NORTHCENTRAL UNIVERSITY

THE CORRELATION OF THE FDA'S COMPUTER SYSTEM VALIDATION ENFORCEMENT WITH THE RATE OF ADOPTION OF ERP TECHNOLOGY BY THE MEDICAL DEVICE INDUSTRY

A Dissertation submitted to the Graduate Faculty

Of the Department of Business and Management

In candidacy for the degree of

DOCTOR OF PHILOSOPHY

By

JAMES A. FARKAS

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As Dissertation Chair, I certify that the committee listed below have read this dissertation and approve it as adequate in scope and quality for the degree of Doctor of Philosophy.

Candidate:

James Anthony Farkas

Title of Dissertation: THE CORRELATION OF THE FDA'S COMPUTER SYSTEM VALIDATION ENFORCEMENT WITH THE RATE OF ADOPTION OF ERP TECHNOLOGY BY THE MEDICAL DEVICE INDUSTRY

Dissertation Committee:

Carol Wells, Ph.D. June 18, 2006

Chair: Carol Wells, Ph.D. Date

List Members:

Richard E. Yellen, Ph.D., Committee Member

Michael Ewald, Ph.D., Committee Member

ABSTRACT

This dissertation is an empirical study of the influence of FDA rules for computer system validation in the regulated medical device industry compared to the non-regulated industry. This empirical study will explore the extent to which such regulations have dampened the rate of technology adoption for ERP in the industry, which is contrary to the assertions made by the FDA upon announcing the rules in 1997. While there is a large body of research on technology adoption models, the influence of government regulation on such models remains an area that has been relatively under-studied. The findings of this research demonstrated that medical device companies installed or plan to install ERP systems at a delayed rate of as much as 48 months later than their non-regulated high technology cohorts. Findings also demonstrated that compliance with regulations was an important consideration in the decision to install ERP at medical device companies. However, compliance as a factor was no more important to regulated companies than it was for non-regulated firms when specific compliance to Sarbanes-Oxley Act was considered across both groups. The survey further showed that fewer than 20% of medical device ERP decision makers were believed to be knowledgeable about compliance regulations at the time it was decided to implement ERP. Finally, there was no significant difference in the installation durations of ERP implementation in the sample studied. For all respondents, the period of approximately 6-12 months was required to install ERP.

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TABLE OF CONTENTS

TABLE OF FIGURES

LIST OF TABLES

CHAPTER 1: Introduction

Overview

This quantitative research studied the relationship of government regulations with Enterprise Resource Planning (ERP) software adoption rates in one segment of the healthcare industry.

Numerous studies have demonstrated that governmental regulations influence public and private activities. The impact of these regulations can be either predominantly positive or negative. Taxes and quotas in stem cell research may impede technological developments (Schachman, 2001). However, incentives such as tax credits help businesses by lowering investment barriers and encouraging adoption of new technology (Stiver, 2002).

Technology adoption rates have been studied since the early 1960s. The focus has been on factors that influence the rate at which firms adopt new and improved technology (Rogers, 1962, 2003). Researchers have also concluded factors, which drive a firm to invest in technology include the size of firm, knowledge of regulations, and the perceived benefit of the technology (Al-Qirim, 2001; Au, 2003; Bass,1969; Davis,1989; King,1996; Rai,1997; Rogers, 1962,2003; Thong, 1995; Waarts, 2002; Walden, 2002).

Within the scope of U.S. regulatory activities, the Food and Drug Administration (FDA) is chartered to promote and protect public health. FDA enforcement activity includes monitoring the way in which regulated companies implement and use computer systems that may support their decisions on product efficacy, approvals and product recalls (FDA, 1997). In the Code of Federal Regulations (CFR), the FDA specified in 21 CFR Part 11, requirements for regulated companies regarding procedures for system

access, electronic signatures, copies, and electronic audit trails. These mandates were intended to influence the way regulated ERP technology was implemented in FDA-regulated industries. Non-regulated industries are not required to comply with the FDA mandates.

Statement of the Problem

A crisis in healthcare may be imminent, as baby boomers move into the high healthcare need stage of their lives. Haldorn (2004, p.1) said, "The combination of an aging baby boomer population, highly paid health care providers, and increasingly expensive and effective treatments is conspiring to produce a major crisis in access to health care." The government can encourage or discourage various healthcare practices by regulating and funding them. History is evidence that real solutions to a healthcare crisis, much like the cure for polio, must come from scientist-entrepreneurs within the Life Sciences industry. This Life Sciences industry consists of pharmaceutical, bioscience and medical device companies.

The medical device sector is a critical segment of the Life Sciences industry. This industry consists of medical device developers and manufacturers. The industry is located predominately in regional enterprise clusters in the Northeast, the Silicon Valley and in Southern California. The focus of the medical device sector is the creation of technologies to accelerate highly productive delivery of healthcare benefits. To accomplish this objective, medical device firms must establish technology based businesses. The use of enterprise-wide computer systems is part of becoming an efficient and effective business. A vital business software application today is the enterprise software offered by large software developers such as SAP, Oracle, PeopleSoft (JD

Edwards) and Microsoft (Axapta), or mid-sized developers like QAD, Baan and Ross. These software packages, referred to as ERP applications, can literally operate the company's processes for users. ERP systems provide companies with commercial off-the-shelf solutions to their business process requirements. The applications span the full spectrum of departmental and interdepartmental functionality from finance to sales, order processing, warehousing, purchasing, inventory control and production.

Rather than hiring a staff of programmers to write its software in-house, a company opting to use ERP shifts responsibility for system product development, enhancement and configuration management from the enterprise IT department to the independent software vendor. In most cases, the ERP software meets a wide variety of business requirements and is better than what might otherwise have been developed in-house. Many IT departments maintain a belief in best practices related to software and system development lifecycles. These best practices include configuration controls, rigorous testing, and thorough documentation, which have been reduced to a less accountable level since the 1960s. These methods were originally conceived for use in critical weapons and aerospace applications. Today, however, expectations for quality software appear to be much lower (FDA, 2003).

Since 1862, the predecessor of the FDA was chartered to promote and protect public health. Today, the scope of the FDA's activity includes enforcement of implementation practices for the software within medical devices, as well as for the ERP business software upon which product efficacy and recall decisions may be based (FDA, 2003). Current FDA regulations require Computer System Validation (CSV) that

necessitates extensive planning and the collection of documentary evidence. This process verifies that the system is in compliance with the business specifications of the user.

The researcher's experience included the implementation of Enterprise Resource Planning (ERP) systems, in both non-regulated and regulated industries. In the process, significant differences in executive attitudes toward testing and documentation between industries have been noted. This experience demonstrated that most IT departments, and their third-party implementation service providers, did not include the costly 1960's best practices in their methodologies for system development unless such requirements were mandated by law.

