___ Resources available for supporting the process of development of VMP
___ MTS personnel who can provide support
___ Key success factors
___ Best practices/examples of VMP

b. Roles & Responsibilities:
___ Owner
___ Parties accountable for VMP activities
___ Specific responsibilities of each contributor to the VMP

c. Documentation & Schedules:
___ Standard identification
___ Pre-execution approval
___ Post-execution review
___ Post-execution
___ Archiving
___ Requirements for detailed Work Plans

d. Facilities:
___ Preparation of Facilities description and their intended use
___ People, equipment & material flows

e. Commissioning:
___ Governing standards for commissioning activities
___ Preparation of User Requirements for new equipment or facilities
___ Preparation of User Requirements for re-qualification of existing equipment or facilities
___ Antecedents required for the initiation of the commissioning activities

f. Qualification:
___ Governing standards for qualification activities
___ Description of qualification documentation process/generation of

protocols
___ DQ, IQ, OQ, PQ for direct impact equipment and utilities
___ Planning for continuing maintenance
___ Antecedents required for the initiation of the qualification activities
___ Assessment of the qualification status of all existing equipment

g. Direct Impact Utility Validation:
___ Utility validation (e.g., gas, water, steam)
___ Room classification
___ Assessment process for existing direct impact utility validation

h. Validation of Laboratory Based Assays:
___ Governing standards for validation of laboratory based assays
___ Governing standards for qualification of lab equipment
___ Planning for identifying, transferring, and validating the supporting laboratory based assays
___ Antecedents required for validation of laboratory based assays
___ Assessment of existing assay validation

i. Automation and Computer System Validation:
___Governing standards for automation and computer system validation
___ Risk assessment process
___ Description of the documentation process for computer system validation
___ Antecedents required for the initiation of computer system validation activities
___ Assessment of the qualification / validation status of existing computer systems

j. Cleaning Validation:
___ Governing standards for cleaning validation
___ Description of the documentation process for cleaning validation/ generation of protocols
___ Assembling list of processes and systems to be validated
___ Antecedents required for the initiation of cleaning validation activities
___ Assessment of the qualification / validation status of existing cleaning packages

k. Process Validation:
___ Governing standards for process validation
___ Description of the documentation process for process validation/ generation of protocols
___ Definition of plans for prospective and concurrent validation
___ Linkage to the Process Flow Document
___ Description of measures used to demonstrate control of product and processing

___ Antecedents required for the initiation of process validation activities

l. Maintenance of Validated State:
___ Governing standards for the maintenance of the validated state
___ Description of the documentation process for maintaining the validation state
___ Managing changes to the integrated VMP
___ Change control

Comments:

3) Process Flow Document (PFD):
___1 (*Do not need clarification*)
___2 (*Need some clarification*)
___3 (*All aspects need to be clarified*)

I need more information about (*check ALL that apply*):

a. General Aspects:
___ Purpose and scope
___ Rationale for creating PFD
___ Advantages of PFD
___ Recommended strategy for creating PFD
___ Resources available for supporting the process of development of PFD
___ MTS personnel who can provide support
___ Best practices/ examples of PFD

b. Minimum Expectations of a PFD:
___ Requirements for Process Flow Charts
___ Requirements for Equipment Flow Charts
___ Requirements for narrative description of operations (length, level of details, use of technical terminology, etc.)

c. Measures & Acceptable Ranges:
___ Description and justification for Criteria for Forward Processing (CFP)
___Description and justification for Proven Acceptable Ranges (PAR)
___ Description and justification for Critical Process Parameters (CPP)
___ Justification of other monitored parameters

d. References:
___ Types of documents that should be referenced in PFD
___ Format for references/Standard referencing style
___ Reference examples

e. Routine Periodic Reviews:
___ Change control requirements

Comments:

4) Process Validation:

___1 (*Do not need clarification*)
___2 (*Need some clarification*)
___3 (*All aspects need to be clarified*)

I need more information about (*check ALL that apply*):

___ Conducting prospective and concurrent validation activities
___ Documenting validation activities
___ Linking validation process to PFD

Comments:

5) Equipment Qualification:

___1 (*Do not need clarification*)
___2 (*Need some clarification*)
___3 (*All aspects need to be clarified*)

I need more information about (*check ALL that apply*):

___ Steps for conducting equipment qualification activities
___ Documenting equipment qualification activities
___ Developing methods for conducting qualification of older equipment
___ Documenting the qualification of older equipment according to the current standard

Comments:

6) Technical & Quality Evaluations:

___1 *(Do not need clarification*)
___2 (*Need some clarification*)
___3 (*All aspects need to be clarified*)

I need more information about (*check ALL that apply*):

a. <u>Quality Product & Process Assessments (QPPA):</u>

___ Accountability
___ Critical elements/process steps and tasks
___ Context of use, time of conducting
___ Documentation requirements
___ Required and optional attendance
___ Inputs and outputs
___ Process for cascade of review

Comments:

b. Annual Product Reviews (APR):
___ Accountability
___ Critical elements/process steps and tasks
___ Context of use, time of conducting
___ Documentation requirements
___ Required and optional attendance
___ Inputs and outputs
___ PPQE - APR transition process
___ Process for cascade of review

Comments:

c. Product Quality Evaluations (PQE):
___ Accountability
___ Critical elements/process steps and tasks
___ Context of use, time of conducting
___ Documentation requirements
___ Required and optional attendance
___ Inputs and outputs

Comments:

d. Manufacturability Reviews (MR):
___ Accountability
___ Critical elements/process steps and tasks
___ Context of use, time of conducting
___ Documentation requirements
___ Required and optional attendance
___ Inputs and outputs

Comments:

7) Countermeasures:
___1 (*Do not need clarification*)
___2 (*Need some clarification*)
___3 (*All aspects need to be clarified*)

I need more information about (*check ALL that apply*):
___ Definition of countermeasures
___ Impact of the results of technical and quality evaluations on other aspects of

the Process Control and Capability Cycle (e.g., VMP or PFD)
___ Results of technical and quality reviews as triggers for other reviews
___ Documenting and archiving countermeasures/recommendations

Comments:

8) Site Quality Plan:
___1 (*Do not need clarification*)
___2 (*Need some clarification*)
___3 (*All aspects need to be clarified*)

I need more information about (*check ALL that apply*):
___ Role of Site Quality Plan in MTS processes
___ The impact of Process Control and Capability Cycle on development of Site Quality Plan
___ Integration of the Site Quality Plan with the overall network portfolio of technical projects

Comments:

9) World-Class Commercialization:
___1 (*Do not need clarification*)
___2 (*Need some clarification*)
___3 (*All aspects need to be clarified*)

I need more information about (*check ALL that apply*):

a. <u>General Aspects:</u>
___ Purpose of technical governance process
___ Definition and justification of WCC framework
___ Constituents of WCC process (stages)
___ Technical Review steps
___ Type of technical projects governed by WCC
___ Essential elements of Manufacturability Review (MR) process
___ Best practices/ examples of MR

Comments:

b. <u>C0 – C7 Manufacturability Reviews</u>:

Please indicate the number of MR(s) for which you request information:
_____

___ Definition and purpose

___ Start and finish conditions
___ Key inputs and outputs
___ Critical success factors: general (applied to all projects) and product-specific
___ Risks and opportunities
___ Metrics

Comments:

III. CHANGE AGENDA IMPLEMENTATION STRATEGIES

The purpose of this section is to ask you to share your strategies for implementing the change agenda requirements in a real business context, and obtain information about your needs and concerns related to strategy implementation.

1. Analyze the following business scenarios and answer the questions focused on the issue contained in each scenario. Check all the answers relevant to the described situation.

Scenario 1: In preparation for C6 Manufacturability Review at your site, you discover that the agitation rate listed as a critical process parameter in the Process Flow Document was not measured by Operations, and, in fact, cannot be measured because the capability for making this measurement was not considered when the process was initially transferred to your site.

1) What factors may have caused this issue?

___ Lack of Development PFD
___ Insufficient operational data
___ Lack of PFD prior to conducting Classification
___ Design Review was not properly conducted
___ User Requirements were not available during equipment installation

2) What processes are directly affected by this issue?

___ Process Validation
___ Annual Product Review
___ Analytical Assay Validation
___ Node-to Node Technology Transfer
___ Performance Qualification

3) What functional units are directly involved in the situation?

___ Development
___ MTS
___ Analytical
___ Engineering
___ Environmental Monitoring

4) What action(s) are required for addressing this issue?

___ Amend User Requirements
___ Requalify equipment
___ Review historical data
___ Revalidate process
___ Amend PFD

Comment on how this situation impacts your site from inspectional, technical, scientific, and business perspectives and explain how your choice of action(s) will help to improve it:

Scenario 2:
During the inspectional visit to your site, the inspectors point out the discrepancy between corporate requirements and local practices for the 15-year old water system. While the inspectors do not dispute the argument that the site practice is in full conformance with the local SOPs and the fact the water has no impact on product quality, they issue a major finding that the operations conform neither to external nor corporate guidance.

1) What factors may have caused this issue?

___ Poor communication between the global and site-based MTS
___ Misalignment between corporate quality policies and local standards
___ Failure to qualify the equipment
___ Poor communication between Regulatory and MTS
___ Manufacturing process using the water system has not been properly validated

2) What processes are directly affected by this issue?

___ Annual Product Review
___ Periodic Quality Evaluation
___ Process Validation
___ Performance Qualification
___ Safety Evaluation

3) What functional units are directly involved in the situation?

___ Quality
___ MTS

___ Operations
___ Engineering
___ Regulatory

4) What action(s) are required for addressing this issue?

___ Review local standards to conform with corporate policies
___ Requalify equipment
___ Amend corporate policies to accommodate aged equipment
___ Revalidate process
___ Purchase new equipment

Comment on how this situation impacts your site from inspectional, technical, scientific, and business perspectives and explain how your choice of action(s) will help to improve it:

2. Please indicate your level of agreement with the following statements:

1) I find it challenging to assign tasks during execution of the processes defined by the change agenda.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

2) I find it challenging to assign specific roles to manufacturing units during execution of the processes defined by the change agenda.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

3) I find it challenging to establish priorities for task completion during execution of the processes defined by the change agenda.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

4) I can describe the deliverables associated with the processes defined by the change agenda.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

5) I find it challenging to explain how the change agenda requirements apply to the vendor processes.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

6) I can explain how the change agenda requirements are aligned with regulatory expectations.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

7) I can explain how the change agenda requirements are aligned with the World-Class Commercialization framework.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

8) I can apply the change agenda requirements to existing manufacturing practices.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

9) I find it challenging to explain the value of the change in our manufacturing practices.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

10) I can define the risks that our organization will face if the change agenda is not implemented.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

11) I can identify the factors (e.g., current processes, practices, documents) supporting the change agenda implementation.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

12) I can explain how those factors can be leveraged to support change process.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

13) I can identify the problems that present barriers to the change agenda implementation.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

14) I can explain how those problems can be eliminated or minimized to ensure the progress of change-related activities.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

15) I can plan the execution of the manufacturing processes following the change agenda requirements.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

IV. CHANGE AGENDA COMMUNICATION APPROACH

This section asks questions about the current approach for communicating the MTS strategic information at your site and your preferences for receiving the change agenda-related documents and other critical information.

1. Please indicate how often you use the following communication methods to receive change agenda-related information:

   1) Email:

   ___*Never* ___ *Rarely* ___*Occasionally* ___*Often* ___ *Always*

   2) MTS Web site:

   ___*Never* ___ *Rarely* ___*Occasionally* ___*Often* ___ *Always*

   3) MTS Online Community:

   ___*Never* ___ *Rarely* ___*Occasionally* ___*Often* ___ *Always*

   4) Teleconferencing:

   ___*Never* ___ *Rarely* ___*Occasionally* ___*Often* ___ *Always*

   5) Paper copy:

   ___*Never* ___ *Rarely* ___*Occasionally* ___*Often* ___ *Always*

   6) BTV:

   ___*Never* ___ *Rarely* ___*Occasionally* ___*Often* ___ *Always*

   7) Team Meetings:

   ___*Never* ___ *Rarely* ___*Occasionally* ___*Often* ___ *Always*

Please list any other communication channels not included here and describe how often you use them for obtaining the change agenda information:

2. Please indicate the level of your agreement with the following statements:

   1) The strategic change agenda-related information is shared within our site in a timely manner.

   ___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

   2) I am satisfied with the ways that strategic documents and information are shared within our site.

   ___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

   3) I am satisfied with the amount of guidance provided to our site regarding the use of the change agenda documents.

   ___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

   4) I am satisfied with the quality of guidance provided to our site regarding the use of the change agenda documents.

   ___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

   5) There is a process at our site that provides our employees with an opportunity to discuss the change agenda requirements with the local leadership.

   ___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

   6) There is a process at our site that provides our employees with an opportunity to discuss the change agenda requirements with the global leadership.

   ___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

   7) There is a process at our site that provides our employees with an opportunity to discuss the change agenda requirements with their peers.

   ___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

   8) Our site needs a designated person responsible for communicating strategic change agenda-related information.

   ___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

Please comment on the above responses, if necessary:

3. Please indicate your preferences regarding the following communication methods used for sharing the change agenda-related information:

   1) Email:

   ___*Most preferred method* ___ *Less preferred method* ___*I prefer a different method*

   2) MTS Web site:

   ___*Most preferred method* ___ *Less preferred method* ___*I prefer a different method*

   3) MTS Online Community:

   ___*Most preferred method* ___ *Less preferred method* ___*I prefer a different method*

   4) Teleconferencing:

   ___*Most preferred method* ___ *Less preferred method* ___*I prefer a different method*

   5) Paper copy:

   ___*Most preferred method* ___ *Less preferred method* ___*I prefer a different method*

   6) BTV:

   ___*Most preferred method* ___ *Less preferred method* ___*I prefer a different method*

   7) Team Meetings:

   ___*Most preferred method* ___ *Less preferred method* ___*I prefer a different method*

Please elaborate on your preferences, if needed:

V. CHANGE AGENDA TRAINING APPROACH

This section asks questions about the change agenda-related training available to you at your site and about your preferences for learning the change agenda-related content and implementation strategies.

1. Does your site currently provide any form of training focused on the change agenda topics?

   ___ Yes ___ No

If your answer is "Yes", please provide the detailed description of how the change agenda-related training is currently organized at your site:

2. Please indicate the level of your agreement with the following statements:

   1) I am satisfied with the format of the change agenda-related training at our site.

   ___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

   2) I am satisfied with the teaching methods used in the change agenda-related training at our site.

   ___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

   3) I am satisfied with the frequency of the change agenda-related training at our site.

   ___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

   4) Our site needs a designated person responsible for the change agenda curriculum.

   ___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

   5) I am satisfied with the range of the change agenda-related topics taught at our site.

   ___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

Please comment on the above responses, if necessary:

3. Please respond to the following statements and check the topics that you would be interested in for yourself or your staff as a part of the MTS site/network training program *(you may select as many topics as needed):*

   1) I need to improve my knowledge and skills in the area of Research Methods.

   ___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

   ___ Experimental Design Principles & Methods
   ___ Use of Statistical Methods for Data Analysis
   ___ Analytical Sampling & Lab Scale Models
   ___ Data Mining & Predictive Models in Manufacturing
   ___ Issues in Data Integration Processes

   2) I need to improve my knowledge and skills in the area of Project Management/ Technical Governance.

   ___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

___ Principles of Effective Development & Implementation of Technical Project & Portfolio Management
___ Daily Technical Support vs. Technical Process Governance: Issues & Strategies
___ Organizational Issues in Technical Project Management: People, Processes, Documents

3) I need to improve my knowledge and skills in the area of Technical Documentation Management.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

___ Methodology for Conducting Scientific and Technical Peer Reviews
___Technical Documentation Retrieval and Analysis for Supporting Technical Decision-Making: How to Use Electronic Libraries and Archives to Support Technical Projects
___ Leader's Strategies for Technical Documentation Standardization, Management, and Change

4) I need to improve my knowledge and skills in the area of Technical Communication.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

___ Decision-Focused Technical Discussion: Strategies for Participation and Facilitation
___ Technical & Scientific Mentorship: Strategies for Supporting Newcomers in a Complex Regulated Industry Environment
___ Developing Strategies for Exchanging Best Practices and Scientific and Technical Knowledge among Sites & Networks

5) I need to improve my knowledge and skills in the area of Problem Solving Methods and Tools.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

___ Applying Critical Incident/Critical Decision Methods in Manufacturing Problem Solving
___ Probabilistic Analysis for Addressing Technical Project Management Problems
___ Development of Countermeasures on Root Causes in Manufacturing Problem Solving Practice
___ Evaluating barriers and enablers for implementation of the MTS strategic decisions
___ Using Theory of Constraints for Diagnosis of Process-Related Problems in Manufacturing

6) I need to improve my knowledge and skills in the area of Strategy and Systems Design.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

___ Manufacturing Systems Design
___ Integration of manufacturing strategy with the business and corporate strategies
___ Alliance management strategies: Integrating World-Class Commercialization process with 3rd parties

Please elaborate on the above responses, if needed:

4. Please indicate your preferences regarding the following teaching approaches that may be used in the change agenda-related training:

   1) Facilitated workshops:

   ___*Most preferred approach* ___ *Less preferred approach* ___*I prefer a different approach*

   2) Presentations:

   ___*Most preferred approach* ___ *Less preferred approach* ___*I prefer a different approach*

   3) Round table discussions with other MTS employees at the site meetings:

   ___*Most preferred approach* ___ *Less preferred approach* ___*I prefer a different approach*

   4) Web-based self-study:

   ___*Most preferred approach* ___ *Less preferred approach* ___*I prefer a different approach*

   5) Web-based facilitated course with group discussions/activities:

   ___*Most preferred approach* ___ *Less preferred approach* ___*I prefer a different approach*

   6) Computer-based course on CD-ROM:

   ___*Most preferred approach* ___ *Less preferred approach* ___*I prefer a different approach*

   7) Self-study using performance support resources (document databases, reference libraries, example case studies, etc.):

   ___*Most preferred approach* ___ *Less preferred approach* ___*I prefer a different approach*

   8) Case studies from one of the Medex manufacturing sites:

   ___*Most preferred approach* ___ *Less preferred approach* ___*I prefer a different approach*

   9) Business games/simulations/role playing:

___*Most preferred approach* ___ *Less preferred approach* ___*I prefer a different approach*

10) Problem scenarios based on the Medex-specific situations:

___*Most preferred approach* ___ *Less preferred approach* ___*I prefer a different approach*

Please elaborate on your preferences, if needed:

VI. ORGANIZATIONAL SUPPORT

This section asks questions about the change agenda-related training available to you at your site and about your preferences for learning the change agenda-related content and implementation strategies.

1. Please indicate your level of agreement with the following statements:

   1) Our site experiences difficulty implementing the change agenda requirements due to the poorly defined roles and responsibilities.

   ___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

   2) Our site experiences difficulty implementing the change agenda requirements due to lack of time.

   ___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

   3) Our site experiences difficulty implementing the change agenda requirements due to lack of/insufficient resources.

   ___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

   4) Our site experiences difficulty implementing the change agenda requirements due to lack or insufficient amount of required operational data.

   ___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

   5) Our site has sufficient data management support.

   ___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

   6) Our site has sufficient scientific expertise for implementing the change agenda requirements.

   ___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

7) Our site has sufficient technical expertise for implementing the change agenda requirements.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

8) Our site experiences difficulty implementing the change agenda requirements due to competing priorities of the business tasks.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

9) Our site receives sufficient guidance from the global MTS regarding implementation of the change agenda requirements.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

10) Our site experiences difficulty implementing the change agenda requirements due to insufficient communication with other functional areas.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

11) Our site experiences difficulty implementing the change agenda requirements due to insufficient alignment with the third party operations.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

12) Our site experiences difficulty implementing the change agenda requirements due to insufficient training.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

Describe any other challenges for the change agenda implementation that are not listed above. Explain what factors, from your perspective, may cause those challenges.

Please describe how your site supports your individual change agenda implementation efforts and provide your feedback on how this process may be improved.

Thank you for completing this survey!

Appendix C: Need Analysis Interview & Focus Groups Questionnaires

INTERVIEW QUESTIONNAIRE
For the VP of the MTS organization

Date: _____

Start/End Time: _____

1. Please explain the goals and rationale for developing the strategic change agenda and comment on its current status.
2. Please describe expectations and requirements of the change agenda and how they are related to the current organizational processes.
3. What activities under each business area in the change agenda do you consider the most critical? Why?
4. What are the primary directions of the MTS change agenda for the next 2 years? What do you plan to accomplish within this time frame?
5. The MTS change agenda has been communicated to the MTS employees for the past 2 years. What have been accomplished so far? Are there any concerns you can share?
6. What are your recommendations in terms of communication, training, and workplace support related to the MTS strategic change agenda?

INTERVIEW QUESTIONNAIRE
For members of the Strategic Planning Group

Date: _____

Start/End Time: _____

Participant(s): _____

Explain the purpose of the interview: Thank you very much for making time for this interview. We are currently working on the analysis of the issues surrounding implementation of the change agenda at MTS, and this discussion will help us to identify the challenges and provide recommendations for addressing them. The interview results will be also used for informing the design of a training event that will take place at the MTS conference in June 2004.

Explain confidentiality aspect: We would appreciate your input on the context of the change agenda development, and clarification of the requirements for specific manufacturing processes defined by the agenda, such as technology transfer, process validation, and some others. We also are hoping to receive your perspective on the implementation issues. Everything we discuss today will be kept confidential. The analysis of our discussion will be used in the report prepared for the VP, but your name will not be identified in this report, and the report will not contain the direct quotes from this

interview in order to ensure confidentiality. Please feel free to ask for clarification at any time, or not to answer if the question makes you uncomfortable.

Request permission to record: We'd like to record our discussion today with an audio recorder. No one in your organization will have access to these recordings. If you feel uncomfortable with audio recording, please let us know, so we can make notes instead.

GENERAL INFORMATION

1. What aspects of the change agenda are considered to be a priority? Why?
2. How have these priorities been communicated to the MTS employees in the past 2 years?
3. Do you have any concerns regarding change agenda implementation in the MTS organization? Please elaborate.
4. What must be done in terms of communication, employee education, and workplace support to ensure that change agenda expectations and requirements are fulfilled?

PROCESS VALIDATION

1. Why is process validation included in the change agenda?
2. How do the current validation activities differ from the validation requirements outlined in the change agenda?
3. Are there any external/internal risks associated with continuing current validation practices?
4. How is the current validation practice expected to change to meet the new requirements?
5. What are the critical success criteria for implementing a new validation approach?
6. What are the implementation barriers?
7. What do you expect the MTS employees to accomplish in the next 2 years?
8. What value does the proposed process validation change bring to the MTS organization, its functional units, and individual employees?

TECHNOLOGY TRANSFER (Initial from Development & Node-to-Node)

1. Why is technology transfer included in the change agenda?
2. How do the current technology transfer activities differ from the requirements outlined in the change agenda? Please elaborate on 2 transfer types: acceptance from Development to Manufacturing and transfer to a new site.
3. Are there any external/internal risks associated with continuing current technology transfer practices?
4. How is the current technology transfer practice expected to change to meet the new requirements?
5. What are the critical success criteria for implementing a new technology transfer approach?
6. What are the implementation barriers?
7. What do you expect the MTS employees to accomplish in the next 2 years?

8. What value does the proposed change in technology transfer process bring to the MTS organization, its functional units, and individual employees?

ANNUAL PRODUCT REVIEW (APR)

1. Why is APR included in the change agenda?
2. What product quality evaluation activities are currently in place and how they differ from the APR requirements defined by the change agenda?
3. Are there any external/internal risks associated with continuing current product quality evaluation practices?
4. How is the current product quality evaluation practice expected to change to meet the new requirements?
5. What are the critical success criteria for implementing the APR process?
6. What are the implementation barriers?
7. What do you expect the MTS employees to accomplish in the next 2 years?
8. What value does the APR process bring to the MTS organization, its functional units, and individual employees?

TECHNICAL GOVERNANCE

1. Proper governance of technical issues is considered to be a critical capability for the MTS employees. Why?
2. How are the major technical issues currently handled in MTS?
3. Are there any issues related to management and resolution of the major technical problems that the MTS currently experiences? What are the causes of those issues?
4. How is the current practice supposed to change to meet the requirements related to technical governance and process-related problem management outlined in the change agenda?
5. Are there any external/internal risks associated with continuing current deviation management practices?
6. What are the critical success criteria for implementing the technical governance principles, strategies and methods outlined in the change agenda?
7. What are the implementation barriers?
8. What do you expect the MTS employees to accomplish in the next 2 years?
9. What value does the new approach to managing technical issues bring to the MTS organization, its functional units, and individual employees?

Appendix D: Study Participants Information

Table 1: Network affiliations

Position	Network LMBN		Network SMBN		Network DPN		Network PPN		MTS Central		Partners	
	#	%	#	%	#	%	#	%	#	%	#	%
Sr. Associates	1	7	4	33	3	23	2	12	5	24	0	0
Team Leaders	3	20	2	17	1	8	2	12	2	10	2	22
Process Consultants	2	13	2	17	1	8	3	19	6	28	3	34
Managers	8	53	3	25	6	46	6	38	2	10	2	22
Directors	1	7	1	8	2	15	3	19	6	28	2	22
Total:	15	100	12	100	13	100	16	100	21	100	9	100

Table 2: Functional unit affiliations

Position	MTS		Engineering		Quality	
	#	%	#	%	#	%
Sr. Associates	15	19	0	0	0	0
Team Leaders	10	13	1	25	0	0
Process Consultants	14	18	0	0	0	0
Managers	25	33	3	75	5	100
Directors	13	17	0	0	0	0
Total:	77	100	4	100	5	100

Table 3: Workshop group affiliations

Position	Green		Blue		Red		Yellow	
	#	%	#	%	#	%	#	%
Sr. Associates	2	10	3	14	4	20	6	27
Team Leaders	4	17	3	14	2	10	2	9
Process Consultants	4	17	4	20	3	15	3	14
Managers	10	43	8	38	8	40	7	32
Directors	3	13	3	14	3	15	4	18
Total:	23	100	21	100	20	100	22	100

Table 4: Workshop group composition by functional unit affiliation

Functional Unit	Green		Blue		Red		Yellow	
	#	%	#	%	#	%	#	%
MTS	21	92	20	95	19	95	17	77
Engineering	1	4	0	0	1	5	2	9
Quality	1	4	1	5	0	0	3	14
Total:	23	100	21	100	20	100	22	100

Appendix E: Email Soliciting Participation in Needs Analysis Survey

SUBJECT: MTS Strategy Survey

Dear Colleagues,

You have been already informed about the upcoming MTS global conference "Driving World-Class Commercialization", which will take place in June 2004 and will focus on the MTS change agenda implementation.

In order to plan the conference meetings and meet your professional needs, we have put together a questionnaire addressing various aspects of the MTS strategy. We appreciate your time answering our questions. Your input is very important as it helps to organize the conference time around relevant issues and further assist you in fulfilling the change agenda requirements.

The survey outputs will be kept strictly confidential. The names will be coded, and individual responses will be aggregated prior to preparing a report, which will be shared broadly within MTS organization. Please respond to the attached questionnaire as completely as you can, and return your responses via email or interoffice mail to Jamie Smith (jsmith@medex.com, DC: 54672) by January 20, 2004.

Thank you.
MTS Communications Group

Appendix F: Strategy Implementation Workshop - Facilitator's Guide

The abbreviated version of the Facilitator's Guide is included here for reference purposes. The instructional content of the guide is included in its entirety; however, this copy does not follow the original page layout and fonts, and it does not include auxiliary graphics. Additionally, some elements of the guide are collapsed for easy reading. Changes are explained by the comments provided in [ ] brackets.

Manufacturing Technology & Science

Strategy Implementation Workshop

FACILITATOR'S GUIDE

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I. WORKSHOP OVERVIEW

The purpose of this Guide is to assist you in effective facilitation of the *MTS Strategy Implementation Workshop*. This document contains information about goals and outcomes of the workshop, explains your role as a facilitator, and provides guidelines for the workshop activities.

The Need

The MTS leadership has developed the World-Class Commercialization (WCC) process model and Process Control and Capability Cycle (PCCC) in 2002 in order to communicate a systemic approach to technical stewardship for post-launch products across our sites and networks. Alignment of manufacturing processes with the business strategy represented by these strategic tools is expected to increase process efficiency, enhance capacity, capability, and control, and to facilitate integration of good science and technology principles from product development to its commercialization and optimization. The MTS strategy grounded into the WCC and PCCC frameworks is stated in the MTS change agenda that is currently being implemented at the global and local levels. Although we are moving forward with implementing the change agenda requirements, there is a need in our organization for better understanding of the following aspects:

- addressing the PCCC process requirements at every phase of the WCC timeline;
- delivery of the PCCC-determined technical and scientific documentation at every phase of the WCC timeline;
- interdependency of the PCCC process steps and the impact that every step makes on the preceding and consequent steps of the process;
- accomplishing the goals identified by change agenda given the constraints and capacity issues specific to each manufacturing network and site;
- identifying critical success factors for change agenda implementation;
- implementing the MTS strategy in the context of the critical manufacturing events, such as acceptance from Development, technology transfer, process validation, product and process quality evaluations, and process deviation management.

The workshop addresses this need through "setting the stage" for the consequent conference events and provides you with an opportunity to learn about the MTS strategy in collaboration with your colleagues.

The participants will work collaboratively on developing capabilities for managing organizational change and approaches for balancing the demands of everyday workplace processes and the MTS strategy requirements.

Learning Objectives & Outcomes

The objectives of the *MTS Strategy Implementation Workshop* include the following:

- examine the principles of the PCCC and WCC frameworks in the context of Medex-specific business situations;
- discuss application of common standards and requirements across functions, sites and networks;
- analyze critical elements of the major manufacturing processes and identify enabling and constraining factors that have an impact on the change agenda implementation;
- discuss how these factors can be leveraged in order to achieve the MTS strategic objectives.

Upon completion of the workshop, the participants are expected to:

- explain the connection between the concepts of WCC and PCCC and the change agenda expectations and requirements;
- explain application of the technical standards and requirements across functions, sites and networks;
- describe critical elements of the major manufacturing processes and explain how the dynamics between them enables and constraints the implementation of strategic objectives;
- develop and rationalize a strategy for managing the enabling and constraining factors and prepare a draft of the change agenda implementation plan for 2004-2005 to deliver to the site head.

Workshop Design & Structure

The change agenda identifies the following four manufacturing events that are critical milestones in the product life:

- Acceptance from Development (Initial Technology Transfer)
- Node-to-Node Technology Transfer
- Process Validation
- Deviation Management

Effective implementation of these processes ("events") demonstrates the MTS capability and effectiveness and ensures sustainability of its efforts.

The workshop consists of three interactive, team-based activities focused on the MTS change agenda implementation process. The overview of the instructional techniques utilized in each activity is provided in *Section III: Facilitator Support*. The detailed guidance for facilitating the activities in provided in *Section IV: Learning Activities*.

Activity 1: "Connecting the Dots"

The workshop participants will start with the analysis of the complex systems of people, technologies, documents, requirements and expectations comprising each of the four manufacturing events, and identify the issues that present barriers to effective management and execution of those events. They will then identify and discuss the changes to be made in order to address those issues and engage in designing the improved models for each of the four events.

Activity 2: "Making It Real"

In the second activity, the workshop participants will focus on identifying the course of action for implementing the proposed changes, discuss feasible steps and timelines for implementing those changes and evaluate the pros and cons of each potential solution.

Activity 3: "Putting the Moose on the Table"

The third activity invites the participants to examine the Medex-specific issues presented in brief business scenarios. Each scenario is related to one of the four critical manufacturing events that are in focus of the workshop. The workshop participants will collaboratively analyze the problems, propose solutions and evaluate them from technical, scientific, business, and regulatory compliance perspectives in order to find a balanced solution.

The progression of the workshop activities will allow the participants to learn how the MTS strategic change requirements can be interpreted and systematically implemented at the practical level when dealing with the specific business challenges.

In order to work on activities, which will last from 40 to 60 minutes, each of the four workshop groups led by two facilitators will be divided into 4 small teams, 5-6 participants per team. The teams work will be followed by a large group debrief at the conclusion of every activity as well as at the end of the workshop. During the workshop, the groups will work in separate rooms.

Workshop Delivery
The workshop will be delivered on the first day of the Global MTS Conference, on Monday, June 15, 2004 from 8:30AM to noon. The workshop will begin with a message from Dr. Caroline Brown, Vice President of MTS, explaining the purpose and importance of this event: setting the tone and context for the following topical discussions and planning sessions of the MTS conference focused on strategy implementation (specifically, issues surrounding validation, technology transfer, and technical governance processes).

II. AGENDA

Activity	*Duration*	*Time*
Introduction - Define workshop objectives - Set expectations and ground rules	10 min	8:30 – 8:40
Activity 1: "Connecting the Dots" - Analyze the goals, roles, processes, technologies, requirements, and outcomes of the four major MTS manufacturing events - Identify strong linkages, gaps and tensions between the event components and discuss their causes - Brainstorm and model process improvements	60 min	8:40 – 9:40
BREAK	10 min	9:40 – 9:50
Activity 2: "Making It Real" - Evaluate enablers and constraints associated with the proposed improvements - Discuss strategies for leveraging the enabling and constraining factors and develop an action plan	40 min	9:50 – 10:30
BREAK	10 min	10:30 – 10:40
Activity 3: "Putting the Moose on the Table" - Examine Medex-specific business problems and developing balanced solutions	60 min	10:40 – 11:40
Conclusion - Share key insights from the workshop	20 min	11:40 - 12:00

- Workshop evaluation		

III. FACILITATOR SUPPORT

The facilitators will form teams of four per group. Network directors in partnership with global senior management will represent a facilitator team in every group:

Network LMBN: Facilitator [name1] / Facilitator [name2]
Network SMBN: Facilitator [name3] / Facilitator [name4]
Network DPN: Facilitator [name5] / Facilitator [name6]
Network PPN: Facilitator [name7] / Facilitator [name8]

Facilitator's Role
You are expected to support the workshop participants' learning process through encouraging them to identify critical questions for addressing during the workshop and later at the conference, exchange experience and ideas, analyze business problems and identify solutions. Your role is to ensure that participants develop an understanding of the complexity and scope of the strategic change agenda, learn to set priorities for their daily business tasks aligned with the strategic requirements, and evaluate the impact of their business decisions on the overall organizational performance. There are no ready answers and easy solutions - you are driving thought and interactions at the workshop.

The specific facilitator responsibilities include:
- explaining the goals and expected outcomes of the workshop;
- applying organizational analysis and design techniques (activity system analysis & modeling, force-field analysis, and business issue analysis) for organizing team-based learning activities;
- leading group discussions and debriefings focusing on issue questions (*Why? What-if?* types);
- conveying strategic messages to the workshop participants and elaborating on specific change agenda requirements;
- offering relevant examples from your experience;
- sharing your technical and scientific expertise when discussing business problems;
- mobilizing silent participants and refocusing dominant participants;
- providing support for communication between teams and groups and working out conflicts;
- clarifying difference in opinions and providing feedback;
- managing time allocated for each workshop activity;
- discussing the workshop outcomes, key learning insights and next steps.

Preparation Steps & Post-Workshop Activities
The following steps are recommended for using this Guide:

Step 1: Review the business case "Implementation of the Process Control & Capability Cycle." This document has been distributed to all workshop participants as a pre-read, and it provides all main strategic points identified by the MTS change agenda documentation. It also contains all necessary terms and definitions that will assist you in facilitating the activities.

Step 2: Become familiar with the analysis techniques used in instructional activities (activity system analysis & modeling, force field analysis and business issue analysis). The detailed description of each technique is provided in the Overview of Instructional Techniques" section.

Step 3: Study the section that outlines every activity and provides the facilitation guidelines. In conjunction with studying the activities outline, review the *Facilitator's Glossary* section that provides a list of action words describing your facilitation activities. This list will support you during the workshop sessions when you need to quickly reference the steps to make.

Step 4: Review the Learner's Guide provided in Appendix H to become familiar with the activities from a learner's perspective.

Step 5: Review handouts, presentation slides, and other support materials provided in appendices to be able to use them effectively during the workshop.

Step 6: Review the Workshop Evaluation Questionnaire provided in Appendix I. You will be provided with the copies of this questionnaire for all participants in your group before the workshop. You will administer the questionnaire at the end of the Closing session, and return the participants' responses to the representative MTS Communications Group.

You are encouraged to meet all other facilitators shortly after conducting the workshop to reflect on the experience, and exchange important observations. If the face-to-face meeting is not feasible, try to record your observations as soon as possible after the workshop. Make notes on the content of the discussions as well as the dynamics of the group work.

Instructional Techniques

The workshop activities will employ different organizational analysis techniques that will help the participants to structure their work and focus discussions on critical strategic matters. Brief description of each instructional technique is provided below.

1. Business System Analysis & Modeling Technique (Activity 1)

Purpose & Rationale:

In order to reduce the tendency of isolating critical PCCC components (people, processes, documentation, roles, expectations, standards), the MTS employees need to learn how to recognize and effectively manage the linkages between all the components. This activity will assist the workshop participants in advancing their understanding of the ways the critical elements of the strategy play in the context of specific business events and also will help to clarify the roles, expectations, and specific procedures involved in managing those events.

The business system analysis & modeling technique has been conceptualized specifically for this workshop and is based on Activity Theory model (Engeström, 1991). It provides a structure for

analyzing business processes that require improvement, identifying strong linkages, gaps and tensions between the organizational components, and designing optimized processes. The learners use a graphical template to collaboratively work on the following aspects: 1) identifying goals and outcomes of a specific business process ("event") and associated organizational context, regulations and requirements, participants, and technologies; 2) defining the relationships between the event components (e.g., what technologies or methods are used in manufacturing process to ensure that FDA requirements regulating our business are met); 3) identifying issues in these relationships that have an impact on organizational performance; 4) discussing the impact of these gaps and tensions and potential ways of leveraging them; and 5) modeling optimal interactions and relationships between the event components for making the future business actions more efficient.

This technique allows one to assess the tasks within the context in which they occur. Using this technique for mapping critical processes managed by MTS has a promising potential for successful change interventions since it helps the MTS employees understand the dynamics within the implementation environment that either help or hinder the change.

Process:

To facilitate a business system analysis and modeling activity, follow these steps:

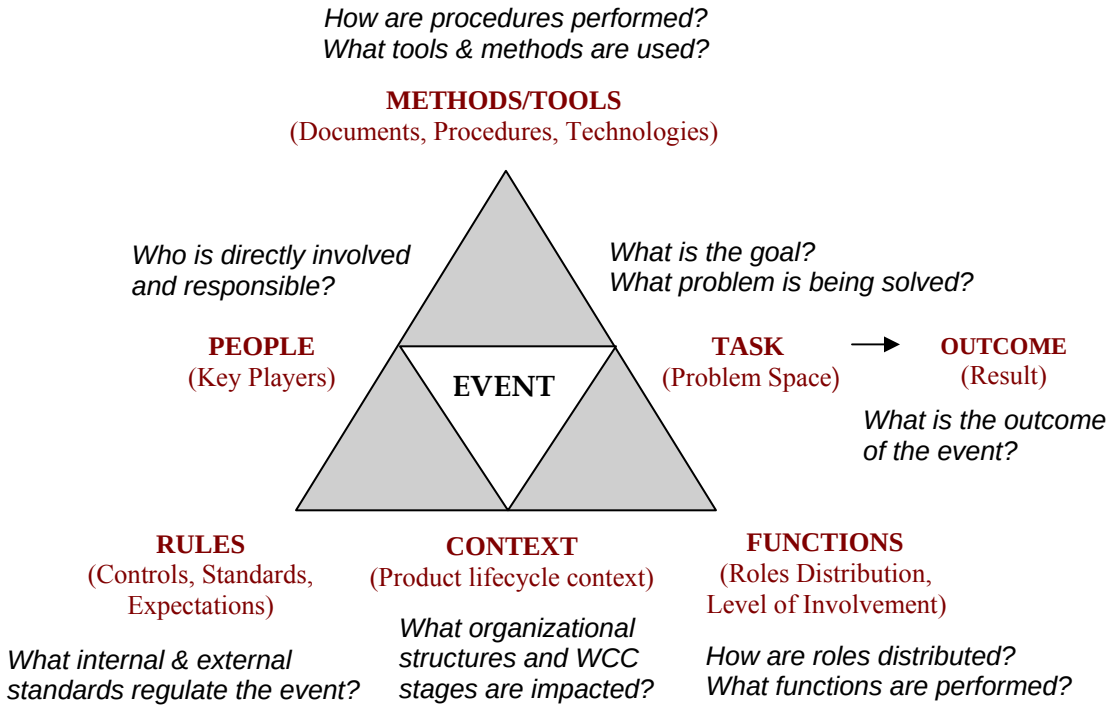
1. Identify a business event that the MTS owns or participates in (e.g., Technology Transfer).
2. Explain to learners that each event is a complex business system and involves relationships and interactions with multiple functional areas within the company and with external regulating agencies.
3. Engage learners in collaborative discussion focused on identifying the major components of the system using the questions provided in the template:
    1) What is the main goal of the business event? What problem is being solved?
    2) What is the expected outcome of the event?
    3) What functional areas are directly involved in this event and who are the key players?
    4) How are the roles distributed among the key players? What expertise do these people have/must have?
    5) What is the context within which this event takes place? What organizational structures are affected?
    6) What rules/standards regulate this event? What are the sources of those rules?
    7) What procedures, methods, tools and technologies are used to carry out the event?

    Ask learners to use the template for organizing the answers to the above questions into the categories included in the template: *People, Context, Rules, Functions, Tasks, Methods/Tools, Outcome*.
4. Invite learners to the discussion of interactions between the event components they have identified. Use the following guiding questions aligning them with the context of a specific event:
    1) *People – Methods/Tools – Tasks*: How do technical documents, procedures and technologies affect the ways the key players perform their tasks?
    2) *People – Rules – Tasks*: How do the external and internal regulations and performance expectations affect the task completion?
    3) *People – Functions – Tasks*: How does role distribution among key players impact the achievement of the event's goals?

4) *Methods/Tools – Context – Tasks*: What is the impact of the context in which the event takes place on the technical documents, procedures, and technologies used for completing the tasks?
5) *Rules – Context – Tasks*: How does the context of the event determine the rules regulating task completion?
6) *Functions – Context – Tasks*: How does the context of the event affect the distribution of responsibilities among the functional areas involved in execution of the tasks?

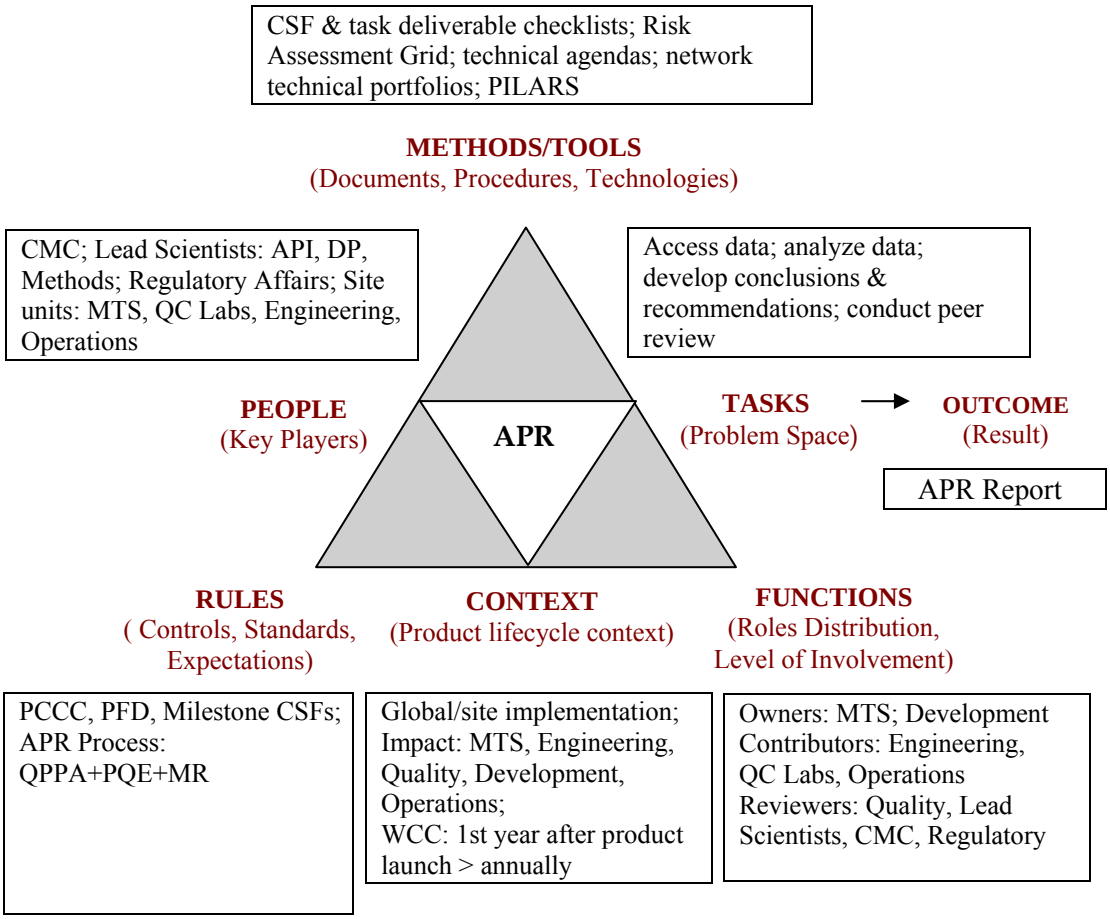
5. As the learners analyze the system's dynamics using these guiding questions, ask them to identify, justify and record: a) strong relationships between the system components that help driving the event towards successful completion, and 2) gaps and tensions that present barriers to the successful completion of the event.
6. Invite learners to analyze identified problems and discuss potential ways of eliminating or reducing them.
7. Ask learners to make necessary modifications to their initial designs to reflect their recommendations on improving system performance.

Template:
Use the following template to work on this task:



MTS Example:

The example below demonstrates some of the activity outcomes provided by a pilot MTS team. Their analysis and modeling work was focused on the Annual Product Review (APR) business event:



1. The following **strong relationships** between the components were identified that help driving the event towards successful completion:
    1) Availability of the WCC framework that determines, the scope and timeline for conducting APR (*Rules – Context – Tasks*).
    2) Availability of checklists and templates for creating technical documentation required by APR (*People – Methods/Tools – Tasks*).
    3) Availability of quarterly process and product assessments and periodic quality evaluations required for conducting APR (*People – Rules – Tasks*).

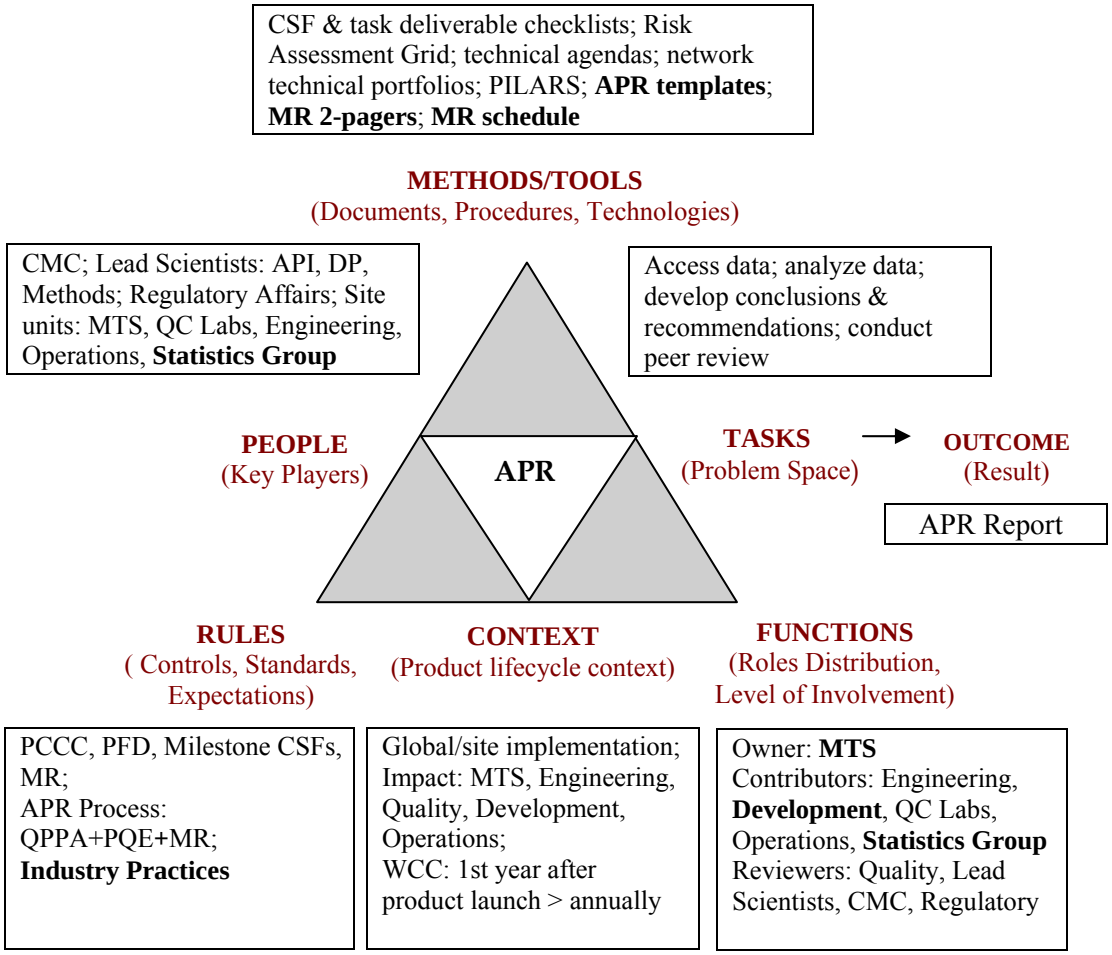
2. Several **gaps and tensions** were identified, and the following changes were made to the design to address them:
    1) Site-based and global statistical groups have not been initially considered as one of the key players sharing responsibility for the APR-related tasks. They must be

systematically involved in APR-related data organization and analysis as well as providing necessary training and support to other functional units.

2) The responsibilities and ownership over the specific APR activities are not sufficiently defined for all functional units involved thus causing confusion and delays with deliverables. There must be clear distribution of the following roles among the functional units: APR business owner, APR contributors, APR reviewers.
3) There are currently no external benchmarks for APR. Since APR is not specified by FDA regulations, it is recommended to align APR activities with successful industry practices.
4) Manufacturability Reviews are interpreted differently by different functions, which results in inconsistent use of the criteria they provide.
5) There is no APR template that would ensure consistency among the APR deliverables across sites and networks.

3. Based on the analysis, the following additions and changes to the APR system were recommended:
    1) Add Statistics group to the *People* category.
    2) Assign roles to functional units listed under People category based on the following criteria: owner (manages the process and signs off final report), contributor (provide necessary technical materials), and reviewer (evaluate APR report against standards and technical requirements).
    3) Add industry practices to the Rules category.
    4) Finalize and include MR-related documentation (schedule, 2-page guidance) under the *Methods/Tools* category.
    5) Add APR template to the *Methods/Tools* category.

4. The following design completed by the pilot group demonstrates the optimized APR process model:



2. *Force-Field Analysis Technique (Activity 2)*

Purpose & Rationale:

The complexity of the change agenda requires from the MTS employees an ability to establish priorities for making steps toward an implementation of the new strategy while considering the effects those steps may have on organizational processes. This activity teaches one how to evaluate the feasibility of specific change activities. Force-field analysis is a technique developed for diagnosing organizational situations and planning organizational change. It allows one to assess the driving and restraining forces that influence change activities. The equilibrium, or present level of productivity, can be raised or lowered by changes in the relationship between the driving and the restraining forces through the introduction of action strategies. This technique allows organizational members to make prognosis for specific time periods (e.g., 3-6-12 months). It also helps them to establish priorities among multiple change agenda items. You will use this technique in Activity 2: "Making It Real".

In the context of this workshop, the participants are expected to analyze the strong organizational factors and constraints they identified for each of the four business events in Activity 1. Their goal is to generate a list of actions focused on eliminating or significantly reducing constraints and

leveraging strong relationships between the events' components. This deliverables will be used as blueprints for network-specific discussions at the conference.