Complicating this situation further for regulated firms, the enforcement of CSV regulations, mandated in 1997 by the FDA, had been inconsistent. Enforcement had ranged from infrequent random monitoring of CSV records to aggressive enforcement and written citations. Regulatory agencies are dependent on their budgets. Related to this, the variable of which political party was in office resulted in a larger or smaller budget. The Republican administration, since 2003, showed a preference for less regulation and reduced enforcement, which followed the more aggressive level previously evidenced during the Democratic administration (Olson, 1999).

The overall effect of this chain of converging events resulted in delayed adoption of ERP technology in the medical device industry. The following issues were researched in this study:

1. Have medical device companies installed ERP applications later than similar but non-regulated high technology companies?

2. Did Medical Device IT managers who were familiar with the computer system validation regulations mention compliance with such regulations as a concern in their decision to implement ERP?

This topic was important because government regulations may affect the well-being of the economy and the people in that economy. Specific regulations have inhibited both investment and progress in the healthcare field, and specifically within the medical device industry. Studying the impact, that CSV regulation may have on business decisions to adopt ERP technology by the medical device industry can prove useful to regulators and industry IT management. The affect on the adoption decision for ERP appears to have impeded, rather than promoted, the application of value added technology, which would benefit public health. Knowing more about the influential aspects of the CSV requirements for medical device firms could lead to regulatory activity that would lessen any negative impact, and perhaps even promote public health, which is an element of the FDA's regulatory charter.

Definition of Terms

The terms used in this study, defined in this section, include researcher-developed explanations of terms for which citations were not provided. The terms were divided into groupings of General Terms, Regulatory Terms, Software and Implementation Terms and Technology Adoption Terms:

General Terms

Baby boomers: the demographic term for population born between the years 1946 to 1964.

Equivalent firm: in this study, firms of similar size based on the total number of employees.

Risk averse: the aversion to undertaking what an individual perceives to be a risky investment, or pursuing an activity surrounded by uncertainty.

Regulatory Terms

Mitigating incentives: in cases where the Regulatory Impact Analysis (RIA) demonstrates there will be a significant economic impact, measures are taken to mitigate the impact of such regulations on small businesses, and thereby encourage compliance. Specific forms of mitigation are not detailed in the RIA, but could include tax credits and delayed enforcement.

Regulated versus non-regulated: In this study, the term regulated specifically referred to that body of regulations that applied to Life Sciences firms and is commonly called validation, or Part 11. Non-regulated meant equivalent companies not required to comply with the FDA regulations.

Regulations: The specific laws that require FDA to regulate Life Sciences companies are also referred to as the Predicate Rule, or 21 CFR Part 11, or 21 CFR paragraph 820.70(i).Based on this law, the FDA prepared interpretive rules that were used to monitor, investigate and regulate activity, and prosecute instances of non-compliance.

Regulatory Impact Analysis (RIA): The Regulatory Flexibility Act of 1980 required a qualitative and quantitative analysis of all FDA interpretive rules to determine whether there would be significant impact on small businesses. Impact was judged to be an effect of more than $100 million.

Validation: This procedure establishes documented evidence, which provides a high degree of assurance that a specific process will consistently produce a product which meets predetermined specifications and quality attributes (FDA, 1997).

Technology Diffusion Terms

Adopter Category: There are five generally accepted categories that define the timing of technology adoption by users. These range from very early to very late in the life cycle of the technology being adopted (Rogers, 2003).The categories do not relate to whether a firm is regulated, they simply give names to the timing pattern of technology diffusion. These categories, along with their percentages, are as follows:

Innovators- first 2.5% to adopt.

Early Adopters- next 13.5% to adopt.

Early Majority Adopters- next 34% to adopt.

Late Majority Adopters- next 34% to adopt.

Laggards- final 16% to adopt.

Bass Forecasting Model: A model developed to assist marketers of consumer goods to predict the long-term sales volume of new products. The model was based on a normal distribution of consumer decisions to purchase over time (Bass, 1969). The model's key parameters are:

m = estimated total market size

p = coefficient of innovation

q = coefficient of imitation

Rate of Adoption This term refers to the relative speed with which an innovation is adopted by members of the social system (Rogers, 1962; 2003). The term diffusion is often used synonymously.

Technology Adoption Model: This term is a broadly used one, which refers to a framework of influential factors employed to predict the diffusion rate at which a technology will be adopted by the marketplace (Rogers, 1962; 2003).

Software and Implementation Terms

Decision maker: This is the person in a company who was directly involved in making the decision for the company to purchase and adopt an ERP package.

Enterprise Resource Planning (ERP): This software application links and serves the process needs of multiple departments (e.g., Finance, Accounting, Manufacturing, Logistics, Human Resources and Sales). It is often called a back office system (Enterprise Resource, 2004). Similar to Waarts (2002, p. 418), the questionnaire defined ERP as an application being installed in more than one functional area of the organization.

Go-live: This term points to the time, late in the software implementation process, when system users move from testing to production and the system is declared as live. This occurs after the *go-live*, system users enter the business transactions of the legal entity into the system.

Informed decisions: In this study, it was important to know whether the decision-making respondents to the survey instrument were aware of and informed about FDA regulations that guide the implementation of ERP. In this context, it was necessary to distinguish among three categories of responders:

Not Familiar- decision maker not experienced with validation of software application.

Familiar- decision maker currently experiencing or had experienced at least one validation.

Very Familiar- decision maker experienced with more than one software validation to FDA Standards.

Medical Device Information Technology Manager: This person was the senior IT Manager or Chief Information Officer (CIO) of firms listed in the FDA's public list of Medical Device Establishments.

Non-regulated High Tech IT manager: This person was the senior IT Manager or CIO of firms with similar size, but *not* in the regulated Life Sciences field.

Brief Review of Related Literature

This study referenced background literature on broad findings in these two areas: technology diffusion and regulatory correlates of impact on small businesses. The first area included a broad overview of studies in the literature related to Technology Diffusion (Rogers, 1962; 2003) as refined through further research and additional influential characteristics (Sonnenwald, Maglaughlin, & Whitton, 2001; Thong & Yap, 1995; Walden & Browne, 2002; Al-Qirim & Corbitt, 2001). Surprisingly, *none* of these studies considered the potentially impeding or accelerating impact of CSV government regulations on technology adoption. Bansler, Damsgaard, Scheepers, Havn, & Thommesen (2000) reported a case study on a large PharmaCo that made no mention of these CSV regulations in the industry. The second broad area included works related to

the requirement for RIA in the United States (SBA, 1993). Formal impact assessments are required by Executive Orders 12866-Impact Assessment and 13272-Regulatory Flexibility Act Compliance by Agencies (Federal Register, 1993; Federal Register, 2002). These Executive Orders clearly demonstrate government awareness that regulations may have significant economic impact and that they influence the agility of small business. The FDA's impact assessment was also described, demonstrating that the FDA asserted that CSV would have no impact on businesses being regulated (FDA, 1997).