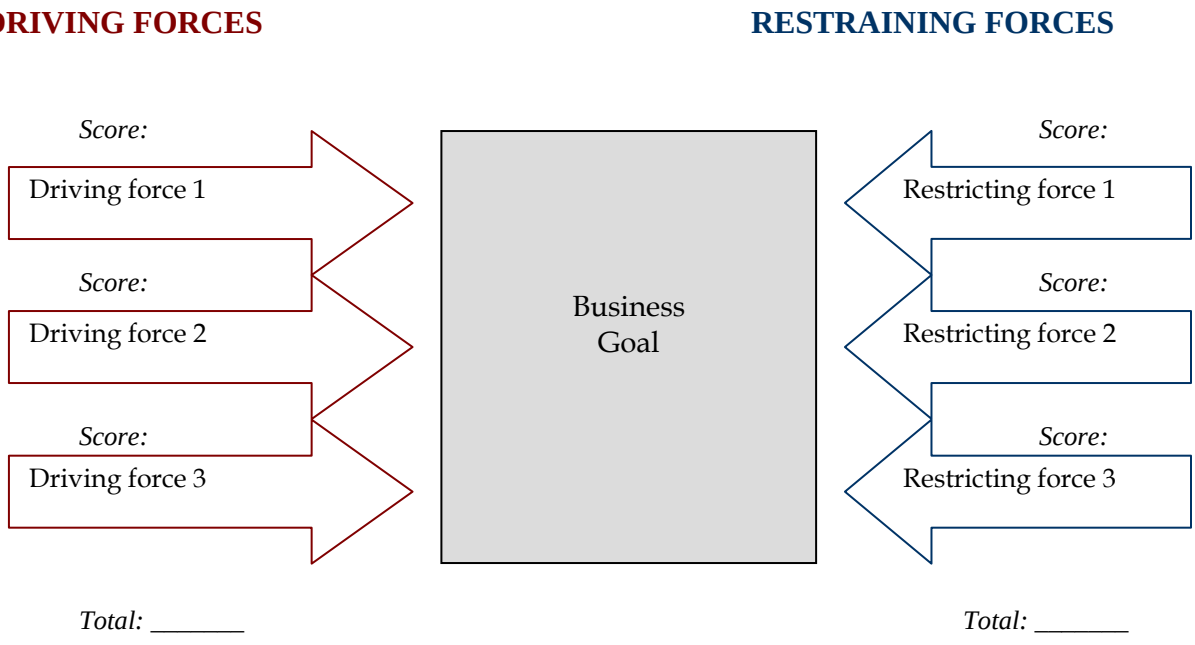
Process:

To carry out a force-field analysis, follow these steps:

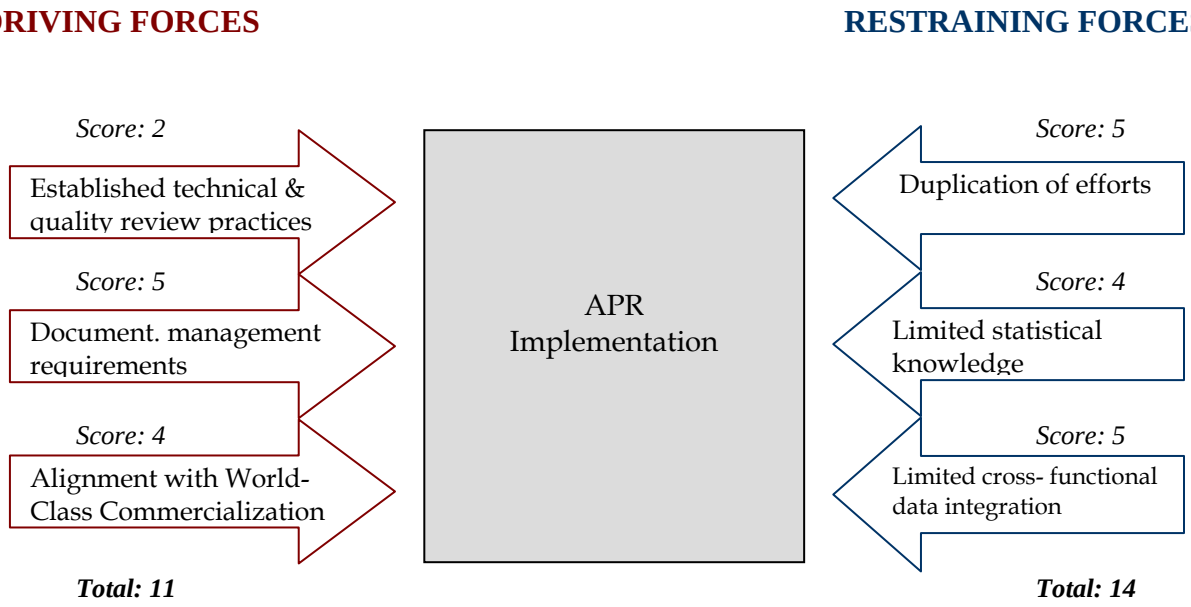
1) Create a flip chart using the template provided below.
2) Write down the business goal that needs to be analyzed. In the context of this workshop, a goal will be implementation of one of the four business events discussed in the previous activity.
3) Ask learners to summarize and write down the strong aspects that support implementation of the event and problems that present barriers to implementation. Strong aspects should be listed under "driving forces", and problems should be listed under "restraining forces". Driving forces help an organization to achieve a specific business objective and effectively implement a process, while restraining forces may inhibit this implementation.
4) Ask learners to prioritize the driving and restraining forces; select 3 most important driving forces and 3 most important restraining forces.
5) Ask learners to assign the score to each force using a numerical scale: from 1 (very weak) to 5 (very strong).
6) Facilitate learners' discussion of action strategies focused on reducing or eliminating the restraining forces and enhancing the driving forces. Emphasize those action strategies that impact multiple forces or create additional driving force.
7) Discuss how the proposed action strategies may impact both forces and improve the situation.
8) Invite learners to make snapshots of the three months from now, six months from now, 12 months from now: which forces can be reduced during these periods of time, which forces can be enhanced?

Template:

Use the following force-field analysis template to work on this task:



MTS Example:
The following example has been created by the pilot group to evaluate the situation with implementing the Annual Product Review:



Analysis:
The diagram reveals very strong restricting forces: 1) poorly defined roles causing duplication of efforts across functional units; 2) limited knowledge of statistical methods and tools required for APR as well as sporadic involvement of statisticians; and 3) limited cross-functional data integration. The mixed set of strong and weak driving forces includes: 1) established periodic product and process review approaches that can be utilized in developing a process for APR implementation; 2) numerous checklists and templates developed for consistent design of the documents used in APR preparation; and 3) alignment of the APR process with the WCC framework.

A lot of effort is put into the compliance with the documentation management requirements and conceptualizing the position of APR within the WCC framework, yet such critical activities as cross-functional data integration and development of a shared pool of data and its systematic statistical analysis are just emerging. The ill-defined roles and responsibilities among functional units add to the everyday challenges with the APR implementation.

Actions:
The following actions have been identified in order to impact the forces (enhance driving forces and limit restricting ones):

- develop consistent business process that defines roles, responsibilities and time allocations (reduces the force "Duplication of efforts" to zero during 12-month period).
- Assign a professional statistician to every site and develop and deliver statistical training program (reduces the force "Limited statistical knowledge" to one or zero during 12-month period).

- Assign site-based and global MTS liaisons with the site-based and global IT groups to assist them in their efforts in developing cross-functional data integration sources (reduces the force "Limited cross-functional data integration" to three or two during 12-month period).
- Develop guidance documentation for integrating data analysis results from the periodic Quality Evaluations and Quarterly Product and Process Assessments into the APR Report (enhances the force "Established technical and quality review practices" to five during the six-month period assuming the documentation is complete by then).

3. Business Issue Analysis Technique (Activity 3)

Purpose & Rationale:
Business Issue Analysis technique is intended to engage participants in the collaborative evaluation and resolution of the MTS-related challenges. The participants not only become aware of the issues, but they learn to generate solutions with consideration of all the barriers and enablers of the environment in which the problems occur. This technique helps employees to advance their skills related to defining a problem, analyzing multiple options for addressing it, critiquing and supporting potential problem solutions, and developing a solution with balanced technical, business, and regulatory compliance risks. Addressing real-life problems is one of the most effective methods for engaging participants from various manufacturing areas in exchanging expertise, strategies and experiences.
Process:
Divide your group of learners into four small teams. Each team receives a description of the problem, *Problem Scenario*. During 10 minutes, each team needs to come up with a solution, then to pass the notes to the next team, which provides some evidence to support the solution and demonstrates its positive impact. Then the notes are rotated again, and the following team provides a critique to the proposed solution, focusing on the potential issues associated with the proposed solution. The notes are rotated one more time, and during the final round, a new team reads the problem, analyzes the original solution and supporting and critiquing arguments, and develops a balanced version of the problem solution that considers all positive and negative aspects.

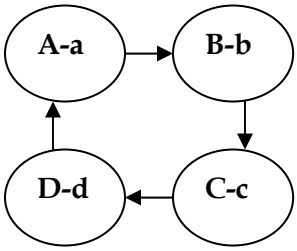
The large group debriefing will follow team work focusing on the supporting and critiquing arguments related to the original and improved problem solutions. The purpose of the debriefing is to demonstrate a systematic way of addressing the problem from various perspectives, and participate in the informed decision making process.

NOTE: For the purposes of this workshop, please advise the participants to focus on compliance, business and technical advantages and risks when evaluating proposed solutions.

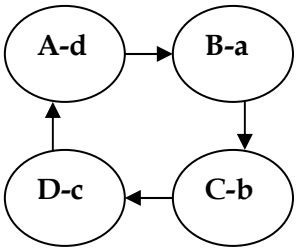
The outline below describes the flow of activity's rounds:

A,B,C,D – team names
a,b,c, d – team products (solutions, testimonials, critiques, improved solutions)

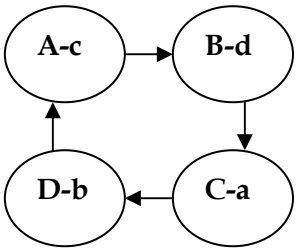
Round 1: Generating Solution. All teams generate problem solutions and pass them to the next team.



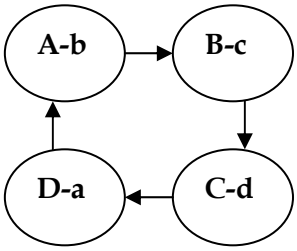
Round 2: Providing Support. Team A support the solution of Team D; Team B supports the solution of Team A; Team C supports the solution of Team B; Team D supports the solution of Team C. All teams pass their testimonials to the next team.



Round 3: Providing Critique. Team A critiques the solution of Team C; Team B critiques the solution of Team D; Team C critiques the solution of Team A; Team D critiques the solution of Team B. All teams pass their critiques to the next team.



Round 4: Generating Improved Solution. Team A develops an enhanced solution for the problem of Team B using the support and critique notes; Team B develops an enhanced solution for the problem of Team C using the support and critique notes; Team C develops an enhanced solution for the problem of Team D using the support and critique notes; Team D develops an enhanced solution for the problem of Team A using the support and critique notes.



MTS Example:

Business Scenario (reviewed by Team A):

The initial process for manufacturing Bomex® was established in 1990's and it was designed for low capacity. After the product launch, the market demands indicated the need for delivery of 150-200 metric tons per year. The existing equipment at the multi-product facility where Bomex® has been manufactured does not have the capacity to deliver the required amount of API to supply fill/finish operations.

Proposed Solution (developed by Team A; reviewed by Team B):

Make process improvements in order to increase capacity of the existing facilities through the lot size increase and optimization of the cycle time.

Strengths/Potential Positive Impact of the Proposed Solution (developed by Team B; reviewed by Team C):

- Cost-effective
- Improvement activities can start immediately
- Meeting market demand within the short period of time

Weaknesses/Potential Negative Consequences of the Proposed Solution (developed by Team C; reviewed by Team D):

- Cycle time improvements and lot size increase are only short-time solutions – they would not be sufficient to deliver the maximum amount of product required
- The proposed revisions may have the risk of introducing new problems in other aspects of manufacturing API
- The proposed process revisions may impact the production cycle of other drugs since Bomex is manufactured at the multi-product facility

Balanced Solution (developed by Team D; reviewed by team A):

Pursue a second supplier of API with multiple manufacturing sites and a high level of plant automation since Bomex API manufacturing process involves safety critical operations. Although it will take some time and financial cost to transfer the process to the vendor, Medex has a previous positive supplying experience with the third party, the transfer will ensure manufacturing the product at the increased scale for a long term and prevent the other products manufactured at the plant from being compromised.

Next section of this Guide provides detailed facilitation guidance for each of the workshop activities.

IV. LEARNING ACTIVITIES

Introduction

1. Welcome your group members. Introduce yourself, and mention that there are participants from different functional units are present in your network-based group.

2. Explain the goals, structure, and format of the workshop.

3. Remind the group that poster-size versions of PCCC and WCC models are available throughout the room and in their participant guides for reference purposes.

4. Briefly review the Process Control and Capability Cycle and World-Class Commercialization models, indicating that these two models drive our strategy and everyday business process. Emphasize the notion that these two conceptual models are highly integrated.

Activity 1: "Connecting the Dots"

Learning Objectives & Outcomes:

- Define key players and critical process and product components involved in major events that span the stages of the World-Class Commercialization process.
- Explain roles, rules, procedures, and documentation expectations related to each major event.
- Define strong linkages, gaps and tensions between all components currently involved in the process.
- Brainstorm process improvements and develop a conceptual model of the optimized business events.

Format:
Four teams of five to six people working collaboratively within a larger group led by two facilitators.

Resources:

- Facilitator's Guide
- Learner's Guide
- Activity 1 Worksheet (*Appendix A).*

Time:
60 minutes

Detailed Guidelines:

1. Introduce the purpose of the activity and expected outcomes.
2. Divide your group into four teams.
3. Distribute *Activity 1 Worksheet* to the teams.
4. Introduce the business system template (Figure 1) and the example constructed for the APR (Annual Product Review) event (Figure 2) provided in the Learner's Guide. Encourage your group to use both illustrations as visual reminders during their brainstorming.

5. Explain each component of the model using a business system template and its description provided in *Section III: Facilitator Support > Instructional Techniques > Business System Analysis & Modeling Technique*.
6. Use *Activity 1 Worksheet* to model the APR example.
7. Invite participants to use the template and identify and record the components of the system using the questions provided in the template.
8. Ask participants to identify and record: a) strong relationships between the components that help driving the event towards successful completion, and 2) gaps and tensions that present barriers to the successful completion of the event. Encourage them to explore the impact of these strengths and weaknesses. Remind them to use the guiding questions provided in *Activity 1 Worksheet*.
9. Invite participants to propose and document changes that address their conclusions about the strengths and weaknesses of the APR system using the activity-based design tool.
10. Ask participants to make necessary modifications to their initial designs to reflect the recommendations made regarding the identified gaps and tensions. Remind them to use a different color for indicating the changed or added components.
11. Ask your groups what they've learned from working on this activity and how their understanding of each event's context and main components changed after completing this activity.
12. Reiterate the role of this exercise in preparing the participants for the conference. Help them brainstorm how they are planning to use the results of their design in supporting their arguments during the conference discussions.

Activity 2: "Making It Real"

Learning Objectives & Outcomes:

- Analyze the strong linkages, gaps and tensions between the system components that were identified in Activity 1.
- Generate a list of actions focused on eliminating or significantly reducing discrepancies and leveraging strong relationships and prioritize those actions.
- Develop a strategic broadcast for six- and 12-month time spans.

Format:
Four teams of five to six people working collaboratively within a larger group led by two facilitators.

Resources:

4. Facilitator's Guide
5. Learner's Guide
6. Activity 2 Worksheet (*Appendix B*)

Time:
40 minutes

Detailed Guidelines:

1. Ask participants to remain in their teams and focus on the business events they analyzed in the previous activity.

2. Introduce the purpose of the activity and expected outcomes.
3. Distribute *Activity 2 Worksheet* to the teams.
4. Introduce the force-field analysis template (Figure 1) and the example of the force-field analysis of the APR event (Figure 2) provided in the Learner's Guide. Encourage your teams to use both illustrations as visual reminders during their brainstorming.
5. Ask participants to use the template provided in *Activity 2 Worksheet* to create flipcharts for their business events.
6. Ask participants to write down the strong relationships they indentified between the event components as well as the gaps and tensions that have negative impact on the event implementation. Strong relationships should be listed under "driving forces", and gaps and tensions should be listed under "restraining forces". Driving forces help an organization to achieve a specific business objective and effectively implement a process, while restraining forces may inhibit its implementation.
7. Ask participants to: a) prioritize the driving and restraining forces, b) select 3 most important driving forces and 3 most important restraining forces, and c) assign the score to each force using a numerical scale: from 1 (very weak) to 5 (very strong). Explain the meaning of the scores.
8. Invite participants to the discussion of specific actions focused on reducing or eliminating the restraining forces and enhancing the driving forces. Ask them to capitalize on those actions that impact multiple forces or create additional driving force.
9. Engage participants in the discussion of how the identified actions will improve business processes they analyzed. Ask them to develop a strategic broadcast for six- and 12-month time spans: Which forces can be reduced during these periods of time? Which forces can be enhanced?
10. Engage all the teams in sharing the results of their work with the rest of the group. In the discussion, make emphasis on evaluating the feasibility of implementing these actions and importance of implementation stages.
11. Ask your groups what they've learned from working on this activity and how their understanding of each event's context and main components changed after completing this activity.
12. Reflect on the role of this exercise in preparing the participants for the conference. Indicate that this was the first step in developing change agenda implementation plans for the MTS networks and sites.

Activity 3: "Putting the Moose on the Table"

Learning Objectives & Outcomes:

- Develop an understanding of internal relations of PCCC model components.
- Generate ideas for dealing with process-focused problems.
- Evaluate strengths and weaknesses of possible solutions.
- Improve the potential value of solutions.
- Analyze the potential value of two different solutions for handling the same problem.

Format:

Four teams of five to six people working collaboratively within a larger group led by two facilitators.

Resources:

- Facilitator's Guide
- Learner's Guide
- Activity 3 Worksheet (*Appendix C*)

Time:
60 minutes

Detailed Guidelines:

1. Ask participants to remain in their teams.
2. Introduce the purpose of the activity and expected outcomes.
3. Distribute *Activity 3 Worksheet* to the teams. The worksheets are included in your facilitator's instructional package.
4. Announce time allocations: 10 minutes for each round and 20 minutes for debrief.
5. Explain that each team will engage in the following actions: 1) read the problem scenario, and generate a two- to three-sentence solution to the issue discussed in the scenario; 2) review the problem solution generated by the partner team, and identify the strengths, and positive consequences of the suggestion by providing a short testimonial; 3) review the solution generated by the partner team and provide a critique, and 4) review the initial solution, supporting arguments and the critique and suggest a balanced solution. The activity will conclude with the group discussion where participants will discuss the results of the problem analysis.
6. Remind participants to use the problem scenarios provided in the Learner's Guide for reference purposes only; all records related to the activity should be made on the *Activity 3 Worksheet* handouts.
7. Ask participants to read their problem scenarios, and generate a summary (two to three sentences) of the solution that could be considered for resolving the situation described in the scenario.
8. At the end of the time limit, ask each team to give the solution description to the next team. Tell the teams that now they need to play the role of supporters of the proposed solution. Request to provide the strengths and positive consequences of the proposed solution, and record them in the form of a short testimonial (can be a bulleted list of three to four items).
9. At the end of the time limit, ask each team to give their testimonials to the next team. Explain that now they need to play the role of "devil's advocate" and identify weaknesses of the proposed solution. Ask to provide a bulleted list of three to four major justification points that would support their position against this solution. Ask to focus on limitations, and negative consequences of the proposed solution.
10. At the end of the time limit, ask each team to give the notes to the next team. At this point, every team has the four items of information: problem scenario, solution, supporting arguments, and a critique. Tell the teams that this last round should be spent on developing the enhanced solution with consideration of strengths and weaknesses identified by the partner teams.
11. Organize a debriefing session where all members of your group would have an opportunity to reflect on different roles they played and compare the solutions to the problems. Engage participants in discussing justifications for their decisions and comparing their solutions.

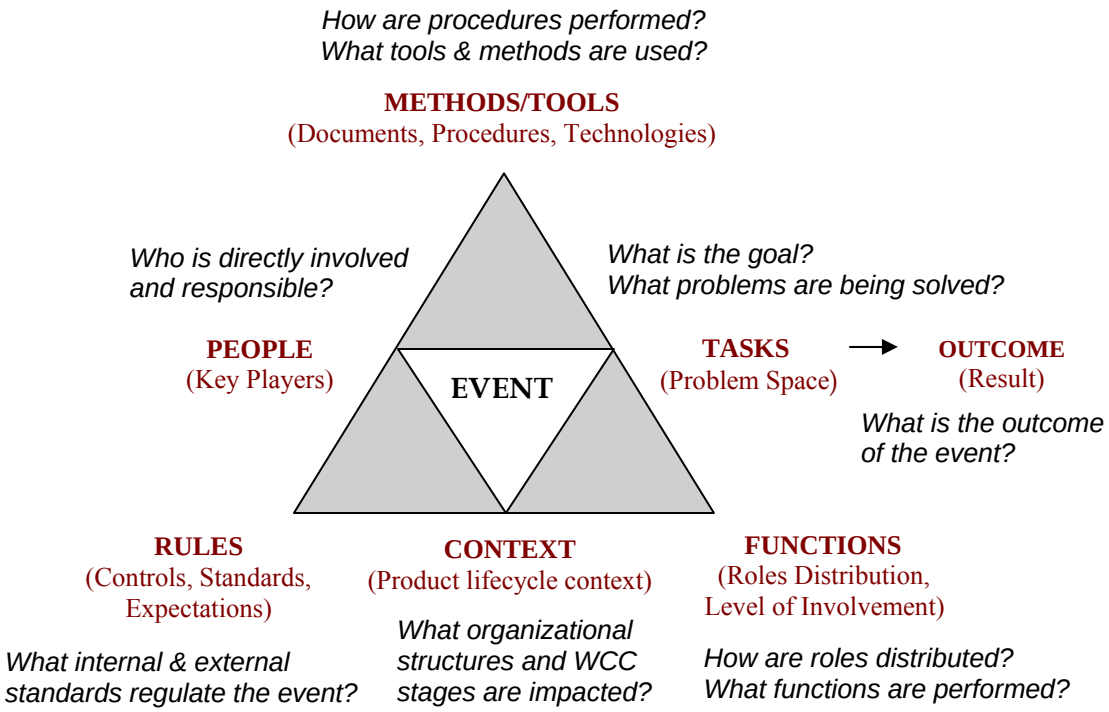
12. Ask participants what they've learned from working on this activity, and why it was important to play different roles.
13. Reinforce the notion of complexity of the workplace issues and the necessity to approach every issue from multiple perspectives in order to balance potential risks. Remind participants that the implementation of the new strategy manifests itself in such concrete daily events that occur during the life of the product.
14. Reflect on the role of this exercise in preparing the participants for the conference. Indicate that this was the activity demonstrating an application of the strategic concepts in solving daily workplace issues.

Conclusion

1. Summarize the activities; encourage participants to use information and materials they developed at the other conference events.
2. Invite participants to share key insights from the workshop; ask what was the most beneficial from learning perspective. Ask what aspects of the PCCC implementation are still unclear to them. Ask about the format of workshop: did they find it beneficial to work in teams? Why or why not? Ask what kind of help related to the topics discussed at the workshop they would like to receive.
3. Ask participants to complete the Workshop Evaluation Form.
4. Thank your groups for their participation in the workshop and address their questions.

V. APPENDICES

Appendix A: Activity 1 Worksheet



1. Define the components of the event:

   BUSINESS EVENT:

   _____

   People:

   _____

   _____

   Tasks:

   _____

   _____

   Context:

   _____

_____

Functions:

_____

_____

Rules:

_____

_____

Methods/Tools:

_____

_____

Outcome:

_____

_____

2. List strong linkages between the event's components:

_____

_____

3. List gaps and tensions between the event's components:

_____

_____

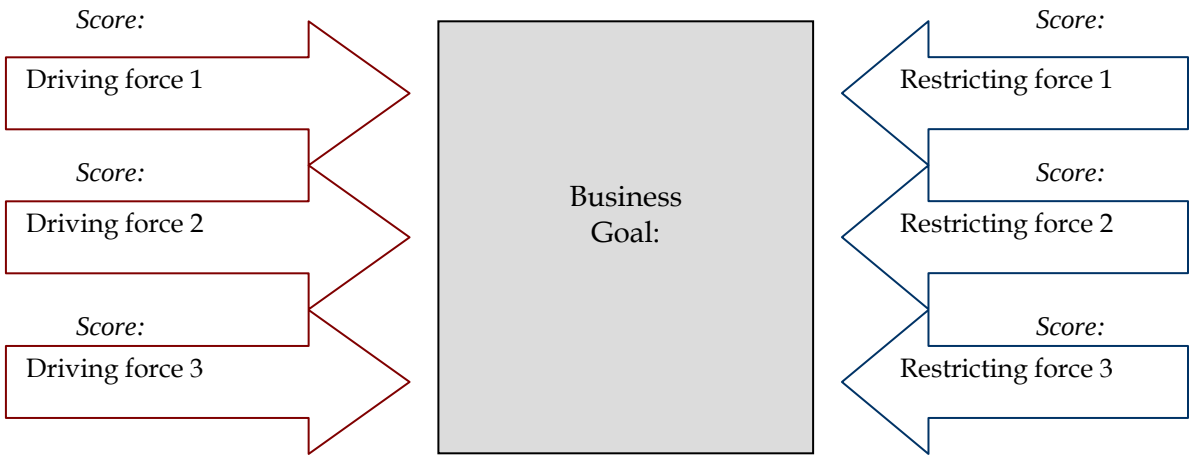
4. Record proposed changes:

_____

_____

Appendix B: Activity 2 Worksheet

DRIVING FORCES **RESTRAINING FORCES**



Total: _____ *Total:* _____

1. List driving forces and associated scores:

_____ _____

_____ _____

_____ _____

2. List restraining forces and associated scores:

_____ _____

_____ _____

_____ _____

3. List planned actions:

_____

_____

_____

_____

Appendix C: Activity 3 Worksheet

[Each activity worksheet distributed at the workshop contained one scenario and a set of questions related to the scenario. Here, all the scenarios collapsed in one page to avoid repetition of the questions that are identical for all four scenarios.]

Problem Scenario 1
MTS group is partnering with plant Engineering to conduct the assessment of the state of equipment qualification. The standards have changed since the particular set of equipment (tanks) was initially qualified. The equipment does not meet the revised standards, although it continues to perform well, and all the maintenance records are complete. Should equipment be re-qualified to the new standards? If not, what should be done?

Problem Scenario 2
During the routine maintenance of the equipment, you observed that spray ball coverage has not been uniform during commercial operations. Equipment qualification and cleaning validation supporting the process were completed several years ago. Prepare your recommendations assuming that this is a multi-product equipment used for preparation of intermediate product.

Problem Scenario 3
Contaminant X cannot exceed 1%. The PFD says that at the time of validation the mean value was 1%, and the process was in control and capable. The assay was accurate to $\pm$ 0.05%. During the process review, it was found that contaminant X never exceeded 0.8%, but the data was significantly out of statistical control. MTS has put renewed emphasis on assessments containing conclusions and recommendations. Should this observation be included in the assessment? What should be the conclusion? What recommendations would you provide?

Problem Scenario 4
A product is manufactured at two different sites. They have never had PFDs before and now have to write them. Justification of operating ranges will largely be based upon actual operating data. Both processes are found to be in control, although mean values and control limits for the two sites are quite different. Only one site is found to be capable for all in-process measures. Both sides make product that routinely meet specifications. How would you address this discrepancy issue? Is the resolution of this discrepancy a priority?

SCENARIO #: _____

Proposed Solution:

_____

_____

_____

Strengths/positive impact of the proposed solution:

_____

_____

_____

Weaknesses/potential negative consequences of the proposed solution:

_____

_____

_____

Balanced Solution:

_____

_____

_____

Appendix D: MTS Abbreviations
[not included]

Appendix E: Process Control & Capability Cycle (PCCC)
[not included]

Appendix F: World-Class Commercialization (WCC) framework
[not included]

Appendix G: Learner's Guide
[The Learner's Guide is a subset of the Facilitator's Guide that contains identical general sections and guidance for learners, and it is not included here due to its length. For the detailed guidance for learners provided by the workshop facilitators, review Section IV: Learning Activities of the Facilitator' Guide.]

Appendix H: Workshop Evaluation Form
[not included]

[end of Facilitator's Guide]

Appendix G: Observation Matrix

1	2	3
Time	Participants' Activity/Discussion Focus	Observer's Comments

Appendix H: Follow-up Survey

MTS STRATEGY IMPLEMENTATION WORKSHOP: FOLLOW-UP SURVEY

Thank you for taking the time to complete this survey. Your answers will help us to better address your change agenda-related learning needs in the future communication and training events and provide better support in the change implementation efforts. Please answer each question to the best of your ability. Your responses will be kept completely confidential, and you will not be identified in any reports generated based on the results of this survey.

Expected survey completion time: 20 minutes.

I. GENERAL INFORMATION

This section asks general questions about your position at Medex.

1. Please indicate your level within the organization:
   ___Associate/Sr. Associate
   ___Consultant
   ___Team Leader
   ___Manager
   ___Director

2. Your tenure at Medex *(in years):* _____

3. Your manufacturing network affiliation:
   ___A
   ___B
   ___C
   ___D
   ___Central
   ___Partner organization *(provide name):* _____

II. CHANGE AGENDA CONCEPTS AND PROCESSES

The purpose of this section is to ask you to share your knowledge of the change agenda main concepts and processes discussed at the workshop. Some of the questions may be familiar to you as they appeared in the survey you completed before the workshop. We would like to receive your responses to these questions again to be able to evaluate the workshop effectiveness in terms of supporting your learning of the change agenda requirements.

1. Indicate the roles of the specific functional units listed in the left column in managing the WCC/PCCC-determined manufacturing events. Use the following role codes:

   "O" = Owner
   "C" = Contributor

Functional Units		*Manufacturing Events*			
		Initial Process Transfer from Development	Node-to-Node Technology Transfer	Validation	Deviation Management
1	MTS				
2	Development				
3	Quality Control				
4	Engineering				
5	Operations				
6	IT/Automation				
7	Analytical Control				
8	Environmental Monitoring				

2. Indicate the processes required for the WCC/PCCC-determined manufacturing events. Use the following codes:

   "P" = Prerequisite
   "R" = Required during the event

Processes		*Manufacturing Events*			
		Initial Process Transfer from Development	Node-to-Node Technology Transfer	Validation	Deviation Management
1	Manufacturability Review				
2	Quarterly Process & Product Assessment				
3	Design Qualification				
4	Classification				
5	Installation Qualification				
6	Commissioning				
7	Operational Qualification				
8	Risk Assessment				
9	Computer System Validation				
10	Gap Assessment				
11	Measurement Uncertainty Analysis				
12	Change Control				
13	Site Acceptance Testing				
14	Technical Approval				
15	Quality Approval				

3. Indicate the required technical components for the WCC/PCCC-determined manufacturing events. Use the following codes:

   "I" = Key Input
   "O" = Key Output

Technical Components		*Manufacturing Events*			
		Initial Process Transfer from Development	Node-to-Node Technology Transfer	Validation	Deviation Management
1	Development History Report				
2	Development Process Flow Document				
3	Manufacturing Process Flow Document				
4	Site Validation Master Plan				
5	Commissioning Documentation				
6	Commercial Development Plan				
7	Product Technical Agenda				
8	Approved Technical Reports				
9	Regulatory Commitment Documentation				
10	APR Report				
11	User Requirements				
12	Deviation Report				

13	Gap Assessment Report				
14	Performance Qualification Documentation				
15	In-Process Controls				
16	Standard Operating Procedures				
17	Risk Assessment Grids				
18	CSF Checklist				
19	System Classification Documentation				
20	Computer System Validation Plan				

III. CHANGE AGENDA IMPLEMENTATION STRATEGIES

This section asks you to apply what you have learned in the workshop in the analysis of the Medex-specific business problem.

1. Analyze the following business scenarios and answer the questions focused on the issue contained in each scenario. Check all the answers relevant to the described situation.

Scenario 1:
In preparation for C6 Manufacturability Review at your site, you discover that the agitation rate listed as a critical process parameter in the Process Flow Document was not measured during operations, and, in fact, cannot be measured because the capability for making this measurement was not considered when the process was initially transferred to your site.

1) What factors may have caused this issue?

___ Lack of Development PFD
___ Insufficient operational data
___ Lack of PFD prior to conducting Classification
___ Design Review was not properly conducted
___ User Requirements were not available during equipment installation

2) What processes are directly affected by this issue?

___ Process Validation

___ Annual Product Review
___ Analytical Assay Validation
___ Node-to Node Technology Transfer
___ Performance Qualification

3) What functional units are directly involved in the situation?

___ Development
___ MTS
___ Analytical
___ Engineering
___ Environmental Monitoring

4) What action(s) are required for addressing this issue?

___ Amend User Requirements
___ Requalify equipment
___ Review historical data
___ Revalidate process
___ Amend PFD

Comment on how this situation impacts your site from inspectional, technical, scientific, and business perspectives and explain how your choice of action(s) will help to improve it:

Scenario 2: During the inspectional visit to your site, the inspectors point out the discrepancy between corporate requirements and local practices for the 15-year old water system. While the inspectors do not dispute the argument that the site practice is in full conformance with the local SOPs and the fact the water has no impact on product quality, they issue a major finding that the operations conform neither to external nor corporate guidance.

1) What factors may have caused this issue?

___ Poor communication between the global and site-based MTS
___ Misalignment between corporate quality policies and local standards
___ Failure to qualify the equipment
___ Poor communication between Regulatory and MTS
___ Manufacturing process using the water system has not been properly validated

2) What processes are directly affected by this issue?

___ Annual Product Review
___ Periodic Quality Evaluation
___ Process Validation
___ Performance Qualification
___ Safety Evaluation

3) What functional units are directly involved in the situation?

___ Quality
___ MTS
___ Operations
___ Engineering
___ Regulatory

4) What action(s) are required for addressing this issue?

___ Review local standards to conform with corporate policies
___ Requalify equipment
___ Amend corporate policies to accommodate aged equipment
___ Revalidate process
___ Purchase new equipment

Comment on how this situation impacts your site from inspectional, technical, scientific, and business perspectives and explain how your choice of action(s) will help to improve it:

2. Please indicate your level of agreement with the following statements:

1) I find it challenging to assign tasks during execution of the processes defined by the change agenda.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

2) I find it challenging to assign specific roles to manufacturing units during execution of the processes defined by the change agenda.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

1) I find it challenging to establish priorities for task completion during execution of the processes defined by the change agenda.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

2) I can describe the deliverables associated with the processes defined by the change agenda.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

3) I find it challenging to explain how the change agenda requirements apply to the vendor processes.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

4) I can explain how the change agenda requirements are aligned with regulatory expectations.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

5) I can explain how the change agenda requirements are aligned with the World-Class Commercialization framework.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

6) I can apply the change agenda requirements to existing manufacturing practices.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

7) I find it challenging to explain the value of the change in our manufacturing practices.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

8) I can define the risks that our organization will face if the change agenda is not implemented.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

9) I can identify the factors (e.g., current processes, practices, documents) supporting the change agenda implementation.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

10) I can explain how those factors can be leveraged to support change process.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

11) I can identify the problems that present barriers to the change agenda implementation.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

12) I can explain how those problems can be eliminated or minimized to ensure the progress of change-related activities.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

13) I can plan the execution of the manufacturing processes following the change agenda requirements.

___*Strongly Agree* ___ *Agree* ___*Undecided* ___*Disagree* ___ *Strongly Disagree*

Thank you for completing this survey!

Appendix I: E-mail Message Soliciting Participation in Follow-up Survey

SUBJECT: MTS Strategy Implementation Workshop: Follow-Up Survey

Dear Colleagues,

Thank you for attending the MTS global conference "Driving World-Class Commercialization". We hope the conference meetings, presentations, learning activities, and informal discussions were useful and assisted you in planning business projects for 2004-2005.

We are requesting your feedback on the Strategy Implementation Workshop conducted on the first day of the conference. Your comments and suggestions will help us to plan and implement future MTS training events and better address your learning needs. Your responses will be kept strictly confidential and will not be disclosed to your colleagues or supervisors.

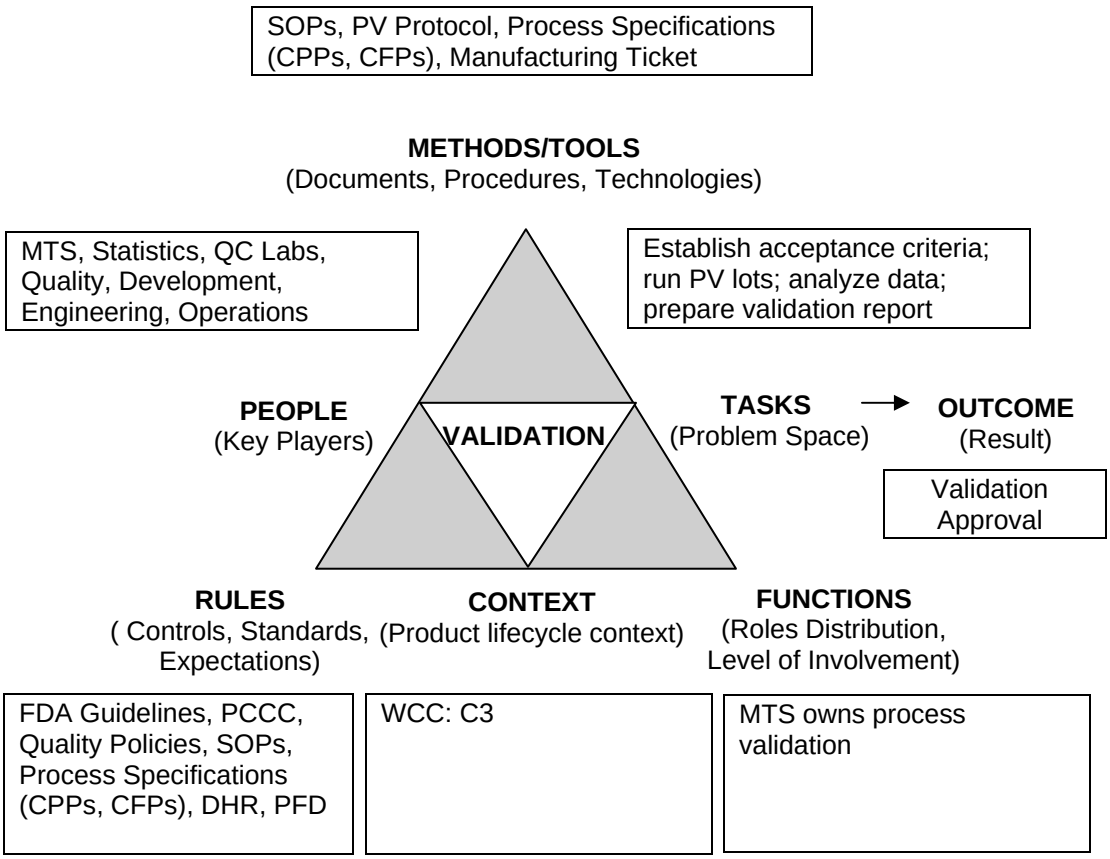
Please respond to the attached follow-up questionnaire as completely as you can, and return your responses via email or interoffice mail to Jamie Smith (jsmith@medex.com, DC: 54672) by March 15, 2004.

Thank you.
MTS Communications Group

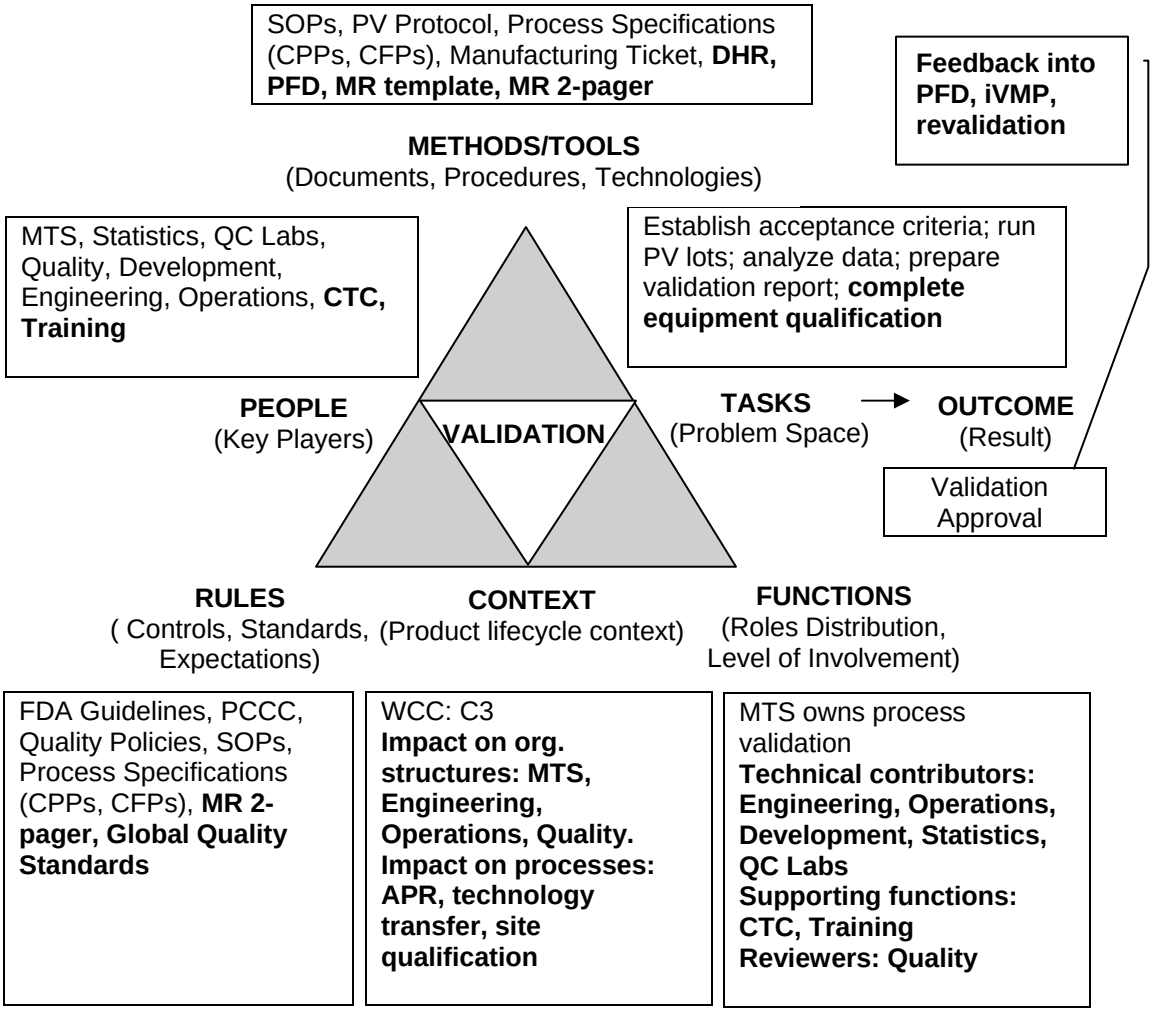
Appendix J: Comparison of Current and Redesigned Business Systems

NOTE: *Bold font in redesigned system graphics indicates the changes made by managers during the analysis and redesign activities which comprised a strategic episode*

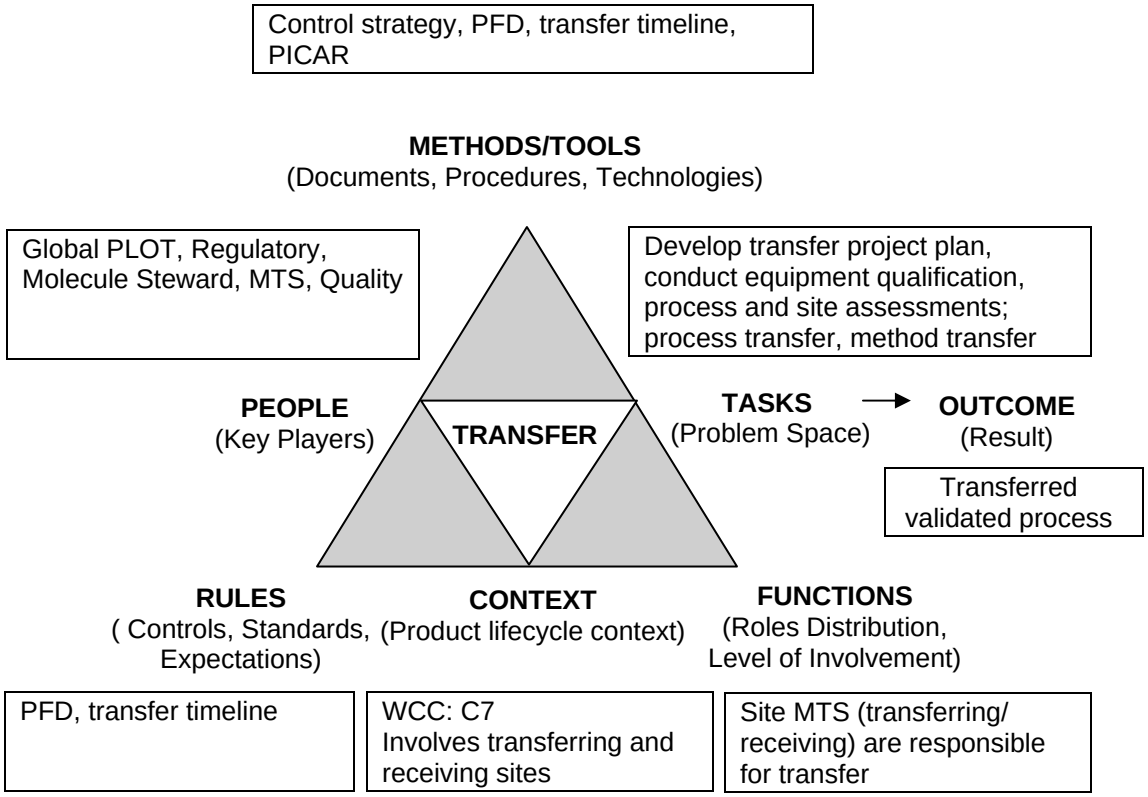
Group Blue: Current Process Validation System



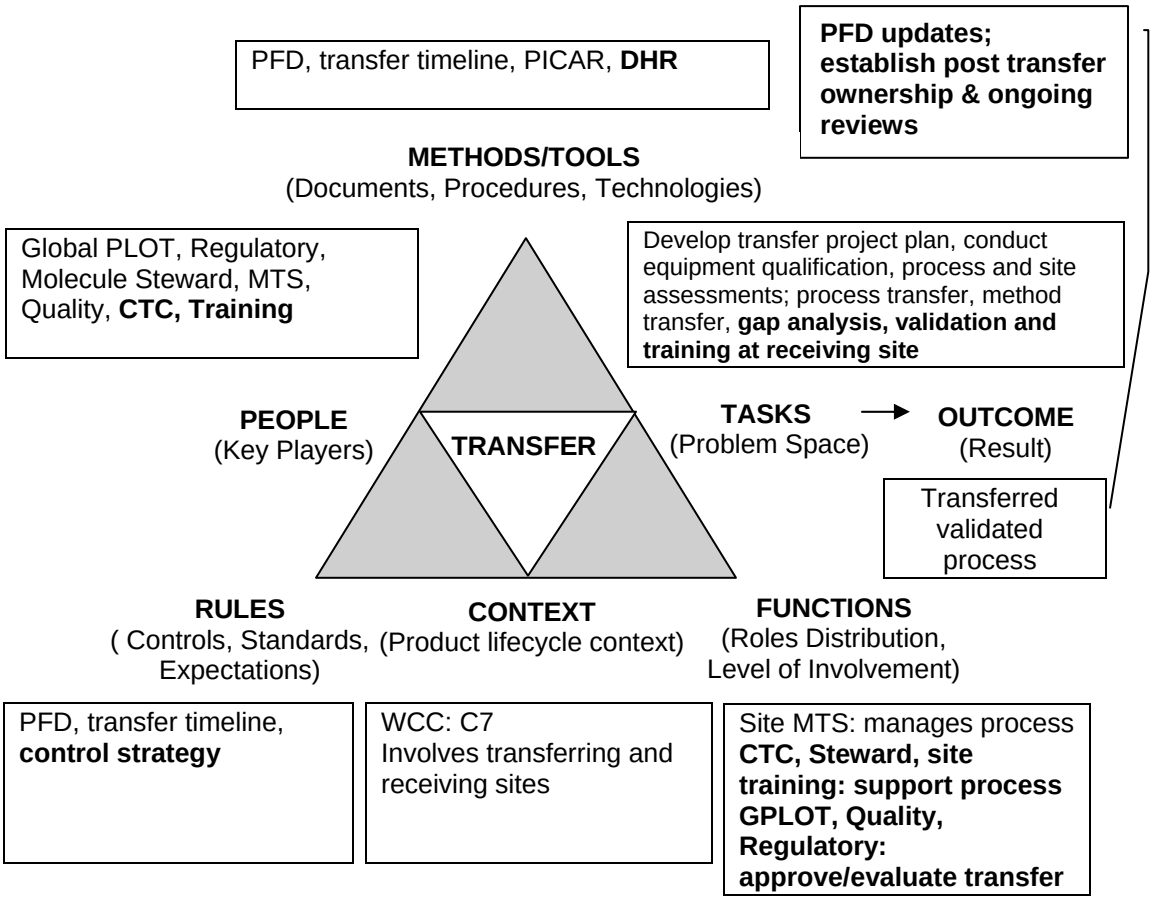
Group Blue: Redesigned Process Validation System



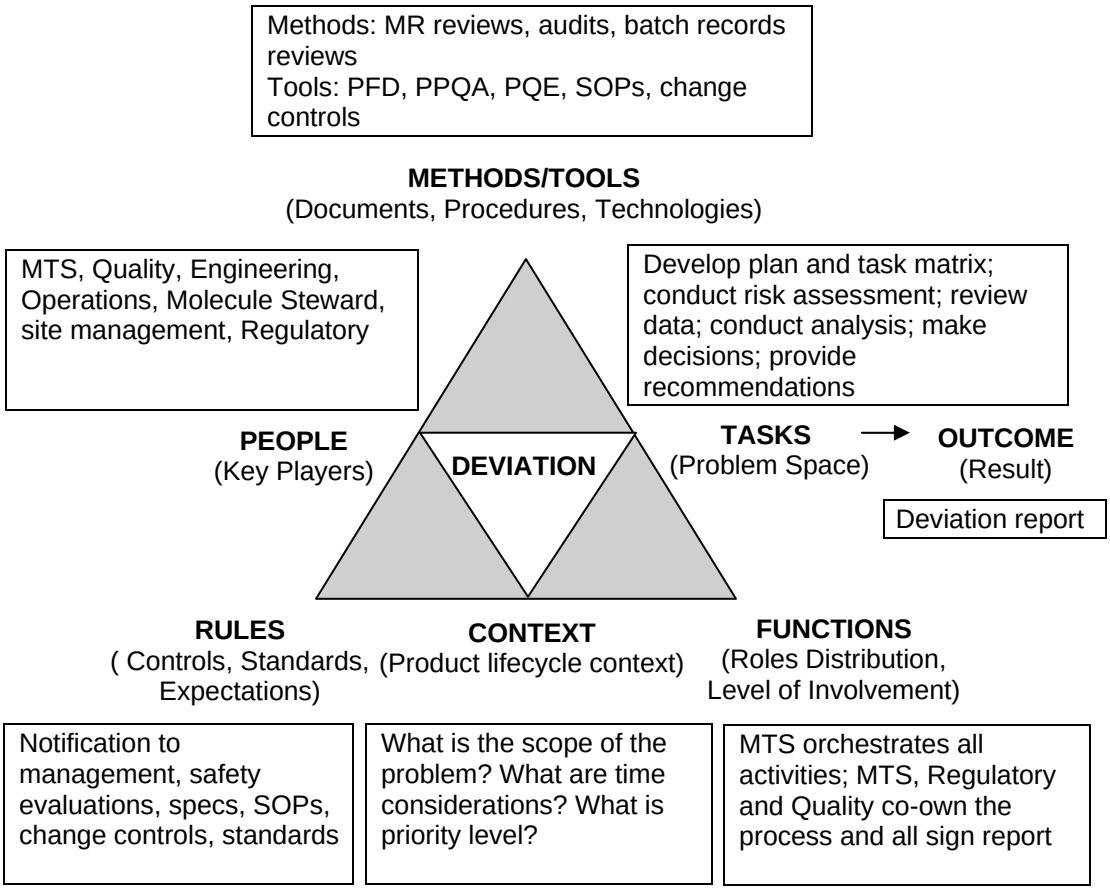
Group Green: Current Technology Transfer System