Clearly, there is a modicum of awareness of the 21 CFR Part 11 requirements for CSV in the industry, if not among IT researchers. The Final Rule was published in the Federal Register, and subsequent guidelines were provided to the public (FDA, 2003). Numerous service businesses have emerged offering CSV services to the industry, (Grunbaum, 2002; Fields, 2003).Extensive FDA reliance on Good Automated Manufacturing Practices (GAMP) is also well known in the industry (GAMP, 2001). This information collectively set the stage for a paradoxical situation in which the FDA claimed that its regulation would have no impact while it has played a significant economic role. The technology adoption modelers have not rigorously tested the impact that CSV regulations may have on diffusion rates. This apparent disconnect provided the rationale for the study and for obtaining empirical evidence.

Following the overview of the literature, numerous scholarly and popular works are presented in detail to describe the Life Sciences industry and the Medical Device segment along with its products and geographic clustering. Literature was summarized to provide facts about the FDA, its charter that was designed to promote and protect the

public health, and the agency's regulatory scope. Critical milestone dates for FDA's rulings and changes in enforcement activity, related to CSV, were referenced.

The next section is a historical background on CSV that includes its evolution in the 1950s outside of government. This chronology illustrates the divergence in validation practices between regulated and non-regulated industries. Referenced studies describe what was previously viewed as best practices in IT, and how the current practices diminished perception of CSV value. Further, how this has resulted in "bug fixes" for faulty software, and widespread poor practices throughout the IT profession. References provide a basis for demonstrating that the FDA is chartered to enforce rigorous CSV for business purpose installations within the medical device segment, even though few other non-regulated companies spend as much effort on the practice of collecting documentation about computer installations.

The hypothesis of a tax-like inhibitor to technology adoption emerged as a logical issue of concern. Next, ERP software applications were reviewed in order to relate ERP installation to technology adoption. The second hypothesis emerged, that the slow rate of ERP implementation in the medical device industry was correlated with decision maker concern about the regulatory environment. Because the ERP installation will be scrutinized by FDA inspectors, the installation of regulated ERP systems occurred later for these firms than it did for non-regulated firms.

Finally, studies describing IT survey instruments were highlighted and the groundwork was set for developing survey questions needed to test the hypotheses. The approach for testing the validity of instrument questions was described as a means of reducing study bias.

Highlights of Methodology

The researcher conducted a quantitative study of the problem and executed the empirical study in these stages:

Stage 1. The researcher identified a sampling framework for both regulated Medical Device companies and non-regulated high technology manufacturing companies, which were of similar size. Then, evaluated appropriate potential sample bias-reducing activities. This process took place in this stage because the research instrument could have been affected by the sample selection.

Existing questionnaires (instruments) were researched and the feasibility of using such instruments was assessed. Two distinct online survey instruments were developed; one for regulated and one for non-regulated respondents. The research determined that survey data from existing studies was not sufficient to address the hypotheses. As a result, a customized instrument was developed and tested. Perceptions of differences in the cost and time of software installation were included in the instrument, as was the degree of management's familiarity with FDA validation requirements.

The resulting survey instrument was administered on a test basis locally in Southern California at several small companies. This provided a means to test the instrument, and to obtain comments used to reduce ambiguity.

Stage 2. The survey was administered to respondents who had been invited to participate in the survey from the two sampling frames, using *Internet survey facilities*. The author was able to reduce the expense of conducting survey activity through the assistance of the Technology Evaluation Center (TEC) online newsletter. Their assistance also enabled responses to statistically significant levels when it became apparent that

invitations sent to more than 6,000 IT manager's email addresses had yielded only 42 completed surveys.

Stage 3. The collected data were analyzed and research hypotheses tested using a statistical software application. This package provided data tools and graphics to generate regression analyses and present results in tabular or graphical form. Regression analysis yielded correlation coefficients, and scores above the 0.40 – 0.50 range were found to be sufficient to demonstrate relationships.

Hypotheses- the results of the survey were tested to determine if:

1. Medical Device companies installed ERP applications later than the similar but non-regulated high technology companies.
2. Medical Device IT managers familiar with the computer system validation regulations mentioned compliance with such regulations as a concern in their decision to implement ERP.

Alternatively, the results of the survey were tested to show the following:

1. Medical Device companies installed ERP applications at about the same time as similar but non-regulated high technology companies.
2. Medical Device IT managers familiar with the computer system validation regulations did not mention compliance with such regulations as a concern in their decision to implement ERP.

Limitations of the Study

There are many influencing factors that may affect executive timing in making the decision to acquire business software. In addition, the relative importance of any specific factor may vary according to the decision at hand. It is unlikely that any study could

quantify all such elements. This study was limited to learning whether the regulations applicable to Medical Device manufacturers caused them to be more averse to risk than non-regulated companies of equivalent sizes.

Within this scope, there were other limitations considered in evaluating the results. First, the subjects in the study were expected to be at the IT Manager or CIO executive level. Due to high employment turnover in these roles, participants may not have responded to the survey instrument based on their own knowledge of ERP system implementation in their companies. It is also possible that some of the responders were not the original decision makers, even if they were present when the decision was made to implement ERP.

As with any survey, the randomness of the sample will affect the results. In this study, email addresses were used to invite respondents to the web site for the survey. An additional open invitation was posted in the TEC newsletter for two weeks. The true randomness of such a set of respondents cannot be determined. This may affect the usefulness and validity of generalizations derived from the study's results.

Additionally, there was a great deal of technology anxiety related to millennium change (Y2K), and that may have biased the results of the Medical Device company decisions. Risk aversion notwithstanding, the uncertainty associated with Y2K may have been viewed as a decision impetus, which carried more weight than the FDA regulations or any other diffusion-influencing factors. This type of decision process influenced many companies prior to 2000. As a result, the responses of those subjects who implemented ERP prior to 2000 were scrutinized for evidence of this type of bias.

Another limitation was the use of a non-standardized instrument. Neither the specific questions, the sequence of the questions in the instrument, nor the online survey tool had been rigorously validated. To mitigate this bias, informal testing of questionnaire ease of use and ambiguity were conducted. Likewise, the final arrangement and branching of questions that were set up within the survey tool online were informally tested by a small representative sample of regulated and non-regulated company IT managers. In both instances, comments from the testers were incorporated prior to the final release of the instrument that was used for the study.

A form of personal bias may have been introduced by the researcher's selection of the test criteria to be used to reject or accept hypotheses. The choice of a difference in means of 'greater than 6 months' for the first test, and a favorable response by 'more than half' of the respondents for the second test was based on the researcher's experience in the field. This bias had no effect on responses, and in the final analysis did not provide undue influence on the study results.