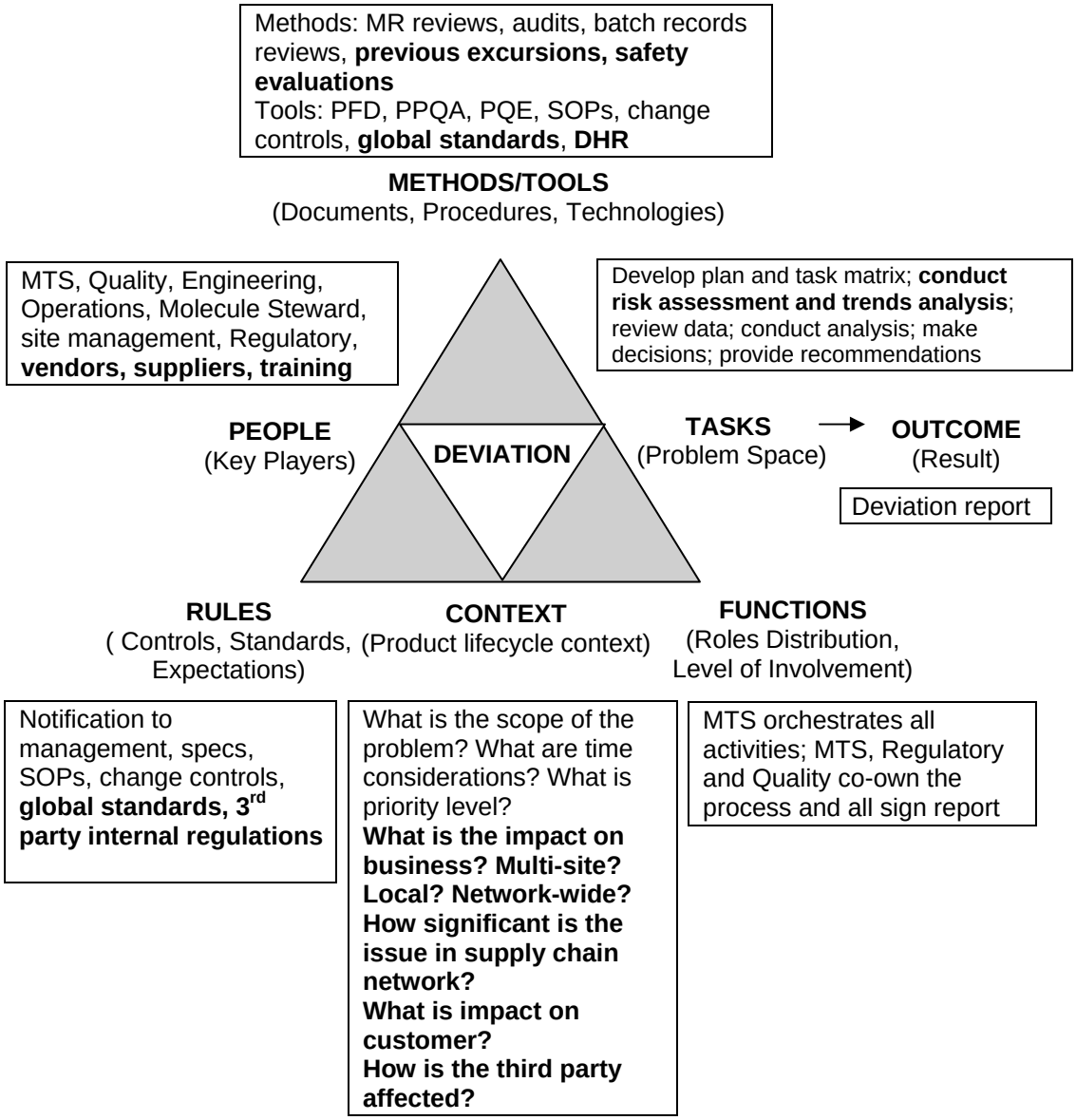
Group Green: Redesigned Technology Transfer System



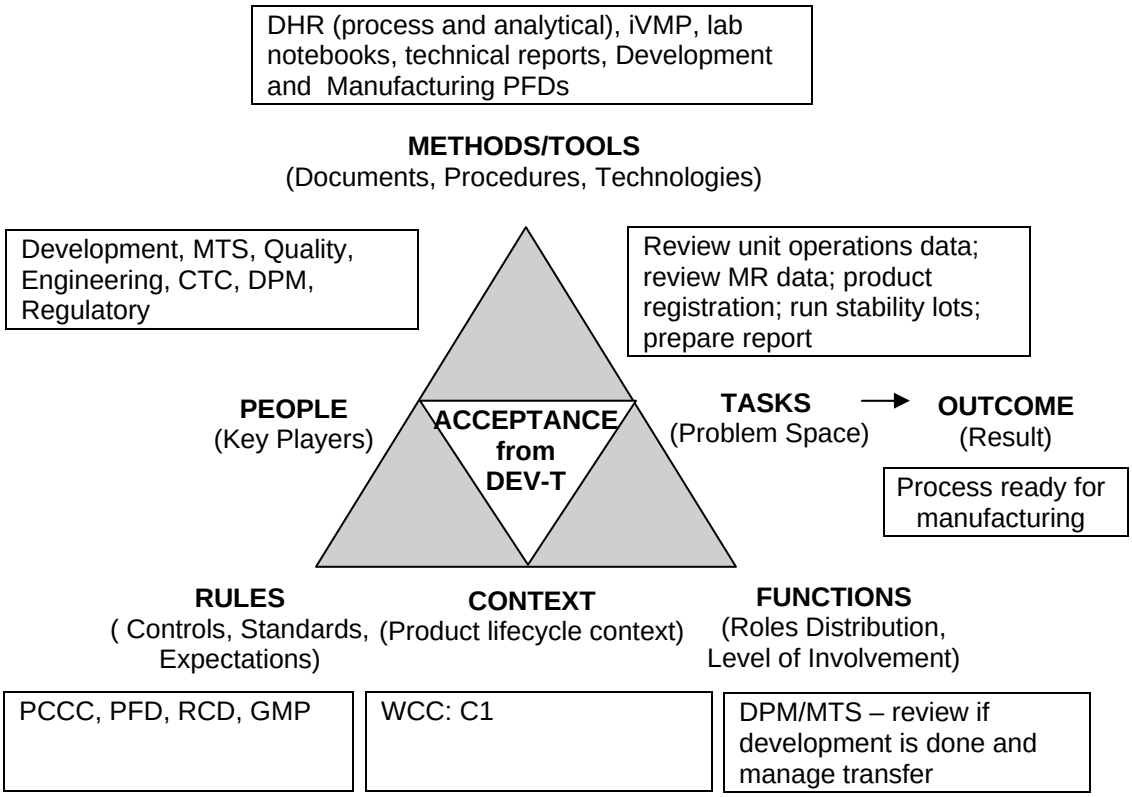
Group Red: Current Deviation Management System



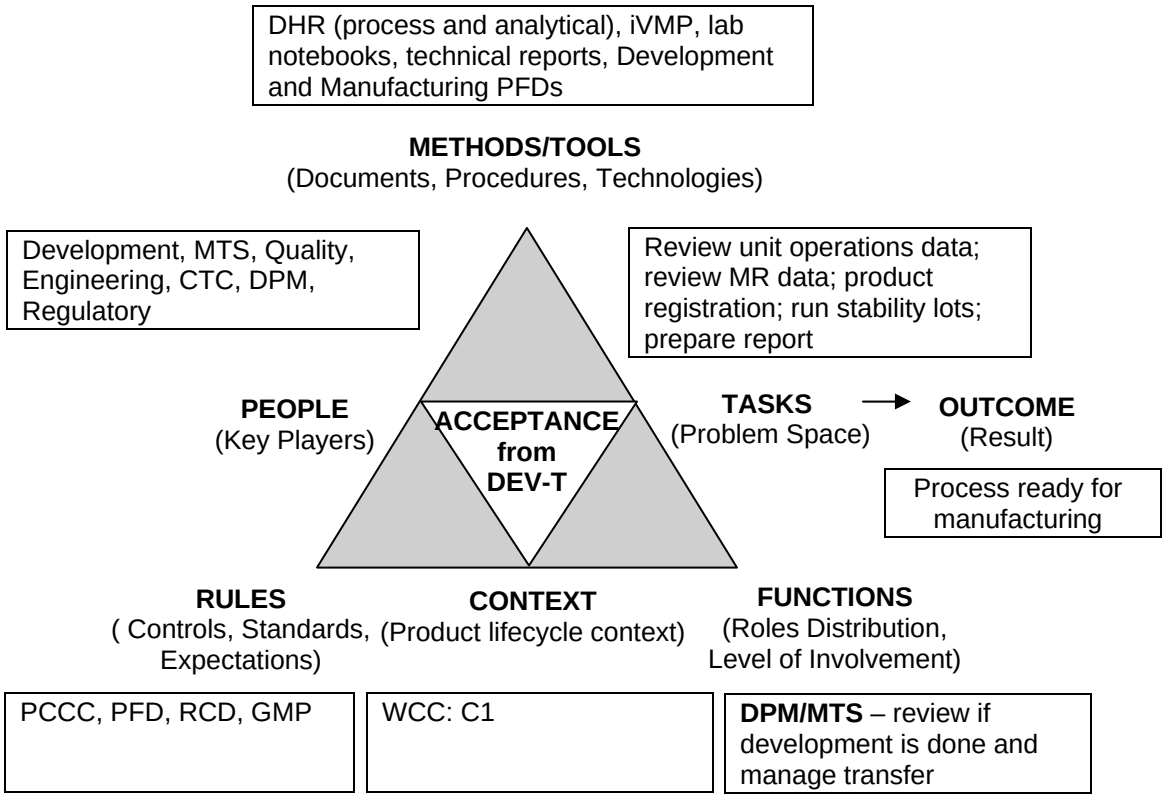
Group Red: Redesigned Deviation Management System



Group Yellow: Current Acceptance from Development System



Group Yellow: Redesigned Acceptance from Development System



Appendix K: Reflection Interview & Focus Groups Questionnaire

Date: _____

Start/End Time: _____

Participant(s): _____

Explain the purpose of the interview: Thank you very much for making time for this interview. I would like to invite you to reflect on your participation in the strategy implementation workshop and share your thoughts on the teamwork and the designs you created in collaboration with your colleagues. This discussion will help me to evaluate the quality of the workshop and develop recommendations for designing the future MTS training events.

Explain confidentiality aspect and provide the Study Information Sheet: This discussion is part of the dissertation research study, therefore, before we start, I will be asking you to review the Study Information Sheet. Everything we discuss today will be kept strictly confidential. Your names will not be disclosed to anyone and will not be identified in the publications resulting from this study. Please feel free to ask for clarification at any time, or not to answer if the question makes you uncomfortable.

Request permission to record: I'd like to use an audio recorder to record our discussion today. No one will have access to these recordings except myself. If you feel uncomfortable with audio recording, please let me know, so I can make notes instead.

1. What business process did you design and analyze together with your colleagues using an activity tool ("triangle")?
2. How was this experience different from other training exercises you ever participated in? Were there any challenging aspects in this exercise?
3. Did the "triangle"-based design activity help you to work on the second and third activities (developing action plan and analyzing MTS-specific business issues)? Why or why not?
4. What kind of process or pattern did your group establish for getting the design completed?
5. How did your team members communicate with each other during the exercise? Was there any leader? Did you see any roles emerge during the design?
6. Did you experience any disagreements with your colleagues during the collaborative design? If so, what was causing them? How were they resolved?
7. How would you describe the contribution of each member of your group, including yourself, to the design you were working on?

8. What did you learn from your colleagues about the business process you designed? What do you think they learned from you?
9. Was there any difference between your initial understanding of the business event (before the workshop) and the design that you constructed in collaboration with your colleagues? If so, how were they different?
10. Did you have any "aha" moments during the design and analysis of the linkages and tensions between the business process components? If so, what were they about?
11. Did this "triangle"-based design activity help you to learn about MTS strategy? If so, in what way? If not, why?
12. If asked to estimate your progress in developing strategic planning knowledge and skills before and after your participation in the workshop, what percent of this improvement could be attributed to your participation in the "triangle"-based design activity? What is the basis for this estimation? What other factors contributed to this progress?
13. Would you apply what you learned during this activity in your work? If so, in what way?
14. What aspects of the "triangle"-based design activity did you find most useful? Why?
15. What aspects of the "triangle"-based design activity did you find least useful? Why?

Appendix L: List of Abbreviations

API	Active Pharmaceutical Ingredient
APR	Annual Product Review
CSF	Critical Success Factors
CM&C PM	Chemistry Manufacturing & Control Project Management
CFP	Criterion for Forward Processing
CPP	Critical Process Parameter
CSOP	Corporate Standard Operating Procedure
CTC	Commercialization Technology Center
CQP	Corporate Quality Policy
C4I	Compliant, Capable, in-Control, Continuously Improving
DHR	Development History Report
DMS	Development-Manufacturing Strategy
DPFD	Development Process Flow Document
DPM	Development Project Management
EFC	Equipment Flow Chart
FP	Final Product
GMP	Good Manufacturing Practice
GPLOT	Global Post-Launch Optimization Team
GQS	Global Quality Standard
iVMP	Integrated Validation Master Plan
JLT	Joint Leadership Team
MMFA	Manufactured Marketed Forms Agreement
MR	Manufacturability Review
NPA	New Product Application
PAT	Process Analytical Technology
PCCC	Process Control & Capability Cycle
PFD	Process Flow Document
PM	Project Management
PPQE	Periodic Product Quality Evaluation
PTS	Product Technical Steward
PQE	Periodic Quality Evaluation
QC	Quality Control
QCL	Quality Control Lab
QPPA	Quarterly Process & Product Assessment
RCD	Regulatory Commitment Document
SOP	Standard Operating Procedure
TS	Technical Services
VMP	Validation Master Plan
WCC	World-Class Commercialization

Appendix M: Descriptive Statistics of Pre-Workshop Survey

Strategic Concepts and Processes

Percentages of correct answers: Q1

	N of answers per event	Event 1	Event 2	Event 3	Event 4	Event 5	Event 6	Event 7	% of total correct answers
Blue	168	49%	43%	45%	39%	35%	52%	56%	46%
Green	184	52%	45%	48%	40%	38%	43%	55%	46%
Yellow	176	51%	43%	46%	40%	33%	51%	47%	45%
Red	160	49%	50%	52%	48%	45%	52%	54%	49%

Percentages of correct answers: Q2

	N of answers per event	Event 1	Event 2	Event 3	Event 4	Event 5	Event 6	Event 7	% of total correct answers
Blue	315	68%	57%	65%	50%	61%	73%	67%	63%
Green	345	71%	61%	69%	61%	77%	54%	66%	65%
Yellow	330	68%	54%	47%	65%	71%	55%	61%	60%
Red	300	55%	48%	53%	59%	60%	44%	56%	54%

Percentages of correct answers: Q3

	N of answers per event	Event 1	Event 2	Event 3	Event 4	Event 5	Event 6	Event 7	% of total correct answers
Blue	420	54%	64%	72%	69%	68%	63%	72%	66%
Green	460	74%	61%	65%	71%	68%	75%	67%	69%
Yellow	440	60%	74%	68%	72%	73%	68%	72%	70%
Red	400	60%	67%	57%	70%	74%	78%	68%	68%

Strategic Problem Solving

Percentages of correct answers in Scenario 1

	N of answers per event	Event 1	Event 2	Event 3	Event 4	% of total correct answers
Blue	105	45%	59%	57%	51%	53%
Green	115	44%	55%	49%	53%	50%
Yellow	110	52%	56%	58%	54%	55%
Red	100	56%	58%	66%	60%	60%

Percentages of correct answers in Scenario 2

	N of answers per event	Event 1	Event 2	Event 3	Event 4	% of total correct answers
Blue	105	62%	60%	71%	69%	65%
Green	115	51%	64%	57%	61%	58%
Yellow	110	56%	64%	61%	66%	62%
Red	100	54%	57%	60%	69%	60%

Self-assessment of Strategic Competencies

	N	Minimum	Maximum	Mean	Standard Deviation
Blue	21	1.87	3.87	2.46	.47
Green	23	1.80	3.60	2.43	.52
Yellow	22	1.60	3.53	2.27	.61
Red	20	1.67	3.53	2.51	.52

5= Strongly Agree; 1= Strongly Disagree
Scale reliability: Cronbach's alpha = .893

ANOVA test results for pre-survey self-assessment of strategic competencies

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.68	3	.23	.81	.493
Within Groups	23.14	82	.28		
Total	23.82	85			

Appendix N: Descriptive Statistics of Post-Workshop Survey

Strategic Concepts and Processes

Percentages of correct answers: Q1

	N of answers per event	Event 1	Event 2	Event 4	Event 5	% of total correct answers
Blue	152	94%	91%	98%	97%	95%
Green	160	90%	94%	84%	94%	91%
Yellow	168	60%	56%	55%	54%	54%
Red	152	81%	85%	92%	89%	87%

Percentages of correct answers: Q2

	N of answers per event	Event 1	Event 2	Event 4	Event 5	% of total correct answers
Blue	315	91%	77%	96%	95%	90%
Green	345	97%	93%	92%	97%	95%
Yellow	330	72%	68%	79%	76%	74%
Red	300	82%	90%	93%	85%	88%

Percentages of correct answers: Q3

	N of answers per event	Event 1	Event 2	Event 4	Event 5	% total of correct answers
Blue	420	95%	96%	91%	98%	95%
Green	460	92%	91%	95%	98%	94%
Yellow	440	69%	84%	78%	80%	77%
Red	400	94%	97%	91%	85%	92%

Strategic Problem Solving

Percentages of correct answers in Scenario 1

	N of answers per event	Event 1	Event 2	Event 3	Event 4	% of total correct answers
Blue	95	88%	84%	97%	95%	91%
Green	100	89%	96%	84%	91%	90%
Yellow	105	84%	70%	66%	79%	68%
Red	95	82%	85%	91%	78%	84%

Percentages of correct answers in Scenario 2

	N of answers per event	Event 1	Event 2	Event 3	Event 4	% of total correct answers
Blue	95	98%	88%	94%	93%	93%
Green	100	83%	91%	85%	90%	87%
Yellow	105	70%	67%	73%	77%	72%
Red	95	85%	86%	83%	91%	86%

Self-assessment of Strategic Competencies

	N	Minimum	Maximum	Mean	Standard Deviation
Blue	20	3.67	4.80	4.27	.26
Green	22	3.53	4.80	4.24	.32
Yellow	18	2.27	3.20	2.80	.25
Red	19	3.40	4.73	4.12	.35

5= Strongly Agree; 1= Strongly Disagree
Scale reliability: Cronbach's alpha = .94

ANOVA test results for post-survey self-assessment of strategic competencies

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	27.67	3	9.22	104.49	.000
Within Groups	6.62	75	.09		
Total	34.29	78			

Appendix O: Comparison of Descriptive Statistics of Pre-Workshop and Post-Workshop Surveys

Strategic Concepts and Processes

Percentages of correct answers: Q1

	Event 1		Event 2		Event 3		Event 4		% of total correct answers	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Blue	49%	94%	43%	91%	39%	98%	35%	97%	42%	95%
Green	52%	90%	45%	94%	40%	84%	38%	94%	34%	91%
Yellow	51%	60%	43%	56%	40%	55%	33%	54%	42%	54%
Red	49%	81%	50%	85%	48%	92%	45%	89%	48%	87%

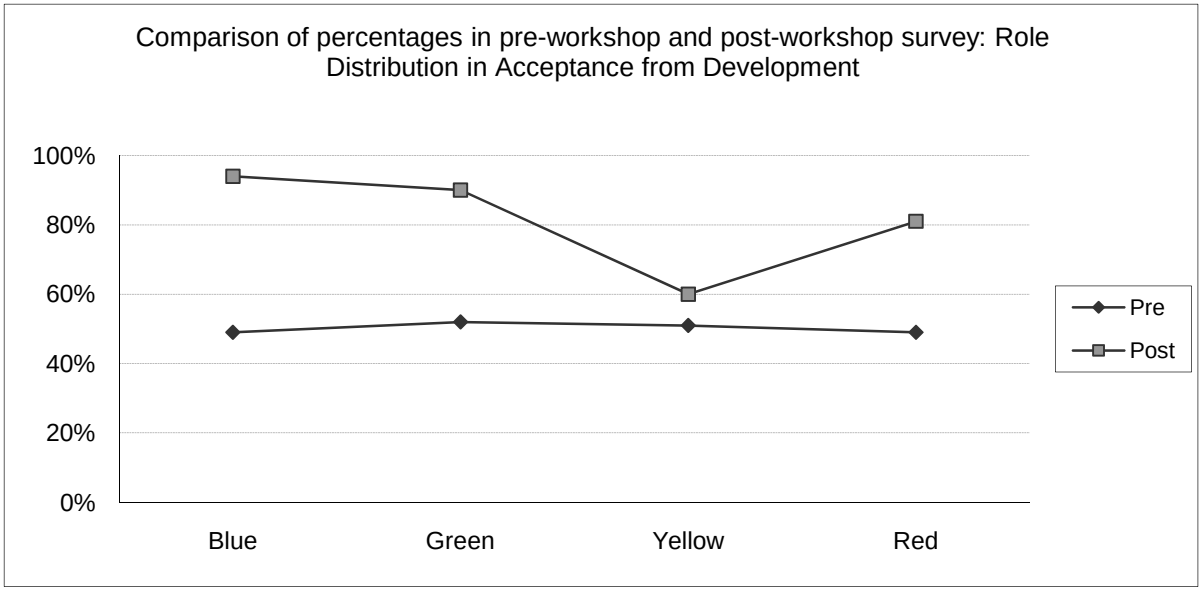
Percentages of correct answers: Q2

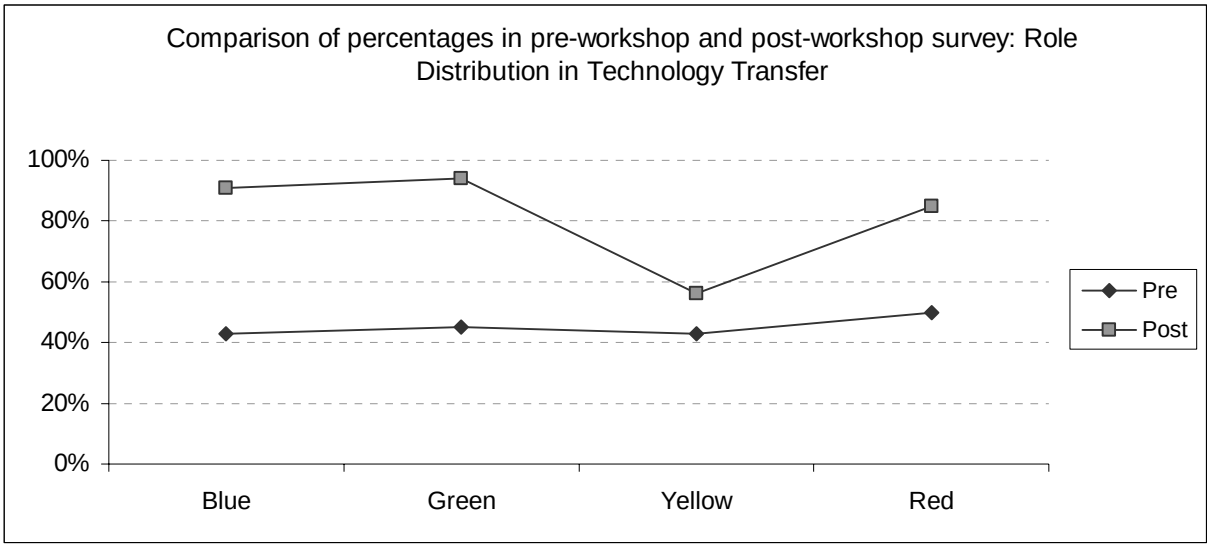
	Event 1		Event 2		Event 3		Event 4		% of total correct answers	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Blue	68%	91%	57%	77%	50%	96%	61%	95%	59%	90%
Green	71%	97%	61%	93%	61%	92%	77%	97%	67%	95%
Yellow	68%	72%	54%	68%	65%	79%	71%	76%	65%	74%
Red	55%	82%	48%	90%	59%	93%	60%	85%	57%	88%

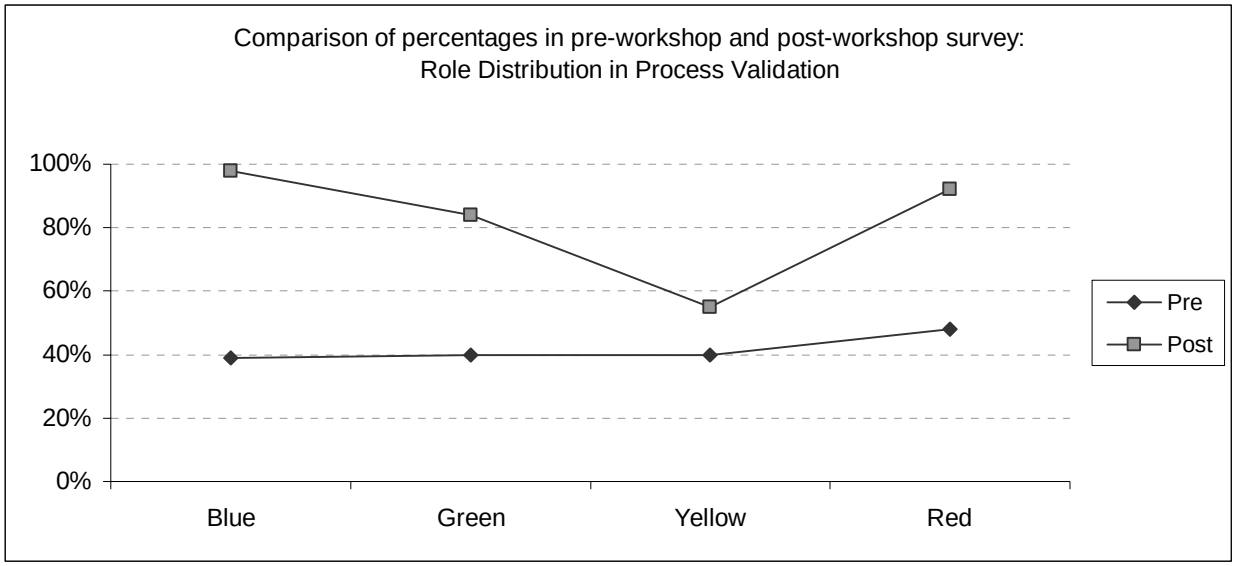
Percentages of correct answers: Q3

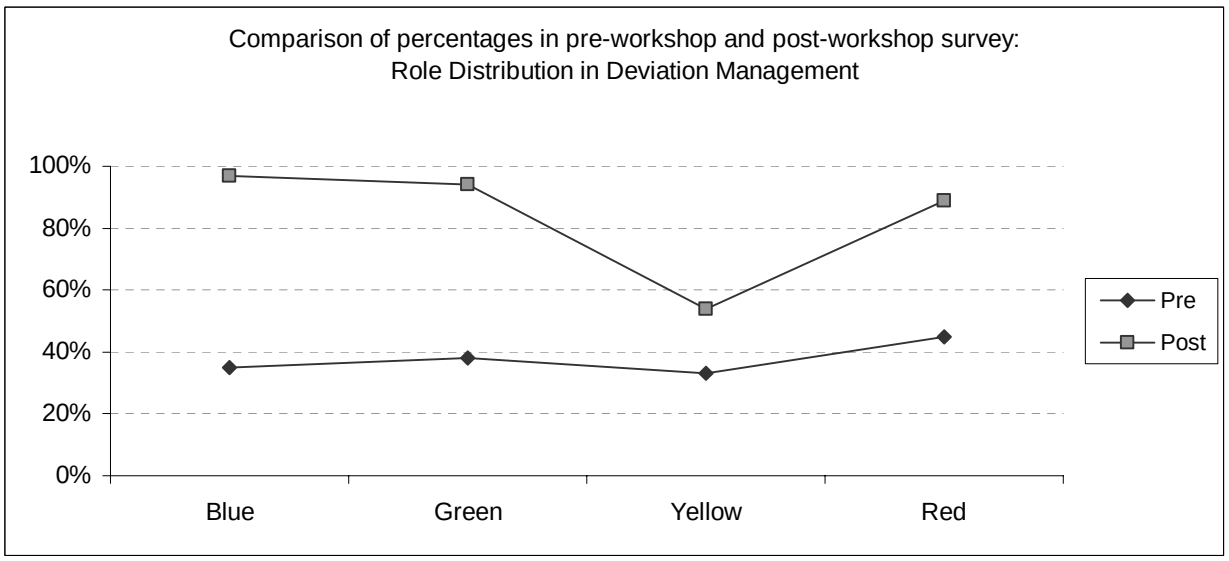
	Event 1		Event 2		Event 3		Event 4		% of total correct answers	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post

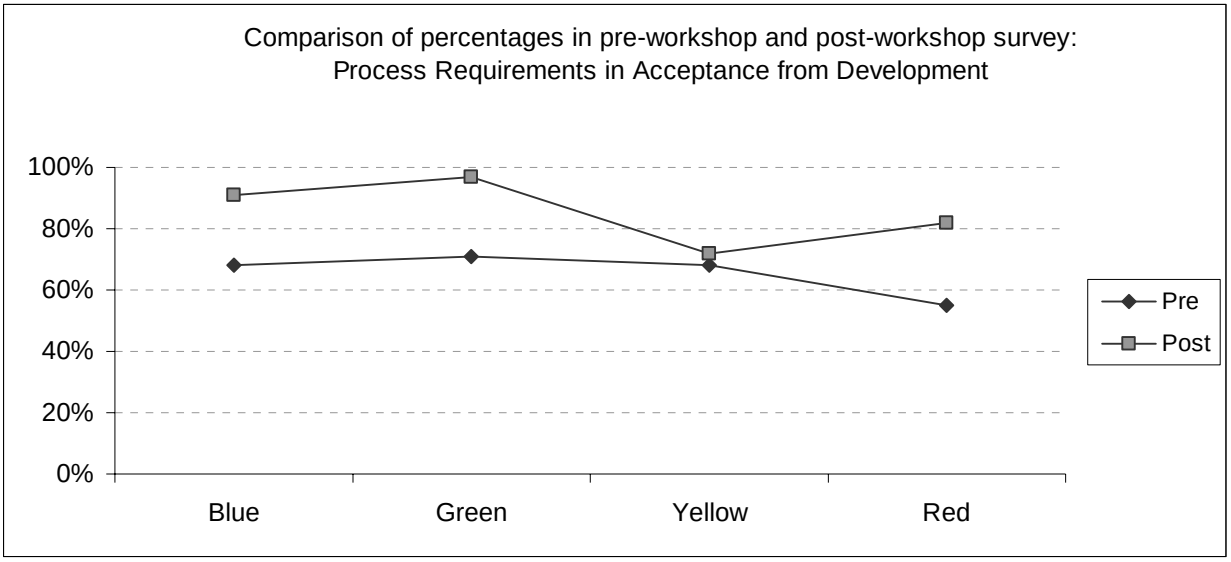
Blue	54%	95%	64%	96%	69%	91%	68%	98%	64%	95%
Green	74%	92%	61%	91%	71%	95%	68%	98%	72%	94%
Yellow	60%	69%	74%	84%	72%	78%	73%	80%	70%	77%
Red	60%	94%	67%	97%	70%	91%	74%	85%	68%	92%