Finally, bias may have been introduced because of non-responders, even though follow-up measures were taken to encourage timely response to the survey instrument. A comparative analysis of the later responses to the earlier ones was conducted to determine if the late responses differed materially from the majority. Thus, non-response bias, if not reduced, was at least noted in the final study results.

Research Expectations

This study was expected to demonstrate that Medical Device companies, as compared to non-regulated companies of equivalent sizes, are more risk averse. That is, they adopted ERP technology at a slower pace, in part, because of the FDA regulations

under which they must operate. The study allowed for quantifying the impact of the specific CSV regulations, resulting in delay of at least six months in the mean time of ERP installation *go-live*.

Significantly, the findings eradicated the apparent conflict this researcher had experienced between FDA's assessment of no impact and a thriving validation professional services industry that had emerged to assist regulated companies in their compliance efforts. Clearly, demonstrating such an impact, in terms of delayed ERP technology diffusion, means that the FDA should have called for mitigating incentives in the case of small businesses that were impacted by the regulations required in the Regulatory Flexibility Act of 1980. Finally, the results contribute to the knowledge base that can be used in both future research and by Medical Device companies to identify possible pathways for overcoming their aversion to risk, and thereby improve public health through the faster diffusion of technology.

CHAPTER 2: Overview of Related Literature

Introduction

This dissertation is a quantitative research study. This chapter is an overview of historical events, recent studies, articles and books on the subjects of technology diffusion and on the impact of government regulations, which may affect decisions to adopt innovative technology. Within these major domains, a research framework was developed to acquaint the reader with knowledge developed in the field of technology adoption, including the importance of predicting technology adoption rates, as well as adoption rate modeling and characteristics that influence adoption rates. This research further illustrates how government regulatory compliance has been neglected in the study of diffusion.

In contrast to literature on technology adoption studies, literature is examined, which shows that government regulations can influence technology diffusion in different ways and to varying degrees. This aspect of the literature review also describes the medical device-manufacturing marketplace and details the regulatory and supportive roles played by the United States government, especially the Small Business Administration (SBA) and the FDA. This study specifically addresses the requirements for regulatory impact analysis according to United States law, definitions related to the Medical Device industry within Life Sciences, the FDA's mandate to protect and promote public health, and a historical perspective of the FDA's computer system regulations, including its regulation of ERP business software.

This literature review contrasts the urgent importance of technological progress in public health with the as yet, un-modeled influence on technology adoption rates

resulting from FDA regulation. Thus, the literature highlighted the necessity of the empirical study that was conducted. The study determined quantitatively that regulation correlated with later ERP technology adoption by medical device manufacturers in the Life Sciences industry.

Technology Diffusion

Contrary to researchers who have found that some technology is foolish (Kerridge, 2002), a major premise in this study is that technology is good; those entities adopting technology will improve their productivity and may even achieve a competitive edge by being *early* adopters. Likewise, improved productivity is good for the economy, and when something affects consumers, the government is interested in it. Finally, improved technology in the Life Sciences industry may be the only condition that will stave off the crushing impact that an aging baby boomer generation will have on the industry.

In 1962, Everett M. Rogers conducted research for the Department of Agriculture. His studies focused on farming and the farmers' use of new, high technology hybrid corn to improve the yield and profits of their farms. From these beginnings, the seminal work on technology diffusion emerged (Rogers, 1962; 2003). The study of technology diffusion progressed from determining what convinced some farmers to plant hybrid corn to more recent cases of computer technology diffusion. Rogers defined adopter categories (i.e., innovators, early adopters, early majority, late majority, and laggards), he clarified an innovation-decision process model, and illustrated five high level variables that can influence diffusion rates (see Table 1). His research provided the framework for continued work in the area of technology adoption models.

Table 1

Technology Adoption Variables per Rogers

Influencing independent variables		Researcher	Dependent variable
Perceived attributes of innovation	Relative advantage	Rogers	Rate of adoption
	Compatibility		
	Complexity		
	Trialability		
	Observation		
Type of innovation decision	Optional		
	Collective		
	Authority		
Communication channels	Mass media		
	Interpersonal		
Nature of social system	Network interconnectedness		
Extent of change agent's promotional efforts			

(Rogers, 1962, 2003)

While this is a solid framework, it is at too high a level of conceptualization to be practical, and some factors appear to be absent. For example, the size of a business is not

included in the original framework, and size has served as the basis for numerous additional studies. Because of this logic, the survey sample was stratified by business size. Likewise, the influence of top management is missing from the Rogers' framework. Study of factors influencing the rate of technology adoption has shown that differences exist for smaller businesses, for the business size and for the CEO's familiarity with the IT to be adopted (Thong & Yap, 1995). The importance of top management support in decisions to adopt IT has also been confirmed (Rai & Deepinder, 1997). Standards adoption has been studied, and the factors that contribute to adoption of XML technology standards, which may replace the EDI standards from the 1990s, have been identified. Findings that are published corroborate other studies and the information that the top management level has influence on the technology adoption rates (Nelson, 2002).

External factors like regulations and governing body or ad hoc standards are not specifically shown to fit in the Rogers' framework, though both may affect technology adoption rates. Germane to this study, the matter of implementation complexity associated with regulations is also missing from the framework. Finally, the Rogers' framework focuses on the one-time decision to adopt, but does not address a decision maker's evaluation of the life cycle of that decision. In the case of business software adoption, considerations such as implementation costs and long-term maintenance and staffing investments are commonplace, but are not readily apparent in the Rogers' framework. Thus, this framework describing independent influences may be useful, but it needs greater specificity of factors beneath the broad variables that Rogers has described.

Importance of Predicting Technology Adoption Rates

Businesses and the government have both studied technology diffusion. Businesses are very interested in technology diffusion rates because knowing how many units of a new tool or device should be manufactured can make the difference between the success and failure of a venture. Information on sales volume will dictate costs and trickle through the economy at the velocity in the supply chain.

Another model, a marketing model of diffusion (Bass, 1969) was reported to have correctly predicted growth rates of consumer durables like color television sets, mainframe computers, and satellite televisions. Its use relies on grouping buyers as either innovators or imitators. The innovators' buying patterns are not predicted by the model, but the imitators, whose purchases are greatly influenced by actions of previous buyers, have been predicted. The formula in this model yields a cumulative S curve for product penetration over time (Van den Bulte, 2002) with the following factors:

$$N(t) = m \times [1 - \exp\{-(p+q)t\}] / [1 + (q/p)\exp\{-(p+q)t\}]$$

where

t is a period of time (week, month, year),

N(t-1) is the number of people who have already adopted before time t,

p is a fixed factor that reflects people's intrinsic tendency to adopt the new product,

q is a factor that captures the influence of *word of mouth.*

In contrast to Rogers, the Bass Model is practical and its simple quantitative features make it immediately deployable by marketers to predict product volume sales over time, provided there is a similar diffusion history. However, with its simplicity and reliance on previous history comes a gap in knowledge of lower level influence characteristics. There is, for example, no way to calculate either p or q without knowing the history, the business size, or a number of other factors. While informative, Bass cannot chart a diffusion S curve for new technology.