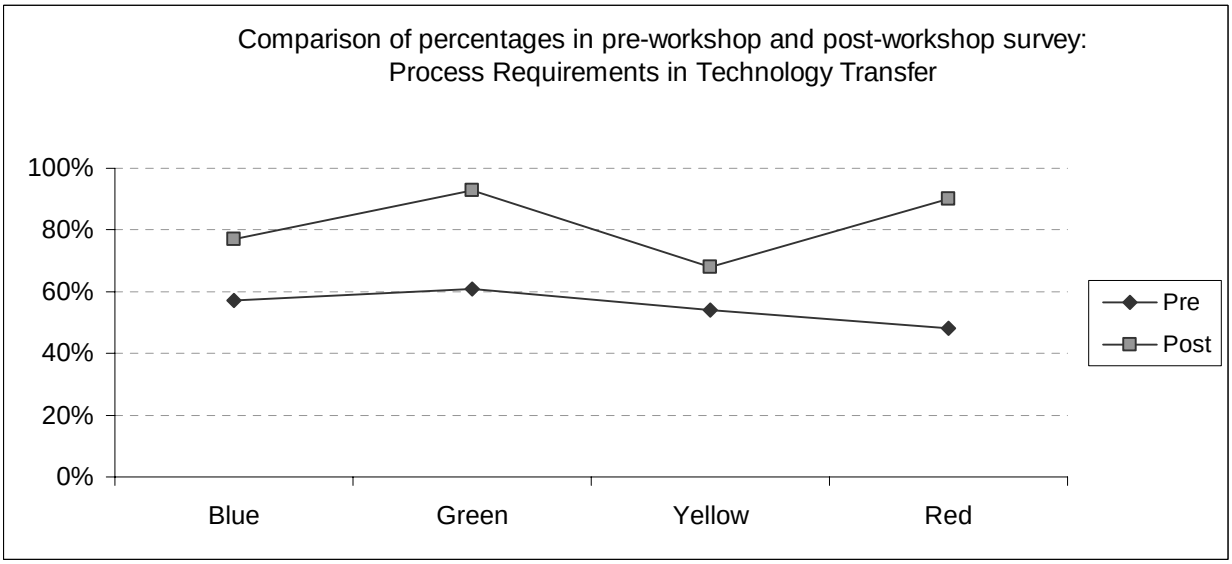


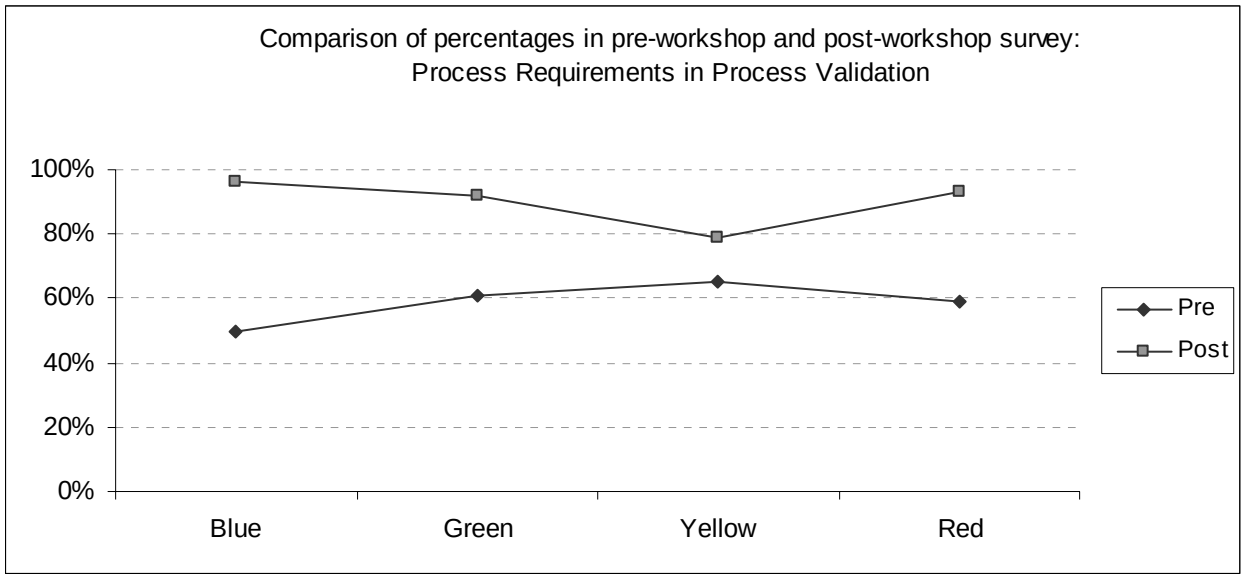


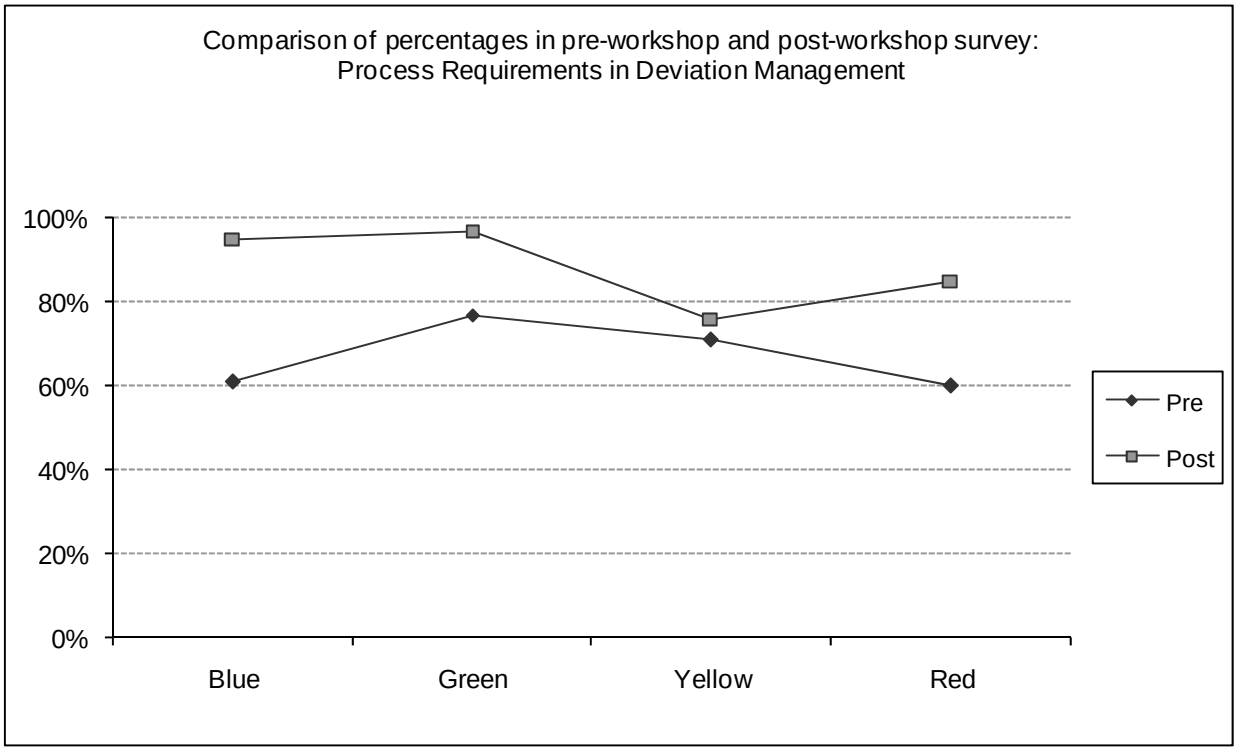


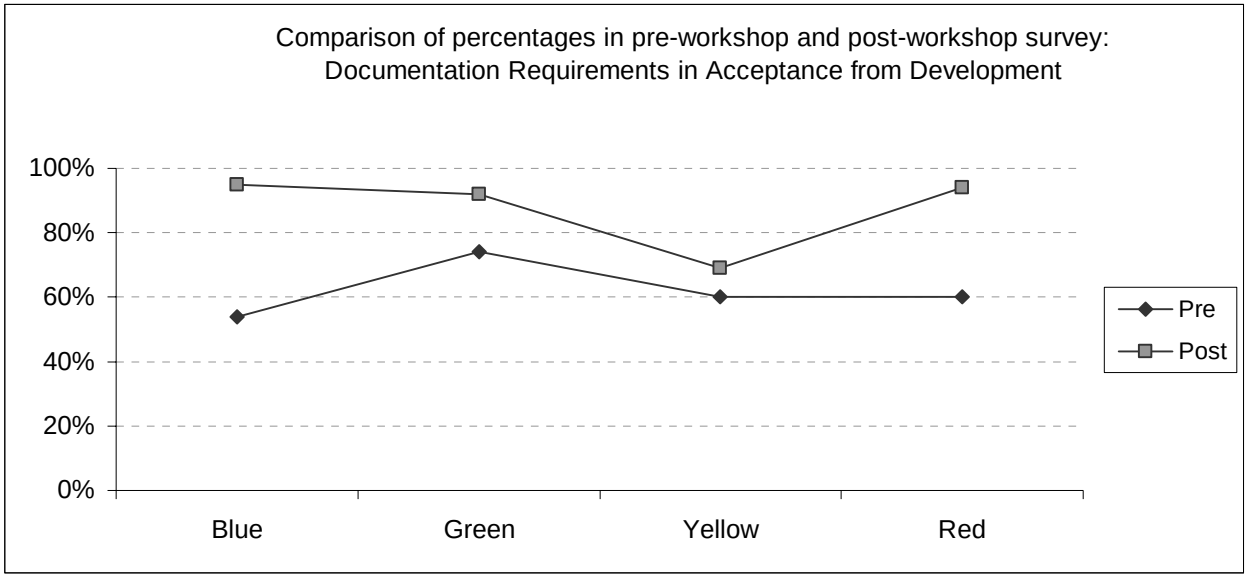


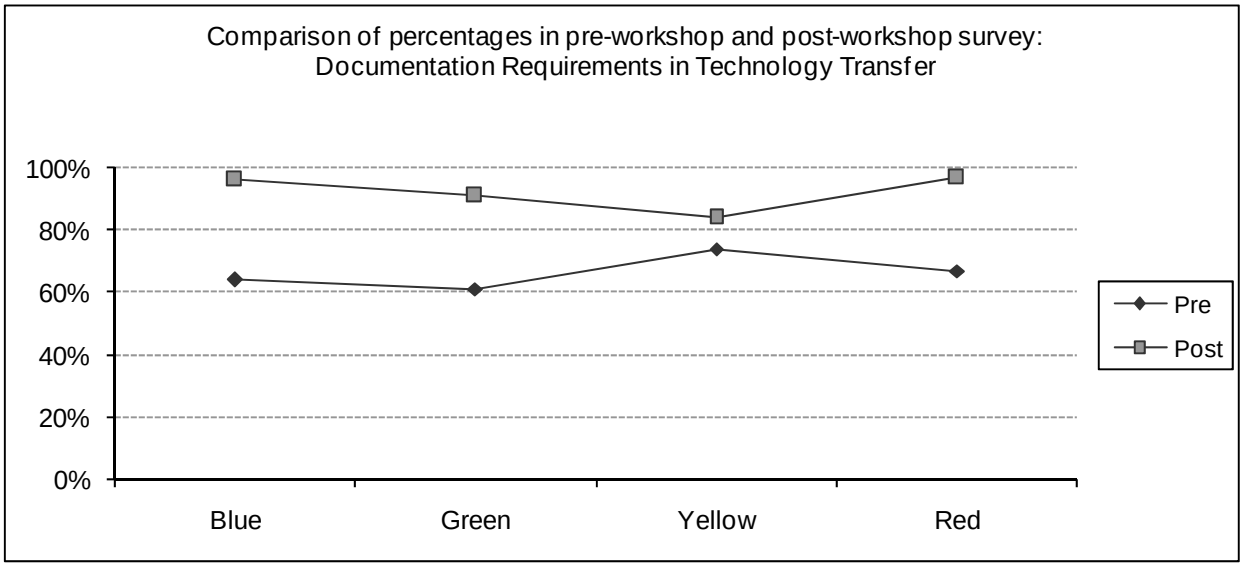


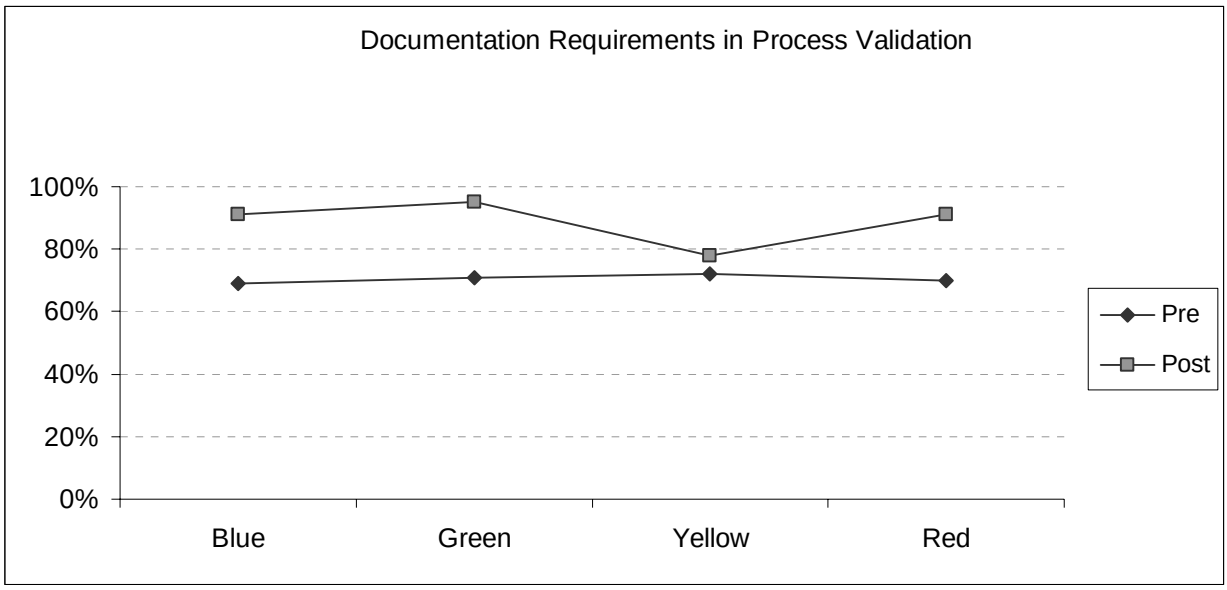


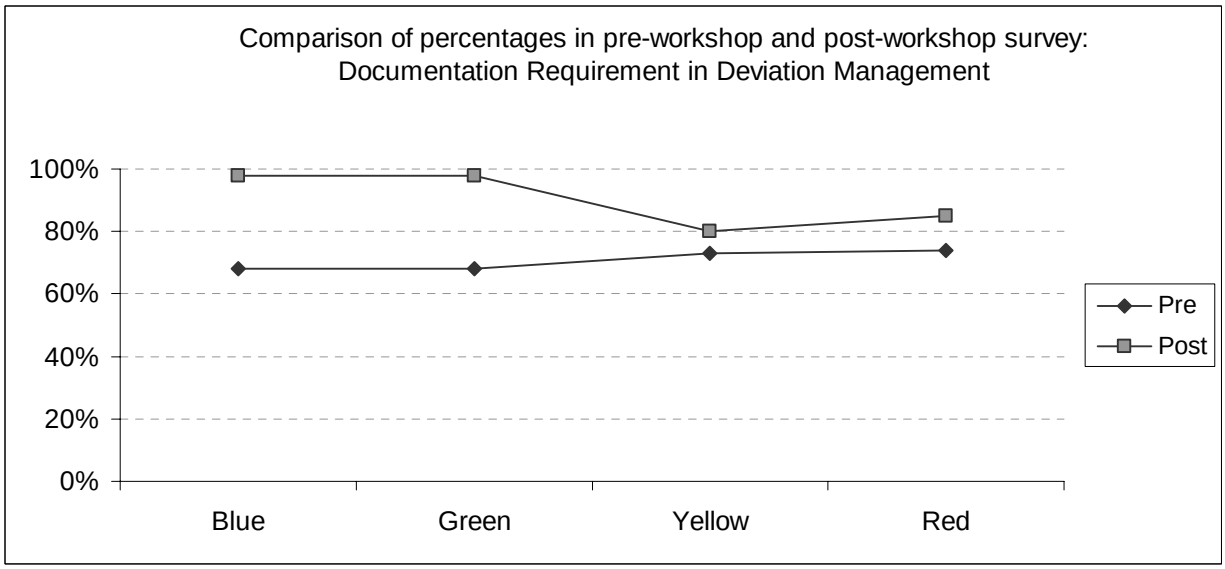








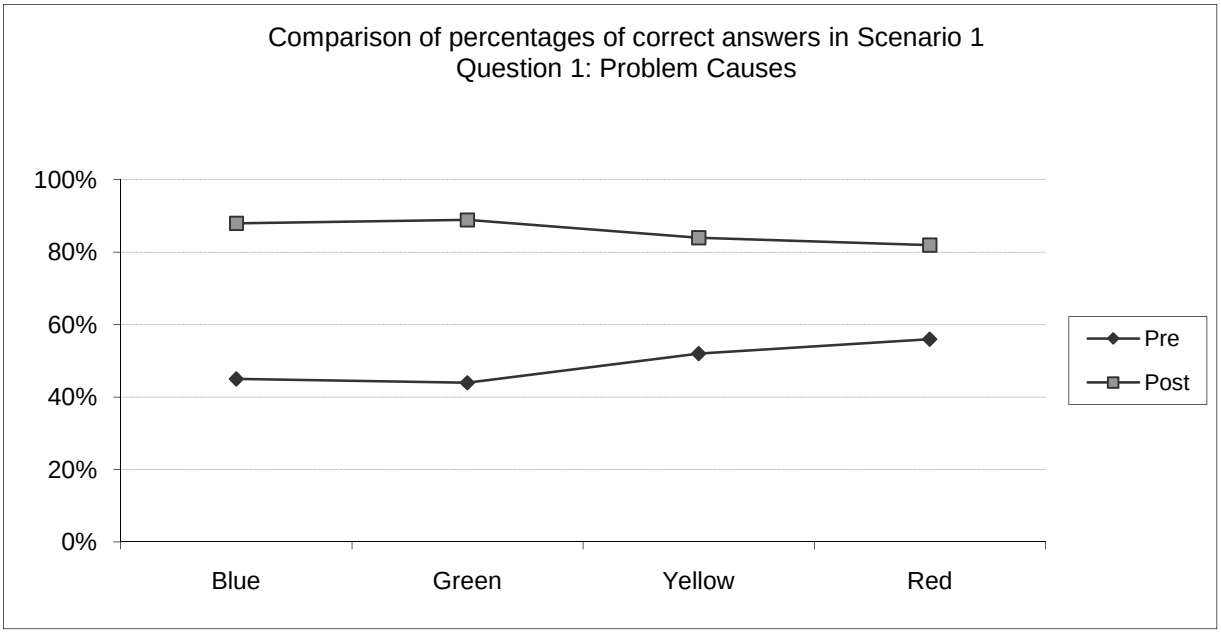


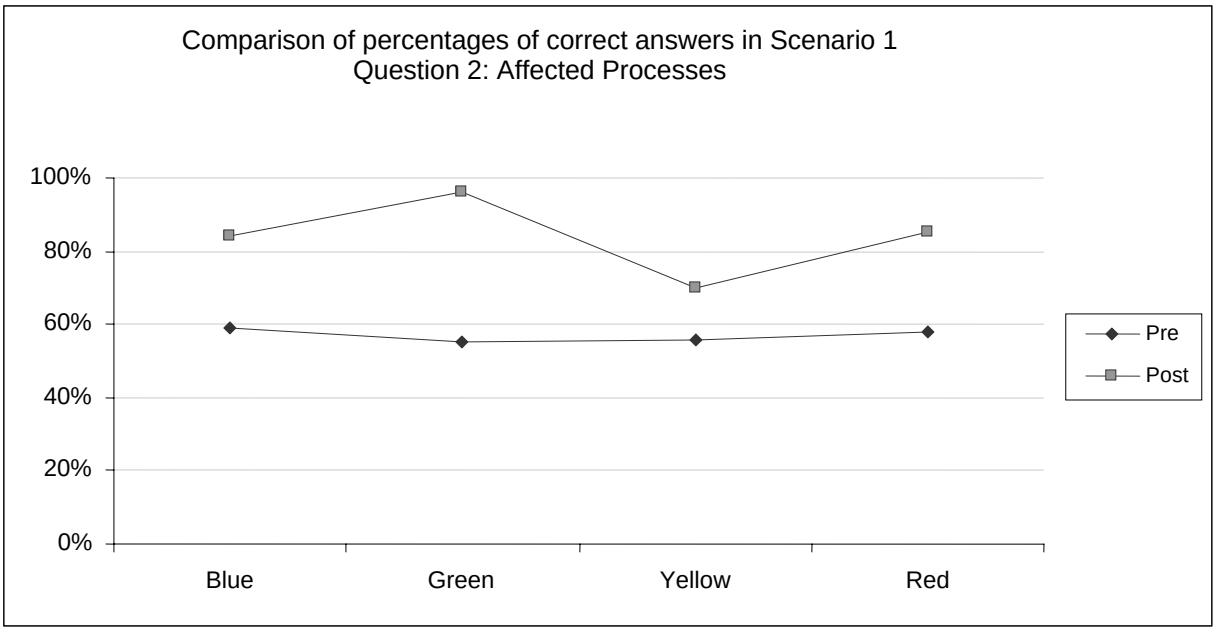


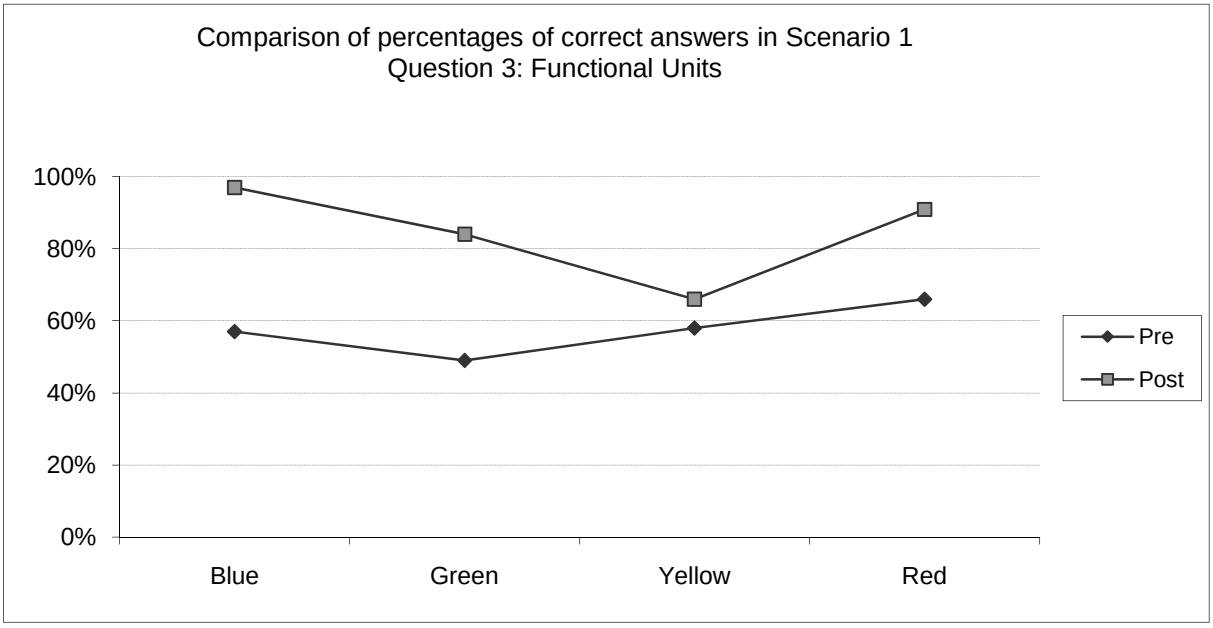
Strategic Problem Solving

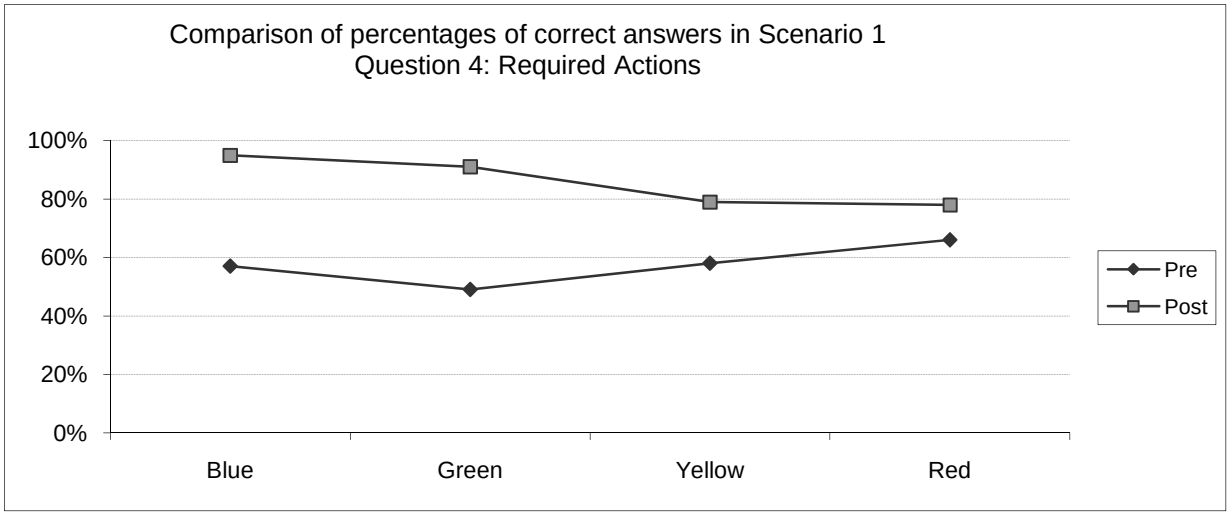
Percentages of correct answers in Scenario 1

	Question 1		Question 2		Question 3		Question 4		% of total correct answers	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Blue	45%	88%	59%	84%	57%	97%	57%	95%	53%	91%
Green	44%	89%	55%	96%	49%	84%	49%	91%	50%	90%
Yellow	52%	84%	56%	70%	58%	66%	58%	79%	55%	68%
Red	56%	82%	58%	85%	66%	91%	66%	78%	60%	84%



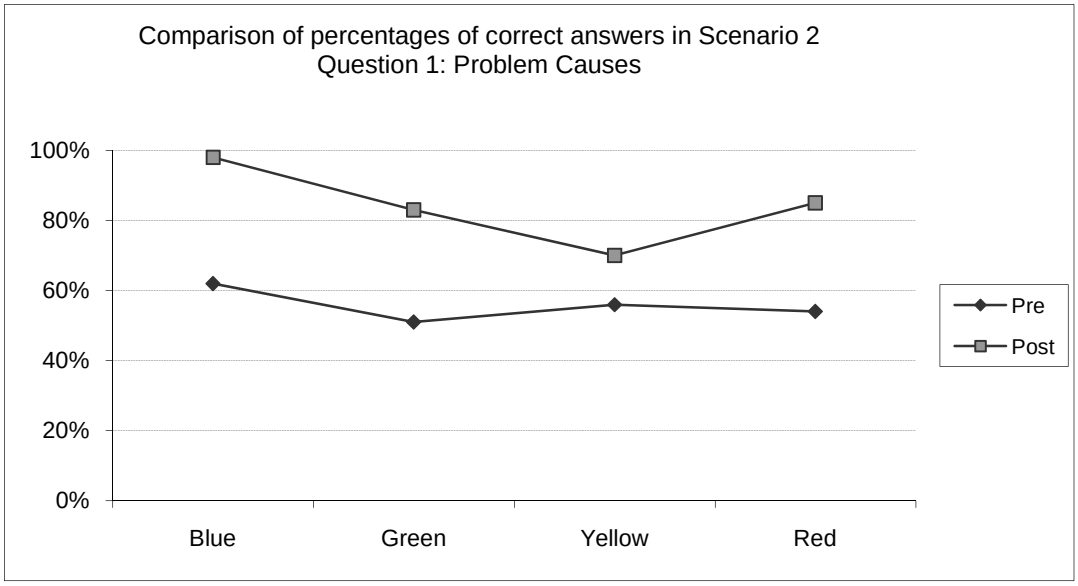


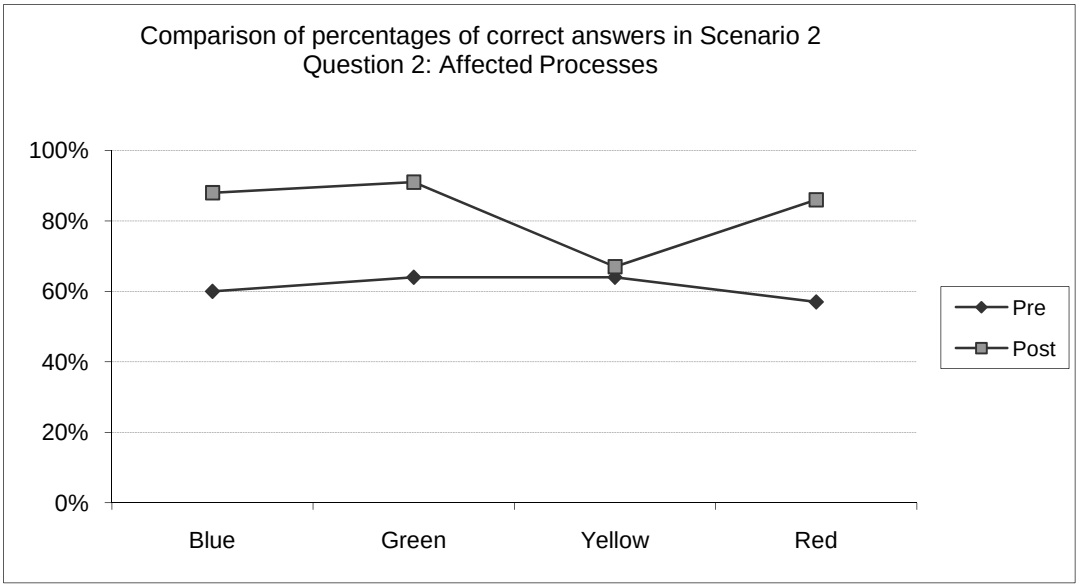


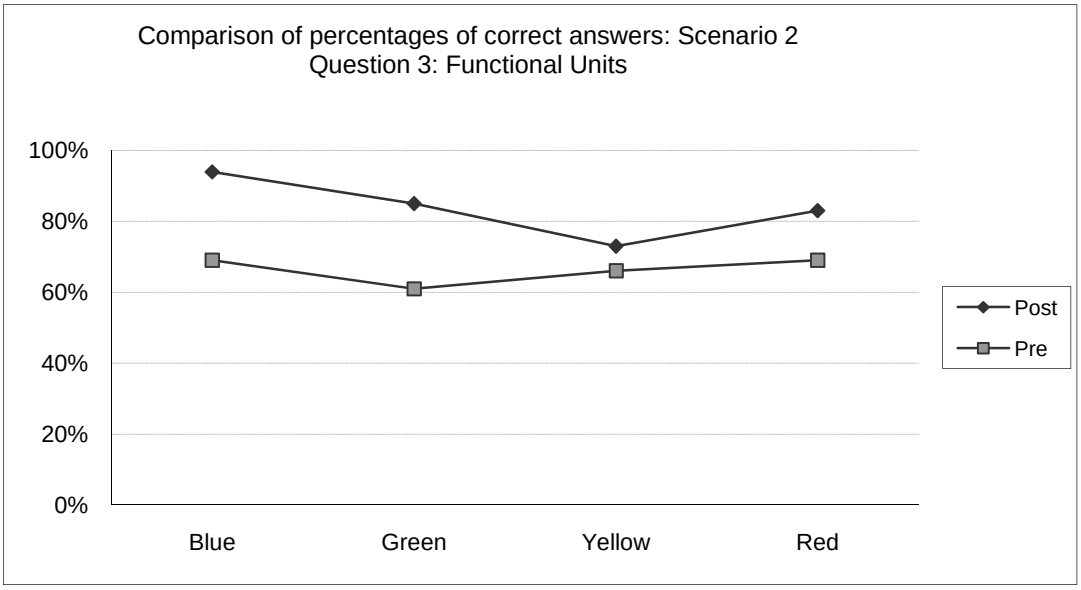


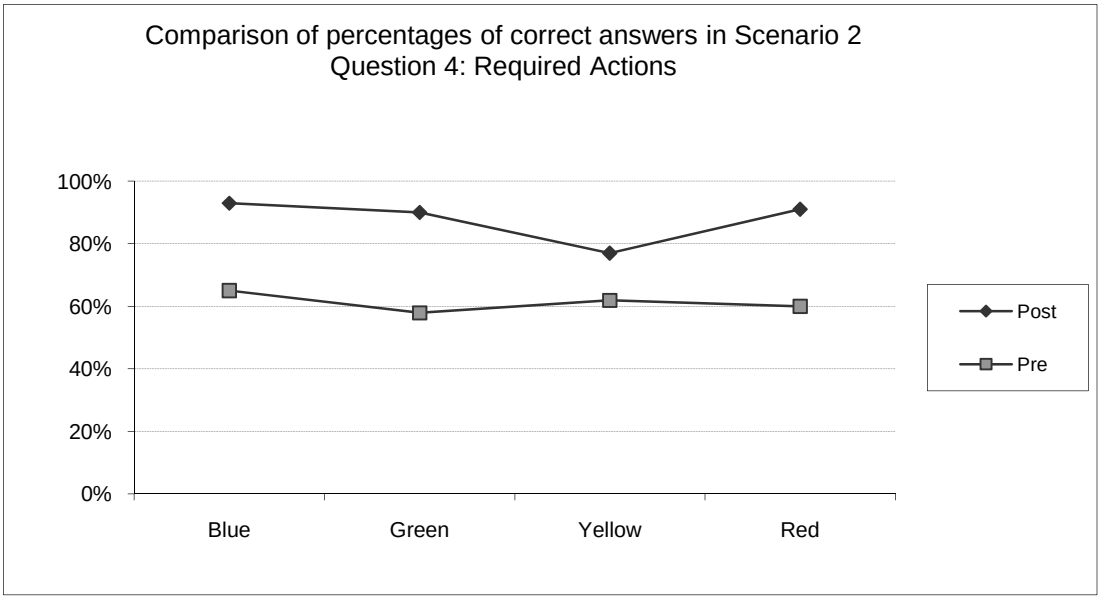
Percentages of correct answers in Scenario 2

	Question 1		Question 2		Question 3		Question 4		% of total correct answers	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Blue	62%	98%	60%	88%	71%	94%	69%	93%	65%	93%
Green	51%	83%	64%	91%	57%	85%	61%	90%	58%	87%
Yellow	56%	70%	64%	67%	61%	73%	66%	77%	62%	72%
Red	54%	85%	57%	86%	60%	83%	69%	91%	60%	86%









Self-assessment of Strategic Competencies

Category 1: Assigning roles and tasks in change-related activities

	Pre-Survey			Post-Survey			Comparison	
	N	Mean	S.Dev.	N	Mean	S.Dev.	t-test	Sig.	Effect Size
Blue	21	2.19	0.68	20	4.80	.38	15.35	.001	4.74
Green	23	2.04	0.90	22	4.41	.43	11.40	.001	3.36
Yellow	22	2.05	1.05	18	2.31	.52	1.04	NS	.31
Red	20	2.08	0.85	19	4.40	.61	9.92	.001	3.14

Category 2: Planning and managing change-related activities

	Pre-Survey			Post-Survey			Comparison	
	N	Mean	S.Dev.	N	Mean	S.Dev.	t-test	Sig.	Effect Size
Blue	21	2.21	.54	20	4.08	.33	13.54	.001	4.18
Green	23	2.27	.59	22	4.15	.38	12.85	.001	3.79
Yellow	22	2.17	.63	18	2.71	.29	3.65	.01	1.10
Red	20	2.43	.54	19	4.09	.49	10.18	.001	3.22

Category 3: Evaluating impact of change on external environment

	Pre-Survey			Post-Survey			Comparison	
	N	Mean	S.Dev.	N	Mean	S.Dev.	t-test	Sig.	Effect Size
Blue	21	1.95	.61	20	3.85	.49	11.13	.001	3.43
Green	23	2.11	.71	22	4.07	.36	11.81	.001	3.48
Yellow	22	1.75	.53	18	2.53	.40	5.51	.001	1.66
Red	20	2.18	.77	19	3.66	.41	7.59	.001	2.40

Category 4: Evaluating impact of change on internal environment

	Pre-Survey			Post-Survey			Comparison	
	N	Mean	S.Dev.	N	Mean	S.Dev.	t-test	Sig.	Effect Size
Blue	21	3.21	.62	20	4.25	.38	6.55	.001	2.02
Green	23	2.98	.59	22	4.23	.48	7.88	.001	2.32
Yellow	22	2.46	.62	18	2.59	.62	0.70	NS	.21
Red	20	3.00	.54	19	4.08	.51	6.50	.001	2.06

Category 5: Identifying and managing strong organizational aspects supporting change

	Pre-Survey			Post-Survey			Comparison	
	N	Mean	S.Dev.	N	Mean	S.Dev.	t-test	Sig.	Effect Size
Blue	21	2.31	.77	20	4.28	.50	9.83	.001	3.03
Green	23	2.28	.74	22	4.12	.65	8.96	.001	2.64
Yellow	22	2.09	.75	18	3.33	.54	6.29	.001	1.90
Red	20	2.50	.61	19	4.29	.59	9.43	.001	2.98

Category 6: Identifying and managing barriers to change agenda implementation

	Pre-Survey			Post-Survey			Comparison	
	N	Mean	S.Dev.	N	Mean	S.Dev.	t-test	Sig.	Effect. Size
Blue	21	2.79	.56	20	4.45	0.38	11.24	.001	3.47
Green	23	2.70	.69	22	4.42	0.46	9.95	.001	2.93
Yellow	22	2.70	.73	18	3.24	0.51	2.84	.01	.86
Red	20	2.72	.53	19	4.19	0.56	8.53	.001	2.70

Appendix P: Fragments of Change Agenda Implementation Plans

Network A

Process Flow Document (PFD)		
CURRENT STATE:		
Key Best Practices:	*Key Enablers & Opportunities:*	*Key Issues:*
1. Readiness assessments at the sites 2. Collaboration with Engineering	1. Availability of Development PFD 2. New global standards provide guidance and consistent approach to PFD development	1. Technical knowledge of PFDs at sites is marginal; gaps in understanding exist depending on if resources have been involved in PFD process or not 2. DHR for [product name] is inadequate to create a complete PFD
IMPLEMENTATION PLAN:		
Action Items:	*Owner/Contributor/Reviewer:*	*2004-2005 Deliverables & Delivery Dates:*
Conduct gap assessment	MTS/Engineering/Quality	09/01/2004
Develop site-based "minimal requirements' list	MTS/Engineering/TBD	09/01/2004
Define link between capability and criticality. Need further discussion on PFD boundaries: Should PFDs cover environmental controls, sterility assurance and associated critical points.	Network leaders	Next network meeting (Fall 2004)
Development History Document (DHR)		
CURRENT STATE:		
Key Best Practices:	*Key Enablers & Opportunities:*	*Key Issues:*
1. DHRs for [product names] can serve as examples 2. Consistent structure/template developed	3. Assignment of Molecule Stewards 4. Use gained information with the PFD effort to redefine our older regulatory submissions	5. No DHR for legacy products 6. Missing data for [product name]; data scattered among technical reports 7. No production history report after 10 years of manufacturing – no continuation of DHR for [product name]
IMPLEMENTATION PLAN:		
Action Items:	*Owner/Contributor/Reviewer:*	*2004-2005 Deliverables & Delivery Dates:*

Fill development history gaps for [product name]	Molecule Steward/Development, MTS/GPLOT	01/01/2005
Work with Development on preparation of DHR prior to technology transfers	MTS/Development/TBD	Plan outlined by 09/01/2004
Develop system to capture production history across sites (continuation of DHR)	GPLOT/MTS, Development, Engineering/Network directors	Plan outlined by 01/01/2005

Network B

1. Critical projects for 2004-2005
    - Project 1: development of iVMPs at all network sites
    - Project 2: development of PFDs across all network sites
2. Project owners and contributors
    - Project 1: MTS (o), Engineering, IT, Operations (c)
    - Project 2: MTS (o), Engineering, IT, Operations (c)
3. Project action items and deliverables
    - Project 1: master plan to use as a sample across sites
    - Project 2: use best practice PFD > learning PFD for other sites to model
4. Required documents and other prerequisites
    - Project 1: TBD (use sample from Bayford for docs)
    - Project 2: CPPs, CFPs, SOPs, standards
5. Issues to address
    - Project 1: lack of template, differences across sites
    - Project 2: disconnect between equipment capabilities and PFDs
6. Available resources
    - Project 1: validation batch records
    - Project 2: development PFDs, manufacturing PFDs at selected sites
7. Timeline
    - Project 1: Q3 2005
    - Project 2: Q2 2005

Network C

Current tasks	Priority Level	Execution barriers	Solutions	Role Assignments	Deadlines
Gap lists for required experiments	1	Limited data integration	Consult with PWC (started list for product X)	MTS, QC Labs	October 2004
Development History Reports for older products	2	DHRs that exist are aging, and	Include assignment in IPPs	Network leaders and Molecule	January 2006

		historical data is not captured; no process to capture manufacturing learning		Stewards	
Develop line of sight across all data availability and standardize practice for extensive APRs	1	Point of failure: lack of data Development data gaps	Use demo lots to fill data gaps. Evaluate risk of moving forward without data.	MTS, Stats	September 2004
Finalize proposal for revalidation	1	Aged equipment/ equipment changes	Develop strategy and standard documentation for equipment that does not meet current standard	MTS, Engineering, Operations	August 2004

Network D

Validation Master Plan				
Required Actions	*Status*	*Resources*	*Deadlines*	*Responsibilities*
Development of site-based guidance: revalidation triggers	In progress	Validation Flow Diagram; Validation Guide. Best practice: network revalidation guidance for cleaning process	By Q4 2004	Owners (names listed)
Develop forum for technical decision communication	In planning	Communication group, online portal, online community	By Q1 2005	Owners (names listed)
Establish partnership with IT in developing VMP need and rationale at every site	In progress	Recent technology transfer experience at [site name]	By Q1205	Owners (names listed)

Appendix Q: E-mail Messages Soliciting Participation in Member Check Procedures

Member Check # 1

Email 1: submitted to managers who completed the pre-workshop survey

SUBJECT: Follow-up on your survey responses

Dear Colleagues,

Thank you very much for making time for answering the MTS survey that we sent out earlier this month. As you know, your responses will inform the agenda of the upcoming MTS global conference "Driving World-Class Commercialization", which will take place in June.

We are currently in the process of preparing a report based on the result of the survey, and we would like to request your review of the comments you provided in the survey and their interpretations that will be included in the report. We would very much appreciate your feedback on both the accuracy of the content presented in the report and the appropriateness of the conclusions derived from your comments.

The document that is attached to this message has several sections. You do not need to review the statistical part of it, please focus specifically on sections 5 – 7 that focus on discussion of results and recommendations developed based on the results. Please use the track changes or comment features of the MS Word to insert your comments into the document. Your reviews will be kept strictly confidential and will not be disclosed to your colleagues or supervisors.

Please return your reviews via email or interoffice mail to Jamie Smith (jsmith@medex.com, DC: 54672) no later than January 15, 2004.

Thank you.
MTS Communications Group

Email 2: submitted to members of the strategic planning group who participated in pre-workshop interviews and completed the survey

SUBJECT: Follow-up on your interviews

Dear Colleagues,

Thank you very much for making time for discussing the strategy implementation issues with us earlier this month. As you know, information we received from these discussions will be used in defining the agenda for the MTS global conference "Driving World-Class Commercialization".

We are currently in the process of preparing a report based on the result of the interviews and the survey we recently administered, and we would like to request your review of the comments you provided in the interviews and well as their interpretations that will be included in the report. We would very much appreciate your feedback on the accuracy of the interview-based notes and the report content and appropriateness of the conclusions derived from your comments.

We would like to ask you do review two types of information: 1) audio recordings of our conversations located on Tiger server at: [location] in the folder "MTS strategy interviews" and the transcription notes made based on those recordings, and 2) sections 5-7 of the attached document, which is the first iteration of the report prepared for [VP].

Please use the track changes or comment features of the MS Word to insert your comments into the reviewed documents and save your review files with your last name in the title. Your reviews will be kept strictly confidential and will not be disclosed to anyone at MTS.

Please return your reviews via email or interoffice mail to Jamie Smith (jsmith@medex.com, DC: 54672) no later than January 15, 2004.

Thank you.
MTS Communications Group

Member Check # 2

SUBJECT: Follow-up on your interviews

Dear [participant's name],

Thank you very much for making time for discussing with me your experiences and suggestions regarding the MTS Strategy Implementation Workshop. Your input is critical for making the training and communication activities at MTS more effective in addressing your professional needs.

As I informed you earlier, our interview is a part of the research study, and the results of this interview along with their interpretations will be included in the research report. In order to avoid errors and misinterpretation of what was said during our discussion, I would like to request your review of the interview notes that I made after we talked on the phone.

I am attaching the notes here. Please use the track changes or comment features of the MS Word to insert your comments into the document. Your review will be kept strictly confidential and will not be disclosed to your colleagues or supervisors. Please return your review via email or interoffice mail to me (researcher@medex.com, DC: 46798) by July 1, if possible.

Thank you so much for your help with an important study that MTS will benefit from,

[researcher]

Appendix R: Indiana University Human Subjects Approval

INDIANA UNIVERSITY

OFFICE OF THE VICE PRESIDENT FOR RESEARCH

BLOOMINGTON CAMPUS COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

Location:
Indiana University
Carmichael Center L03
530 East Kirkwood Avenue
Bloomington, Indiana

Mailing Address:
P.O. Box 1847
Bloomington, Indiana
47402

812-855-3067
Fax: 812-856-1535
E-mail:
iub_hsc@indiana.edu
WWW Address:
http://www.indiana.edu/~resrisk.html

NOTICE OF APPROVAL
EXEMPT REVIEW

TO: Larissa Malopinsky
Education

DATE: June 8, 2004

FROM: Cybil Cole, Director Human Subjects Risk Compliance

RE: Protocol entitled: Using Socio-Technical Approach to Facilitating Orgaizational Learning in the Context of Strategic Change
Protocol #: 04- 9142

Approval Date: June 8, 2004

The Human Subjects Committee (HSC) has reviewed and approved the research protocol referenced above as exempt; §46.101b, ¶#2. As the principal investigator of this study you assume the following reporting responsibilities:

AMENDMENTS: Investigators are required to report on these forms **ANY** changes to the research study (such as design, procedures, study information sheet/consent form, or subject population, including size). An amendment form is attached for your future use. **The new procedure may not be initiated until HSC approval has been given.**

AUDIT OR INSPECTION REPORTS: Investigators are required to provide to the HSC a copy of any audit or inspection reports or findings issued to them by regulatory agencies, cooperative research groups, contract research organizations, the sponsor, or the funding agency.

COMPLETION: Approximately one month after the date you indicated your study will end, we will send a notice to you at the address on your application, requesting information on the current status of your study. You are required to complete and return that form. If this is a student project and we don't hear from you, we will send a notice to your faculty sponsor. If we do not receive any response we will consider the study as ended and change our files to show that. It is your responsibility to let the HSC office know of address changes and project date changes.

STUDY INFORMATION SHEET: All subjects should be given a copy of **the stamped approved** study information sheet.

We suggest you keep this letter with your copy of the approved protocol. Please refer to the exact project title and protocol number in any future correspondence with our office. All correspondence must be typed.

Enclosures: Documentation of Review and Approval
Amendment Form
Approved Study Information Sheet - **stamped copy must be used**

Federal Wide Assurance #FWA00003544-IRB00000222
For additional FWA information, see the Web site at http://www.iupui.edu/~resgrad/spon/fwa.htm

Appendix S: Study Information Sheet

Study # 04-9142

INDIANA UNIVERSITY - BLOOMINGTON
STUDY INFORMATION SHEET

Using socio-technical approach to facilitating organizational learning in the context of strategic change

You are invited to participate in a research study. The purpose of this study is to explore the most effective ways to communicate change agenda and learn about MS&T strategy within our organization.

INFORMATION

You will be asked to participate in 1-2 individual interviews, 1 focus group, or both. Interviews and focus groups will focus on the issues related to change agenda implementation and needs for informational and training support. Each interview will last about 1.5 to 2 hours, and it will be audio taped. The focus group will last about 1 hour, and it will be audio taped. The interviews and focus groups will be conducted during regular working hours in one of MS&T conference rooms.

If you were previously interviewed by MS&T Communications Group, and the interview was recorded, the audiotapes of your interviews will be also used in this study.

BENEFITS

The results of this study will assist MS&T Communications and Learning group in developing effective communication and education methods focused on MS&T strategy implementation, and help you to develop change agenda implementation priorities for 2004.

CONFIDENTIALITY

To preserve confidentiality, references to all names and identifying references will be deleted and/or changed. The data collected during interviews and focus groups will not be shared with your supervisors or colleagues until they are sanitized and aggregated and included into the report that will be shared within MS&T organization.

CONTACT

If you have questions at any time about the study or the procedures, you may contact the researcher, Larissa Malopinsky, at Eli Lilly and Company, Corporate Center, Drop Code 2026, Indianapolis, IN , phone: 317-651-3332, and email: malopinskyln@lilly.com.

If you feel you have not been treated according to the descriptions in this form, or your rights as a participant in research have not been honored during the course of this project, you may contact the office for the Indiana University Bloomington Human Subjects Committee, Carmichael Center L03, 530 E. Kirkwood Ave., Bloomington, IN 47408, 812/855-3067, or by e-mail at iub_hsc@indiana.edu.

PARTICIPATION

Your participation in this study is voluntary, you may refuse to participate without penalty. If you decide to participate, you may withdraw from the study at anytime without penalty. If you withdraw from the study before data collection is completed your data will be returned to you or destroyed.

Information Sheet date: June 05, 2004

1 of 1

IRB Approved
Approval Date: JUN 0 8 2004
Expires: MAY 15 2006

CURRICULUM VITAE

Larissa V. Malopinsky

P.O.Box 5877
Bloomington, IN 47407-5877 USA
lmalopin@indiana.edu

Instructional Systems Technology
School of Education
Indiana University-Bloomington

EDUCATION

Ph.D. in Instructional Systems Technology, Indiana University-Bloomington, 2007

Major program emphasis: Human Performance Technology

Minor program: Information Science

Minor program: Organizational Behavior

M.S. in Education (Instructional Systems Technology), Indiana University-Bloomington, 2001

Doctoral Candidate in Education Administration, St. Petersburg State Pedagogical University, Russia, 1998

M.A. in Language Education, St. Petersburg State University, Russia, 1991

KEY PROFESSIONAL APPOINTMENTS

PRESIDENT, September 2003 – present, Performatics, Inc., Bloomington, IN. Performatics, Inc. is an organizational performance consulting firm that assists corporate clients with strategic human resource development programs and provides R&D services in the areas of competitive intelligence, marketing research and distributed learning. Responsibilities: conducting organizational performance analyses and formulating strategic and tactical recommendations for organizational learning (emphasis on e-learning, mobile learning and Enterprise 2.0 applications); performance and competency modeling; evaluating corporate curricula and generating change recommendations; building curriculum maps and designing metrics grounded into performance analysis results; writing proposals, contracts and RFP/LOA responses; identifying new project opportunities from within assigned accounts; serving as a liaison between business clients and learning product development groups; designing learning intervention concept, pedagogical and instructional design strategy, learning activities and assessments; managing cross-functional domestic and overseas project groups; leading development and implementation of custom result-oriented learning programs and performance support applications; managing project work from launch to delivery; working directly with client IT units to integrate learning product into corporate LMS and ensure its alignment with SCORM, accessibility standards and corporate requirements; following up with client organizations to measure satisfaction, learning transfer and ROI; assisting client training representatives with information and resources on emerging teaching and learning approaches, methods and tools.

PROJECT MANAGER, September 2003 – August 2006, Center for Research on Learning and Technology, School of Education, Indiana University, Bloomington, IN. Managed an international educational partnership project funded by the U.S. Department of State between Indiana University and a consortium of 15 Central Asian universities focused on establishing e-learning capabilities in the

region. Duties included writing the initial grant proposal and securing commitment of participating institutions, implementing project timeline and coordinating project activities, budget planning, leading design and development of online certification program Instructional Design for Distance Education for international faculty, organizing project-related conferences and workshops for participating institutions, coordinating collaborative efforts among research and professional development centers in participating institutions, and completing reports for the funding agency.

INSTRUCTIONAL DESIGNER, September 2002 – September 2003, School of Manufacturing and Quality, Eli Lilly and Company Indianapolis, IN. Developed competency models for Engineering, Quality Control, Operations and Science and Technology managers, designed an onboarding program for executive education curriculum, and developed a strategic plan for integrating e-learning into manufacturing employee qualification program.

ASSISTANT INSTRUCTOR, Fall 2002, Department of Instructional Systems Technology, Indiana University, Bloomington, IN. Instructional Development and Production Process. This hands-on course introduces IST graduate students to the principles, methods and tools used for developing instructional multimedia products and supports students as they become skillful in practices related to the use of technology for educational purposes.

USER EXPERIENCE CONSULTANT, October 2001 – April 2002, E-Marketing Group, Eli Lilly and Company, Indianapolis, IN. Designed and developed instrumentation for marketing research, developed benchmarking tools, designed online educational portal for external customers focused on life sciences content, delivered presentations and workshops on learning theories, needs analysis, cultural impact on perception of educational and marketing content, and product usability topics to marketing specialists.

LEAD INSTRUCTIONAL DESIGNER, September 1999 – August 2002, Center for Research on Learning and Technology, Indiana University, Bloomington, IN. Managed a team of instructional designers developing an online professional development system for K-12 educators focused on technology integration into classroom practices, Learning to Teach with Technology Studio (http://ltts.org). Responsibilities included conceptual and visual design of a problem-based model of instruction for online delivery, designing and developing online problem-based courses in collaboration with K-12 teachers and facilitating design work of teacher-course developers, developing online pedagogical agents for supporting online learning process, and collaborating with the LTTS information technology specialists on development of online facilitation and program administration interfaces and tools.

WEB MANAGER, November 1998 – September 1999, Center for Social Informatics, School of Library and Information Science, Indiana University, Bloomington, IN. Developed and managed CSI Web portal, research project databases and online version of the Journal of Social Informatics, conducted online research on socio-technical networks to support CSI grant projects.

DIRECTOR, April 1996 – August 1998, Center for Educational Technologies, Department of Foreign Languages, St. Petersburg State Pedagogical University, Russia. The CET has as its mission to promote and support a community of scholars dedicated to research and professional development on the design, use, and implementation of technology to improve foreign language teaching and learning. Main responsibilities included overseeing the Center's research and development projects, delivering professional development workshops for faculty and managing distance education language program

designed for corporate partners. Additionally, developed technology-assisted curriculum for supporting faculty teaching foreign languages in multi-level language proficiency classroom, supervised a team of instructional designers, SMEs and information technology specialists, managed development of multimedia applications for supporting language instruction, established linkages with other universities and research centers developing technology-supported language teaching applications, and led the community outreach programs focused on promoting innovative language teaching methods and technologies in high schools.

SENIOR LECTURER, February 1992 – August 1998, Department of Foreign Languages, St. Petersburg State Pedagogical University, Russia. Responsibilities included teaching undergraduate and graduate level EFL (English as a Foreign Language) and CALL (Computer-Assisted Language Learning) courses, supervising student independent studies and thesis work, participation in departmental research and curriculum development committees, and conducting master classes for university faculty on technology integration into foreign language instruction.

POST-SECONDARY TEACHING EXPERIENCE

INSTRUCTOR, Spring 2004 – Spring 2006, Indiana University, Bloomington, IN. Instructional design certification program developed under the scope of international grant project between Indiana University and AzRENA university consortium (Azerbaijan). This program introduced international faculty and instructional technology staff to all essential aspects of online learning systems design, management and evaluation. The program was delivered in both English and Russian and employed problem-based pedagogical strategies. The graduate level online courses were delivered through the Oncourse learning management system and synchronous and asynchronous collaborative tools during academic year and included 2-month summer sessions conducted at partner universities. Teaching assignments:

- AZ01-01: Introduction to E-Learning
- AZ01-02: Needs Analysis
- AZ01-03: Instructional Design and Development
- AZ02-01: Management of Instructional Projects
- AZ02-02: Facilitating Online Learning Process
- AZ02-03: Evaluation of Online Educational Programs

ASSISTANT INSTRUCTOR, R541: Instructional Development and Production Process, Fall 2002, Department of Instructional Systems Technology, Indiana University, Bloomington, IN. This project-based, hands-on course introduces IST graduate students to the principles, methods and tools used for developing instructional multimedia products and supports students as they become skillful in practices related to the use of technology for educational purposes.

INSTRUCTOR for Teacher Certification Program, Spring 2000 – Fall 2003, Center for Research on Learning and Technology, Indiana University, Bloomington, IN. This program was designed to introduce teacher certification students to the use of technology in the preK-12 classroom. Responsibilities included a) teaching instructional design principles and methods, use of problem-based methodology for designing instruction and technology integration into teaching practice; and b) mentoring preK-12 teachers who authored online technology integration courses. Teaching assignments:

- Multicultural Curriculum and the Internet
- Using Web resources for supporting Language Arts curriculum
- Creating a technology supported project-based curriculum for foreign language learners
- Inquiry-based technology tools
- Developing information search strategy and process to help students build critical thinking skills
- Designing collaborative Internet projects to enhance student collaboration and teach cultural awareness
- Developing e-portfolios to support the demonstration of learning

INSTRUCTOR, September 1996 – May 1998, Center for Educational Technologies, Department of Foreign Languages, St. Petersburg State Pedagogical University, Russia. Delivered seminars and workshops for faculty members focused on technology integration into language instruction:

- Use of Web Resources in Classroom Activities
- Integrating Technology into Language Instruction
- Computer-Assisted Language Learning: Principles and Methods
- Strategies for Managing Multi-Level Language Proficiency Classroom

SENIOR LECTURER, February 1992 – August 1998, Department of Foreign Languages, St. Petersburg State Pedagogical University, Russia. Taught undergraduate and graduate courses for language education majors and cross-departmental language programs. Teaching assignments:

- LFL 460: Intermediate English
- LFL 410: English Composition
- LFL 545: Structure of Modern English
- LFL 600: Readings in English
- LFL 690: TEFL Methods
- LED 410: English Grammar II
- LED 585E: Business English
- LED 660E: Computer-Assisted Language Teaching Methods

RESEARCH AND GRANT MANAGEMENT EXPERIENCE

PRINCIPAL INVESTIGATOR, Facilitating organizational change: Using Activity Theory framework for supporting social construction of managerial strategic knowledge, November 2003 – December 2006, $36,000. A grant from Eli Lilly and Company to conduct action research with 86 manufacturing managers working in the U.S. and overseas that included analysis of organizational change readiness and design, implementation and evaluation of strategizing methodology for supporting development of change management competencies. Manuscripts related to this research are currently in preparation.

LEAD RESEARCHER, Designing cross-cultural distance education program for facilitating pedagogical change: Challenges and strategies, September 2003 - August 2006, $430,000. A grant from the Bureau of Educational and Cultural Affairs, U.S. Department of State to develop e-learning capabilities in higher education system of the Central Asian region (emphasis on Azerbaijan). Research foci: examining challenges of online collaboration and cross-cultural knowledge transfer and investigating barriers to e-learning implementation in Central Asian higher education institutions. Principal Investigator: Dr.

Thomas M. Duffy. Responsibilities included grant writing, research agenda development, implementing project timeline, data collection, data analysis and reporting findings. Manuscripts related to this research are currently under review.

PROJECT RESEARCHER, Student engagement and instructional strategies in a large classroom environment, September 2003 – January 2004, Instructional Systems Technology, Indiana University School of Education, Bloomington, IN. Project Director: Dr. Thomas M. Duffy. Departmental research initiative focused on analysis of large classroom teaching practices and developing recommendations for effective instructional strategies. Responsibilities included interviewing university faculty teaching large undergraduate courses and designing a prototype of a portal for faculty offering strategies and tools for managing instructional process.

PRINCIPAL INVESTIGATOR, Impact of information sharing strategies on learning in collaborating groups, September 2002 – August 2003, Maris M. Proffitt and Mary Higgins Proffitt Endowment Grant, $30,000, Indiana University School of Education, Bloomington, IN. Designed and conducted experimental study with 120 undergraduate business major students examining the variables leading to collaboration conducive to learning: the amount of unique shared and unshared information, forewarning, structuring, trust and interaction anxiety while testing complementary knowledge, cognitive interference and social inhibition hypotheses.

PROJECT RESEARCHER, Conducting team-based research: an approach for managing collaborative inquiry, Fall 2001 – Spring 2002, Instructional Systems Technology, IU School of Education. Project Directors: Dr. Thomas M. Schwen, Dr. Barbara Bichelmeyer. Worked with the group of four researchers on developing team-based research strategies in the context of the IST online graduate program, and implemented individual research agenda (impact of online collaboration on individual learning) using shared research data and collaborative data analysis process.

PROJECT RESEARCHER, Impact of power relationships on in intra- and intergroup interactions in a graduate-level educational technology course, Fall 2001, Instructional Systems Technology, Indiana University, Bloomington, IN. Project Director: Dr. Barbara Bichelmeyer. Conducted a case study examining the impact of power distance on team processes. Responsibilities included data collection, data analysis and reporting findings.

LEAD RESEARCHER, Learning to Teach with Technology Studio, September 1999-August 2003, Center for Research on Learning and Technology, Indiana University, Bloomington, IN. A $1,5M grant from the Fund for the Improvement of Postsecondary Education, U.S. Department of Education to design, develop and evaluate online professional development for K-12 teachers focused on technology integration into classroom practices. Principal Investigator: Dr. Thomas M. Duffy. Developed research agenda and managed data collection and analysis process, collaborated with the partner research group from the School of Education and Human Development, University of Colorado Denver (Project Co-PI Dr. Scott Grabinger), prepared journal publications, conference presentations and reports for the funding agency.

RESEARCH CONSULTANT, Comparative analysis of cultural impact on organizational performance in Eastern European countries, October 1998 – May 1999, Department of Strategic Management, Indiana University Kelley School of Business, Bloomington, IN. Principal Investigator: Dr. Paul Marer.

Consulted the research group of doctoral students on the cultural aspects of organizational performance with emphasis on Slavic cultural contexts. Assisted in development of the project research agenda, methodology and data analysis.

VISITING RESEARCHER, August 1998 – July 1999, Center for Excellence in Education, Indiana University School of Education, Bloomington, IN. An individual grant from the U.S. Department of State ($20,000) to study the use of online learning technologies in the U.S. postsecondary education. Conducted observations of technology-supported classroom practices, interviewed faculty using technology to support teaching and learning process, developed methodology for adapting classroom courses for online delivery, and reported findings to the funding agency.

PRINCIPAL INVESTIGATOR, Examining the role of technology in teaching multi-level language classroom, September 1996 – May 1998, Center for Educational Technologies, Department of Foreign Languages, St. Petersburg State Pedagogical University, Russia. Conducted design research evaluating the use of computer-assisted language teaching methods in cross-departmental language programs and examined the impact of multimedia use on the instructor-student interaction and advancement of student language proficiency.

PRINCIPAL INVESTIGATOR, Use of corpus linguistics methods for authorship identification and plagiarism detection, September 1994 – May 1996, Department of Foreign Languages, St. Petersburg State Pedagogical University, Russia. Used concordance tools for evaluating literary corpora and developed recommendations for application of computational linguistic analysis and text mining methods in evaluating student writing.

PRINCIPAL INVESTIGATOR, Translation of culture-specific metaphors: Comparative analysis, September 1989 – May 1991, Philology Department, St. Petersburg State University, Russia. Conducted a comparative study of metaphor interpretation and presentation in English and Russian translation of literary works of S. J. Lec grounded into ideological and cultural contexts of mid20th-century's Poland.

SELECTED PUBLICATIONS

Books Chapters and Journal Articles

Malopinsky, L.V., & Osman, G. (2006). Dimensions of organizational change. In J. Pershing (Ed.), Human Performance Technology Handbook (3rd Edition) (pp.262-286). San-Francisco, CA: Pfeiffer.

Bichelmeyer, B., Misanchuk, M., Dueber, B., Sloffer, S., Graham, C., & Malopinsky, L.V. (2006). Conducting team-based research on distance education: A system for managing collaborative inquiry. In Gary J. Anglin (Ed.), Critical Issues in Instructional Technology, Englewood, CO: Libraries Unlimited.

Malopinsky, L.V. (2006). Systemic change in corporate training. TechTrends, 50(2), 50-56.

Duffy, T.M., Kirkley, J.R., del Valle, R., Malopinsky, L.V., Scholten, C., Neely, G., Wise, A., & Chang, J. (2006). Online teacher professional development: A learning architecture. In C. Dede (Ed.), Online

professional development for teachers: Emergent models and methods (pp.175-198). Cambridge, MA: Harvard Education Press.

Malopinsky, L.V. (2006). An international experience in systemic change. TechTrends, 50(2), 39-41.

Paulus, T.M., Bichelmeyer, B.A., Malopinsky, L.V., Pereira, M., & Rastogi, P. (2005). Power distance and group dynamics of an international project team: a case study. Teaching in Higher Education, 10(1), 43-55.

Bichelmeyer, B.A., Misanchuk, M. & Malopinsky, L.V. (2001). Adapting a Master's degree course to the Web: A case analysis. The Quarterly Review of Distance Education, 2(1), 49-58.

Other Manuscripts

Malopinsky, L.V. (2004). Implementation of strategic change in international corporate context: findings and recommendations. Technical Report. Eli Lilly and Company, Indianapolis, IN.

Malopinsky, L. V. (2003). Learning as Problem-Solving: Revisiting corporate training strategy. Technical Report. Eli Lilly and Company, Indianapolis, IN.

Work in Progress

Duffy, T. M., Kirkley, J., Del Valle, R., & Malopinsky, L.V. (In press, Journal of the Learning Sciences). Online teacher professional development: Design principles, their instantiation, and learning outcomes.

Malopinsky, L.V., Duffy, T.M., & Osman, G. (In review, International Journal of Educational Development, December 2007). Cross-cultural design of distance education program for facilitating pedagogical change: Challenges and strategies.

Malopinsky, L.V., & Schwen, T.M. (In preparation). Strategizing process and management learning: The use of Activity Theory as a framework for social construction of strategic knowledge.

Malopinsky, L.V. (In preparation). Tool-mediated strategic conversations: Developing a framework for capturing and analyzing discourse in strategic episodes.

Malopinsky, L.V., Duffy, T.M., Osman, G., & Muradkhanli, L. (In preparation). Analyzing barriers and enablers of the online education implementation in post-secondary institutions of the Central Asian region.

SELECTED PRESENTATIONS

Designing cross-cultural distance education program for facilitating pedagogical change: Challenges and strategies, with Duffy, T.M. & Osman, G. American Educational Research Association Annual Meeting, Chicago, IL (April, 2007).

The use of Activity Theory as a framework for social construction of knowledge in strategic episodes. The Academy of Management Annual Meeting, Atlanta, GA (August, 2006).

Lessons learned from collaborative cross-cultural design of distance education program, with Duffy, T.M. & Osman, G. Annual Conference on Distance Teaching and Learning, Madison, WI (August, 2005).

The moderating effects of trust on learning and performance in problem solving groups: Experimental study. 6th International Conference of the Learning Sciences, Los Angeles, CA (June, 2004).

Online professional development systems: Integrating technology and supporting inquiry, with Beatty, B.J. National Educational Computing Conference, Seattle, WA (July, 2003).

Lessons from design research: Participatory design strategies in building online inquiry-based professional development courses, with Beatty, B.J., & Duffy, T.M. American Educational Research Association, Chicago, IL (April, 2003).

A critical look at learner attrition in an online learning environment, with Beatty, B.J., and Duffy, T.M. American Educational Research Association, Chicago, IL (April, 2003).

Building performance support systems to assist pre-service teachers in designing online, inquiry-based professional development instruction, with Kirkley J.R., & Duffy, T.M. American Educational Research Association, New Orleans, LA (April, 2002).

Issues and challenges with providing support for teacher-developers of online professional development modules, with Kirkley, J.R., Graham, C., Lim, B., & Duffy, T.M. Association for Educational Communications and Technology, Atlanta, GA (November, 2001).

Adapting a Master's course to the Web: Principles, strategies and recommendations, with Reigeluth, C., Bichelmeyer, B.A., & Misanchuk, M. Association for Educational Communications and Technology, Denver, CO (October, 2000).

Examining issues related to designing a web-based technology integration professional development system: The Learning to Teach with Technology Studio, with Kirkley, J.R., & Graham, C. Association for Educational Communications and Technology, Denver, CO (October, 2000).

An instructional design model for online Problem Based Learning (PBL) environments, with Kirkley, J.R., Stein, R., & Duffy, T.M. Association for Educational Communications and Technology, Denver, CO (October, 2000).

PROFESSIONAL CONSULTING

CONSULTANT, October 2000 – present, Eli Lilly and Company, Indianapolis, IN. Perform organizational development research and consulting and support design of learning and performance improvement solutions in client organizations including Manufacturing, E-Marketing and Quality Management; consult training managers on the approaches for aligning learning programs with organizational business strategy, application of learning theories in the product design, formative evaluation and action research.

CONSULTANT, September 2000 - May 2001, UNext.com, Chicago, IL. UNext.com. Conducted evaluation of the online MBA program developed by UNext for Cardean University, developed a process for combining formative evaluation with usability testing, consulted instructional design group on application of HCI principles in designing instructional products.

CONSULTANT, November 1998 - May 1999, Teaching and Learning Technologies Laboratory, Indiana University, Bloomington, IN. Consulted faculty on the use of technology in instructional process; developed multimedia foreign language teaching applications; collaborated with TLTL designers on development of the commercial case-based program for teaching medical professionals.

CONSULTANT, October 1998 – May 1999, Department of Strategic Management, Indiana University Kelley School of Business, Bloomington, IN. Consulted on the cultural aspects of organizational performance with emphasis on Slavic cultural contexts. Assisted in development of the international grant project research agenda, methodology and data analysis.

CONSULTANT, June 1994 – May 1998, KM Concepts, Ltd., St. Petersburg, Russia. Managed organizational consulting group working with Russian firms that experienced acquisitions by foreign companies. Consulting areas: change management, strategic human resource development, performance improvement. Developed performance models and competency maps aligned with the new management expectations.

SERVICE ACTIVITIES

CONFERENCE PROPOSAL REVIEWER, International Conference for the Learning Sciences, 2008; Academy of Management Annual Meeting, 2007, 2008; AACE Ed-Media, 2008; American Educational Research Association Annual Meeting, 2003, 2005, 2007; Annual Conference on Distance Teaching & Learning, 2000-2006.

JOURNAL REVIEWER, International Journal of Educational Development, 2007; International Journal of Teaching and Learning in Higher Education, 2005-2006; TechTrends, 2005.

COMMITTEE MEMBER, September 2000 –May 2002, Distance Master's Program Curriculum Development Committee, Instructional Systems Technology, Indiana University, Bloomington, IN

COMMITTEE MEMBER, October 1999 –June 2001, Strategic Planning Committee, Center for Research on Learning and Technology, Indiana University, Bloomington, IN.

COMMITTEE CHAIR, December 1997 –July 1998, Curriculum Development Committee, Department of Organizational Learning and Development, St. Petersburg State Pedagogical University, Russia.

COMMITTEE CHAIR, September 1996 –July 1998, Technology Integration Advisory Committee, Center for Educational Technologies, St. Petersburg State Pedagogical University, Russia.

BOARD CHAIR, May 1996 –July 1998, E-Learning Curriculum Development Board, Department of Foreign Languages, St. Petersburg State Pedagogical University, Russia.

COMMITTEE MEMBER, June 1994 – May 1998, Undergraduate Enrollment Committee, Department of Foreign Languages, St. Petersburg State Pedagogical University, Russia.

COMMITTEE MEMBER, September 1993 – August 1997, Applied Linguistics Research Committee, Department of Foreign Languages, St. Petersburg State Pedagogical University, Russia.

PROFESSIONAL COMPETENCIES AND SKILLS

- Competency areas: adult learning theories, organizational development, organizational behavior, strategic human resource development, strategic and competitive analysis, human performance technology, learning systems design, change management, instructional design and development, assessment and evaluation
- Learning systems design: e-learning and classroom-based implementation formats; degree, certification, professional development programs; social networks and online communities; performance support systems
- Instructional methods and technologies: design models: OEM, Iterative Design/Rapid Prototyping, 4C/ID-Model; learner-centered instructional approaches: problem-based business cases, simulations, immersive environments, strategic games, interactive video vignettes, business parables, performance support tools
- Global management competencies: cultural awareness/cross-cultural sensitivity/knowledge of cultural dimensions; effective in culturally diverse environments and cross-functional teams; value-sensitive design of learning systems; participatory decision-making, global communication management
- Project management: extensive experience in instructional project management, client relationship management, vendor management, RFP/LOA preparation and budget management
- Technical expertise: global LMS use, design and integration in corporate and academic settings; content management systems, SCORM and accessibility standards, Web and multimedia development applications, project management and statistical applications
- Personal skills: strong multitasking capability and problem-solving skills; high tolerance to uncertainty and rapidly changing environments and technologies; strong work ethics and commitment to meeting client expectations and delivering quality products; excellent communication and teamwork skills; exceptional ability to analyze and synthesize ill-structured data

PROFESSIONAL AFFILIATIONS

International Society of the Learning Sciences
American Educational Research Association
International Society for Performance Improvement
American Society for Training and Development
U.S. Academy of Management
Organizational Development Network
Academy of Human Resource Development
International Society for Applied Technology