In a broader sense, management must recognize a new business trend in which better firms should embrace a technology adoption strategy as regards disruptive technologies related to their industries (META Group, 2001). The META Group gives a humorous twist to Rogers' adopter categories (e.g., *bleeding* edge, leading edge, early majority, late majority and laggards) to represent types of companies. It is suggested that firms must institutionalize technology adoption planning because they need to better understand (identify, qualify, quantify and codify) how and when to adopt disruptive technologies. More importantly, firms need to utilize their diffusion knowledge to optimize sales of their technology products to consumers. The META study stimulated research questions that seek to differentiate between companies that may choose to be *laggards* in one technology but an *early majority* in another.

Christensen (1997, 2003, 2004) asserts the business aspects of innovation, and specifically the innovator's dilemma by which businesses use technology to improve their products beyond what consumers desire or will pay for. This sets the stage for acceptance by consumers of novel and even underperforming products, until the

improvement cycle eventually reaches its inevitable conclusion in another dilemma of innovative oversupply.

The government is also interested in technology diffusion. It is committed to frequent, long-standing studies of manufacturing productivity and how new technologies may contribute to improvements that result in growth of the economy. Tracking and predicting patterns of technology diffusion are illustrated by findings that show, plants with integrated fabrication and assembly operations appear to use technologies more effectively than plants engaged in only fabrication or assembly (Beede & Young, 1995). This report sampled several thousand manufacturing plants in the United States as part of the 1988 Survey of Manufacturing Technology (SMT) at the Census Bureau's Center for Economic Studies (CES). It demonstrated that technology is associated with the growth of the economy, and that early adopters have higher rates of job growth and labor productivity than laggardly adopters. The gap in this study, and other studies that are similar, is that business software, like ERP or communications software, was not considered as manufacturing technology. These government sponsored studies focus on technology tools like computer aided design (CAD), flexible manufacturing, robotics, automated materials handling, automated sensors, communications networks and programmable manufacturing control. These studies seldom spotlight the unifying ERP applications that can integrate the data coming from such applications into a business dashboard. Likewise, governmental studies are frequently silent about the restrictive impact that compliance with the government's regulations may have on diffusion.

Characteristics that Influence Adoption Rates and Adoption Rate Modeling

Diffusion theory describes statistically significant factors, shows favorable or unfavorable influences, and assesses the size of the effect on the corporate decision to adopt an innovation. After an innovation adoption, its acceptance by users and potential users has also been studied and modeled. Numerous studies have built upon the Technology *Acceptance* Model (TAM) derived by Davis (Davis, Bagozzi, & Warshaw, 1989). One study arrived at the Utilization of Technology and Individual Performance (UTIP) framework of 19 constructs that define an intention to use technology for Microsoft Access™ software (Thompson, 1997). There are also prior claims that the diffusion models are incomplete, and specifically the TAM is incomplete because it does not account for the factor of social influence in adopting and utilizing new information systems (Malhotra & Galletta, 1999).

The literature describes a field survey (King & Teo, 1996) which determined through stepwise discriminate analysis that seven dimensions appeared to define a technology adoption model. Dimensions shown to facilitate adoption include innovative needs, competitive position, environment, economies of scale and top management guidance. Diffusion inhibitors were shown to be the lack of IT drivers, lack of economies of scale and lack of innovative needs. A similar model was developed and tested that contains seven similar factors believed to affect the adoption of open systems (Chau & Tam, 1997).

Organizational practices can also define rates of diffusion. Research contrasted Intranet implementation results through two anonymous case studies; one was a large PharmaCo, and the other was a mid-sized PlayCo. Each company took different

approaches to and provided different environments for technology adoption (Bansler, Damsgaard, Scheepers, Havn, & Thommesen, 2000). The subject of regulatory requirements at the PharmaCo was not considered as an influential factor, even though PharmaCo was subject to FDA compliance.

The literature also demonstrates graphical techniques to present results of diffusion differences (Society of Automotive Engineers, 2000). The study attempted to predict rates of diffusion by tabulating the estimates of survey participants. While this approach relied heavily on opinions of the respondents, the graphical comparisons using S curves demonstrated once again this useful way of visualizing differences in rates of adoption.

The study of Internet use by executives revealed that many executives do not see a connection between what IT does and their own tasks as executives (Pijpers, Bemelmans, Heemstra & van Montfort, 2001). The study also attempted to describe factors influencing executives' use of IT and in particular, the Internet. The resulting paper focused on use of IT rather than decisions to adopt an IT solution. However, a number of survey questions were prompted by the findings in the study; asking respondents to rank the relevance of influencing factors that was incorporated in the instrument. The manner in which the top executive embraces validation activity may well influence decisions to adopt ERP in the regulated environment.

The literature expanded on works to demonstrate that business size and CEO characteristics would influence technology adoption (Al-Qirim & Corbitt, 2001; Thong & Yap, 1995). The universe of potential adopters was defined differently than Rogers' classic adopter groupings, by considering stages that occur prior to actual adoption. The

results categorized influences related to technology (advantage, cost, transformation), to organizational descriptors (size, information intensity), to entrepreneurial/managerial descriptors (innovativeness, entrepreneurship) and to environmental descriptors (competitive pressure, support) factors. The study failed to include any direct influence from government, whether from restrictive regulations or from mitigating incentives like tax credits and other monetary policies.

Enhancing the models further, a novel concept of *information cascades* was introduced to explain a fad characteristic inherent in technology adoption, specifically the need by some individuals to have the *newest* software. Walden & Browne (2002) found that *private signals* that the decision maker responded to were shown to accelerate adoption decisions and even create market bubbles. These bubbles, or fads, were shown to break when new information subsequently weakens the decision maker's confidence (Walden & Browne, 2002).

The literature also supported incorporating a widely used Rational Expectations Hypothesis (REH) from economic theory into technology adoption models (Au & Kauffman, 2003). The primary finding was that a manager's own aversion to technology risk is based on previous positive or negative learning and on the rational expectations of the forecasted value to the manager. Factors considered in the survey instrument for this study included the decision makers' risk threshold, the cash-richness of the firm, and the firm's recent record of accomplishment with IT projects.

The literature has also given labels to various stages of diffusion and to technology product life cycles (Gartner, 2003). Terms such as the Hype Cycle and other phrases like Technology Trigger, Peak of Inflated Expectations, Trough of

Disillusionment, Slope of Enlightenment, and Plateau of Productivity are found in the literature. Changes in the influence of factors, depending upon timing within the diffusion process or life cycle, were studied by researchers (Waarts, van Everdingen, & Hillegersberg, 2002). It was concluded that factors important to late adopters are more technically oriented (e.g., scalability), than the concerns driving early adopters.

Researchers studied 105 articles related to factors influencing adoption rates (Moore & Benbasat, 2001). The study and the articles related the TAM developed by Davis to technology adoption, claiming that Davis' factors are similar to the Rogers' factors, with perceived usefulness and ease of use being added. For the first time, the weighted influence of these factors was tested. That data, while interesting, is outside of the scope of this paper other than to illustrate that government regulations do not appear as a factor of influence.

In summary, Table 2 contains the consolidated listing of factors, related factors, and sub-factors which the literature cites as having positive or negative impact on adoption rates.

Table 2

Technology Adoption Variables Per Researchers

Influencing independent variables		Researcher	Dependent variable
Perceived attributes of innovation	Business size	Thong, Al-Qirim	Rate of adoption
	Perceived usefulness	Davis	
	Economies of scale	King	
	Competitive position, pressure	King, Al-Qirim	
	Cost	Tornatzky, Al-Qirim	
	Information-intensity	Al-Qirim	
	Transformation	Al-Qirim	
	Profitability	Tornatzky	
	Social approval (image)	Tornatzky	
	Relative advantage	Rogers	
	Compatibility	Rogers	
	Complexity	Rogers	
	Perceived ease of use	Davis	
	Trialability	Rogers	
	Observation	Rogers	
	Divisibility	Tornatzky	
	Communicability	Tornatzky	

Table 2

Technology Adoption Per Researchers (continued)

Influencing independent variables		Researcher	Dependent variable
Type of innovation decision	Optional	Rogers	Rate of adoption
	IT drivers	King	
	Collective	Rogers	
	# People already purchased	Bass	
	Word-of-mouth	Bass	
	Intrinsic tendency to adopt	Bass	
	Innovative needs	King	
	Authority	Rogers	
Communication channels	Mass media	Rogers	
	Interpersonal	Rogers	
	Environment	King	
Nature of social system	Network interconnectedness	Rogers	
	Environmental support	Al-Qirim	
	Timing within diffusion life-cycle, or hype-cycle	Waart, Linden	

Table 2

Technology Adoption Per Researchers (continued).

Influencing independent variables		Researcher	Dependent variable
Extent of change agent's promotional efforts	Importance to top management	Thong	Rate of adoption
	Rational expectations hypothesis	Au	
	CEO familiarity w/application	Rai	
	Private signals in cascade	Walden	
	Top management guidance	King	
	Communicating that application is required	Anderson	
	Innovativeness	Al-Qirim	

The models, while strong, lack specific and necessary factors, which may lead to the need for further study of the impact of government regulation as an influence on technology diffusion.

Impact of Government Regulation on Diffusion Somewhat Neglected

Missing from all the influencing factors, which were studied, and from decades of diffusion research, is the specific influence of government regulations (Al-Qirim, 2001; Au, 2003; Bass, 1969; Davis, 1989; King,1996; Rai,1997; Rogers, 1962, 2003; Thong, 1995; Waarts, 2002; Walden, 2002). Such a deficit in the technology diffusion models could lead one to assume that regulations do not then influence technology diffusion, but this would be a wrong assumption. Diffusion can be affected by regulations.

For example, a study on the impact of pollution abatement regulations (Barbera & McConnell, 1990) used time-series data from1960 to 1980s to study the affect of pollution regulations on the productivity of select industries in the 1970s when productivity decreased. The findings demonstrated that environmental regulations accounted for 10-30% of the productivity decline among the most polluting industries as they altered their practices and facilities to accommodate new regulations.

Another study used several Technology Adoption Indicators (TAI), including government regulations and public policy to predict the likelihood of adoption of a new Flow Control manufacturing technology in two diverse industries (Brown & Ehlen, 2003). The authors suggested further research into TAI measures for regulations.

Regulations can retard diffusion of technology by acting as hidden and actual costs to small firms, and may thus add as much as 5% to the cost of production (Joshi & Krishnan, 2002). The government can also influence technology diffusion by halting economic support of its development. In terms of stem cell research, politics and government regulations have ended promising research on Alzheimer's disease and other health problems by regulating constraints in stem cell research and technology development (Schachman, 2002). It was also claimed that, "well-intentioned regulations can limit access to highly convenient, low-priced solutions" in the health care field (Christensen, 2004, p. 198).

On the positive side of regulation, literature has demonstrated that government monetary policy, as in the case of tax credits for expenditures on pollution abatement equipment, positively influenced technology adoption rates (Stiver, 2002). In this way, monetary policy can be used as a mitigating activity where the impact would otherwise

retard desirable technology that nevertheless must be regulated for public safety purposes. Finally, the literature suggested that future IT research should consider whether regulations impede technology diffusion, and that new studies should identify the national IT policies, which might promote diffusion (Straub & Watson, 2000). Thus, it is understandable that government regulations can influence technology diffusion, but this factor was neglected in models that attempt to define diffusion.

Government Regulation

Regarding the specifics of government involvement in Life Sciences technology, it is clear that regulation of industry has been commonplace in United States commerce since the FDA's founding in 1862. The fact that government regulations may impose burdens on business, especially smaller businesses, has been recognized. Who should bear that burden has been hotly debated in economic literature (Coase, 1991). However, it is beyond the scope of this research to ponder the legal, political, or economic justifications for the regulations. Only the empirical results of the FDA regulations are examined in this study.

Even so, mitigation of regulatory burdens has been considered equitable since the Regulatory Flexibility Act (RFA) of 1980. Executive Order 12866 further required Agencies to determine whether a new regulation has a significant impact on business by performing an impact analysis (SBA, 1993). Then, if the anticipated impact on the economy is $100 million or more, that is the trigger for a review of the agency's assessment by the Office of Management and Budget (OMB).

In the public disclosure prior to the FDA's 1997 release of rules regarding CSV, any further required OMB review of the impact assessment was obviated because the

FDA claimed, the Commissioner of Food and Drugs certifies that this rule will not have a significant economic impact on a substantial number of small entities (FDA, 2000). Therefore, the FDA must have believed the impact of CSV rules on the economy would be less than $100 million. The FDA had complied with the requirements, given this belief.

However, agencies have had varying, self-serving interpretation of both the RFA 1980 and EO 12866 as reported by the General Accounting Office (GAO). Agencies had interpreted the Act differently or generally as they see fit, (GAO, 1999). GAO further advised that such a situation also contributed to confusion and frustration among small businesses in how the regulations affected them. That finding brought about a later Executive Order – 13272 (SBA, 2000), in which the President commanded compliance with the RFA, emphasizing that agencies review their draft rules for impact on Small Businesses and other small entities. The SBA Office of Advocacy was established to monitor and report on the progress of agencies regarding the impact of regulations on small businesses.

FDA Protects and Promotes Public Health

The FDA grew from a single chemist in the U.S. Department of Agriculture in 1862 to a staff of approximately 9,100 employees and a budget of $1.294 billion in 2001 (Swan, 1998). Since that founding, the agency has become pervasive in the economy until now. The FDA monitors the manufacture, import, transport, storage, and sale of about $1 trillion worth of products annually at a cost to taxpayers of about $3 per person. Investigators and inspectors visit more than 16,000 facilities a year, and arrange with state governments to help increase the number of facilities checked (Swan, 1998).

Throughout the years, the agency gained strength and expanded its scope as the result of both therapeutic and fraudulent disasters. Corrupt food industry practices that Upton Sinclair described in the period of the early 1900's in his muckraking book, *The Jungle,* was the final precipitating force behind both a meat inspection law and a comprehensive food and drug law (Swan, 1998). The scope of agency control was again widened in 1938 when a false eyelash product blinded hundreds of women. New FDA scope then included the regulation of cosmetics and medical devices, which the Post Office Department and the Federal Trade Commission had overseen to a limited extent prior to 1938 (Swan, 1998).

Even today, the FDA's changing and politically charged role can be seen in cases like Vioxx (rofecoxib) painkiller. Created by Merck & Co. for the management of acute pain in adults and approved by FDA in 1999, by the fall of 2004, Vioxx was withdrawn due to safety concerns of an increased risk of heart attack and stroke. Since 1862, the agency has done much to safeguard public health in line with its charter to protect and promote public health, but the FDA has also made mistakes along the way.

Defining the Medical Device Industry within Life Sciences

There are four generally accepted segments within the Life Sciences industry. All segments are regulated by the FDA. These segments are Pharmaceuticals, Medical Devices, Biotech (Genomics) and Nutraceuticals. The Health Services segment, consisting of hospitals, physicians and health care insurers, is a related industry, but is generally seen as separate from Life Sciences. To contrast the business models and segments within Life Sciences, pharmaceutical enterprises are generally very large, global conglomerates with well-established vertical and horizontal integration. Over the

past decade, there have been significant mergers in this part of the industry, increasing the growth of these firms. Nutraceutical firms produce vitamins, homeopathic remedies, and alternative health products meant to maintain a healthy state; these companies are generally small.

In the broadest sense, Biotech or Genomics companies focus on genetic-based solutions to health problems. Because the technology is relatively new, the business model has evolved from research laboratories, and most of these companies are small, research and development efforts seeking their first commercial product. Amgen and Genentech are large company exceptions to this generalization.

Medical Device firms are generally small to mid-sized manufacturers, although some very large entities such as.Tyco, Johnson & Johnson and St. Jude exist as well. Their medical devices are broadly defined by law as anything, intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease (Schooley, 1998). The devices are classified by the FDA into the hierarchy of three risk classes each with progressively narrow approvals and tighter regulation:

Class 1 – includes devices like microscopes, scalpels, lab equipment, and wheelchairs

Class 2 – includes devices like orthodontics, diagnostic computers, condoms, and catheters.

Class 3 – includes devices like shunts, defibrillators, implants, surgical dusting powder, and synthetic ligaments.

FDA requires registration of devices and their source firms; the recent public listing of such firms totaled more than 38,000 registered firms in the United States and its

territories. Clusters of medical device producers exist near the best universities and near available venture capital to fund promising products and entrepreneurs who are trying to move from university research labs into commerce. These technology clusters are concentrated in and around the North East Corridor (N.Y. = 2,940, N.J. = 1,173, CT. = 593, MA. = 1,190, totaling 5,896) and in CA. (5,722 registered firms).

Historical Perspective of Computer System Validation and FDA Regulations

In the late 1960s, when computer applications were first considered for use to launch nuclear missiles or to avoid the meltdown of nuclear reactors, it was vital that the applications performed as they were supposed to, without fail. Software testing, another term for validation, emerged as a critical process. References from that era are still considered by many to be the best guides for software testing methodology and to provide good tests to catch bad software (Myers, 1979).

In the transitional time, between 1993 and 1997, when the new computer regulations were announced for Life Sciences, the FDA claimed it wanted to encourage industry to adopt technology, but had to ensure that software and system development activities would result in systems that did what was intended. They sought software development best practices. The industry presented an overview of the validation products believed necessary to demonstrate a reliable and consistent computer system (Grigonis & Wyrick, 1994; Budihandojo et al., 2001). Such studies were considered by the FDA prior to its 1997 Final Rule on Part 11, at a time when industry, too, was struggling with the ideal scope and degree of CSV.

Quality Management texts provided an overview of various quality practices throughout industry along with overviews of then eminent practitioners like Crosby,

Juran and Deming (James, 1996). However, there were no best practice *computer validation* requirements included in the text, even though the subject was widely discussed as early as 1994, and long before Myers in 1979.

Between 1992 and 1998, the FDA determined that 79%, or 192 of 242 medical device recalls were caused by software defects that were introduced when changes were made to the software after its initial production and distribution (FDA, 2003, p. 6). With this challenge facing them, the FDA believed it needed rigor in its regulations if such regulations were to benefit public health.

Also in 1996, the literature described numerous Project Management topics, including Software Development Life Cycle (SDLC) methodologies (Forsberg, Mooz & Cotterman, 1996). The literature described a *Spiral Method* that allowed for iterative development of prototypes, as well as a more *gated* methodology like the *waterfall*. The gated V methodology was eventually adopted by FDA as their SDLC of choice.

The FDA looked to the Good Automated Manufacturing Practices (GAMP) V methodology, that is in its fourth iteration, and considered by many to be the validation bible (GAMP, 2001). It was an earlier version of GAMP that the FDA adopted in 1997 as the agency's first guideline because it satisfied the need for an effective and documented state of control (GAMP, 2001). GAMP now serves as the latest methodology for both computer systems validation and embedded software validation.

The specific law, 21 CFR para 820.70(i), requires that systems be validated for their intended use. All production and/or quality system software must have documented requirements, which fully define its intended use, and against which testing results and other verification evidence can be compared, to show that the production and/or quality

system software is validated for its intended use (FDA, 2000, p. 4).The regulation applies to software used to automate device design, testing, component acceptance, manufacturing, labeling, packing, distribution, complaint handling, or to automate any other aspect of the quality system (FDA, 1997, p. 6). The original text of the rule, along with detailed terminology was then subsequently used in inspections at several regulated companies. This regulation is still in place, but its impact on industry was changed by later guidance in 2001 and then again in 2003 (FDA, 2000; FDA, 2003).

Recalling the rules since 1997, one author asserted that Part 11 has had a chilling effect (Smith, 2004). The effect has been that it created a reluctance to authorize dependence on new systems or technologies in the risk-averse industry. Another author recalled that the Pharmaceutical IT staff was jarred into a compliance environment with 21 CFR Part 11 in 1997, IT Principals play a major role in the selection and implementation of networks, and must have a clear understanding of the regulatory compliance aspects of the network (Fields, 2003). Fields described the requirements for FDA compliance as it related to networks connecting computer systems being used in a good lab practices environment.

When the FDA expanded its regulatory scope to include business software regulation in 1997, business software itself was in a state of flux. Two significant external events were underway. One was the emergence of enterprise-wide software solutions, and the other addressed concerns over the transition between calendar years beginning with 19 and the new millennium, Y2K. With all the anxiety about the millennium changeover, many companies between 1997 and 1999 chose Y2K as their overarching reason to adopt the newest business software ERP. Such a seldom-occurring reason could

not have been factored into the various technology adoption models, even though it proved to be a major impetus for ERP adoption.

Prior to the development of packaged ERP, most business software was developed within a company for its own specific purposes and the application generally focused on vertical, departmental requirements. There were financial packages, warehousing packages and manufacturing planning packages. These independently developed applications had created islands of data within a company because the applications were seldom integrated. ERP changed that approach. ERP also launched a new concept of the horizontal enterprise, with business processes spanning multiple departments. ERP then provided functionality, which, for Life Sciences was regulated by FDA (e.g., manufacturing, labeling, recalls).

ERP also enabled value chains that could stretch beyond the enterprise from suppliers upstream to consumers downstream. It integrated all company transaction systems on a common database. This could be done by entering a piece of master data just once, and all elements of the enterprise used it. At the same time, there were a number of ERP implementation failures, like FoxMyers Drugs, which led to the company's bankruptcy (Scott, 1999; Jesitus, 1997). These failures gained notoriety, which was a situation that did not escape the watchful eyes of the FDA. This led to greater emphasis on CSV and ERP success methodologies and further emphasis on the benefits of ERP technology.

ERP success stories were also published. A series of lessons learned and compliance requirements from the 2001 implementation of ERP at Medtronic MiniMed, Inc., was one such success (Rodriguez, 2003). The Validation Deliverables were

described which included a Validation Plan, the Software Vendor Audit, High Level Requirements Specifications, System Requirements and Design Specifications, Process Flow Diagrams, Test Scripts, Installation Qualification, Operational Qualifications, Data Conversion Protocol, Performance Qualification, Training Documentation, Traceability Matrix, Change Control documentation and Certificate of Validation (Rodriguez, 2003).

There were tangible and intangible benefits that companies had received from deployed ERP applications in their businesses. These included 20% reductions in inventory levels, 5% cost reductions in material costs due to improved purchasing productivity, 10% reductions in labor costs due to improved productivity and the reduced need for overtime, and the increased sales of 5% due to improved customer service (Hamilton, 2002). Such impressive results added to the perception that ERP should be adopted.

Just as ERP was a disruptive technology in this timeframe, so was the broader concept of commercial *off the shelf* (COTS) software that was created by entities which became de facto development departments for companies that purchased the new software applications. Many companies came to believe it was no longer necessary to maintain and staff a capable IT development department. The independent software vendor would provide maintenance in perpetuity, as long as the company paid its annual maintenance fees.

When this new thinking and technology finally prevailed by 1999, driven as it was by fear about Y2K, the days of massive, proprietary applications were over. With that change, many of the rigorous validation best practices that existed in the old Information Technology (IT) had evaporated.

The FDA finally began to enforce its 1997 rules, but only after the world's Y2K concerns had passed. A plethora of guidebooks and self-audits abounded that provided numerous recommendations for validating computer systems according to the 1997 FDA rules (Grunbaum, 2000). Just as the Life Sciences industry was convinced that CSV was required, the FDA rules were altered in 2000, and new guidance was issued (FDA, 2000).

There are also those who believe the FDA rules can be beneficial in their own right, and that IT professionals should not need the FDA to mandate validation rigor. Neal (2003) thought that the true business value of validation was achieved through a 13-step plan for success. Neal's article was the stimulus for two possible survey questions: (1) In how many computer system validations have you participated since 1998 (to assess the knowledge base of the respondents)? (2) In what capacity did you participate in the most recent computer system validation?

Most recently, the FDA changed the rules again and released similar guidelines on computer systems validation (CSV), but also introduced a new concept of enforcement discretion based on risk-based assessments (FDA, 2003, p. 6). This meant that full enforcement would be limited to an extent yet to be determined by field inspections. The guidelines still mandate that records that are required to be maintained or submitted must remain secure and reliable in accordance with the predicate rules. Such *Guidance for Industry* documents are generally for comment, and then are formally issued. This guidance document also withdrew all previous guidance and had the effect of confusing the industry (Smith, 2004). Businesses thought they heard *less enforcement*, but they needed reassurance. The agency echoed these concerns,

> Concerns have been raised that some interpretations of the Part 11 requirements would: (1) unnecessarily restrict the use of electronic technology in a manner that is inconsistent with FDA's stated intent in issuing the rule, (2) significantly increase the cost of compliance to an extent that was not contemplated at the time the rule was drafted, and (3) discourage innovation and technological advances without providing a significant public health benefit (FDA, 2003, 3).

This was much different from the claim of no impact by the FDA in 1997.

Importance of the Empirical Study Conducted

There is a health care crisis looming, and technology may be the only solution to this crisis. The combination of an aging baby-boomer population, highly paid health care providers, and ever-more expensive and effective treatments is conspiring to produce a major crisis in access to health care (Hadorn, 2004). What is needed the most is beneficial technology. However, the current regulations may deter adoption of technology. Models of technology diffusion have provided little, if any, empirical data on the actual impact of such regulations on adoption. This study sought to quantify the affect that FDA regulations have had on ERP adoption by Medical Device companies. Knowing that regulations deter diffusion means that agencies must consider mitigating incentives as part of their regulatory impact assessments.

Without new knowledge in this area, future faulty thinking about the impact of regulations could create undesirable barriers for progress in the Life Sciences industry. As the Life Sciences industry seeks to bend new, commercially available technology to

the pressing needs of public health, the efforts may be unfavorably acted upon by regulators. This situation was illustrated in the case of remote medical care via telemedicine (Schooley, 1998). In the context of FDA pre-approval of Medical Devices as related to Telemedicine, the FDA could spawn rules under 21 USC Section 231(h) that would allow the FDA to regulate the communications software component of telemedicine as a medical device. This would result in a promising improvement to health care being technologically out-of-date by the time rigorous FDA approvals of the device could be obtained (Schooley, 1998).

There is already evidence that for medical device firms, the increasing stock of medical device rules has reduced industry compliance among device firms because these rules have increased the complexity and the scope of regulation (Olson, 1999). This situation has made it too costly for smaller firms to stay abreast of rules. A fear of publicly reported non-compliance, with its ensuing impact on stock prices, has driven the medical device industry to be risk-averse, thus, slowing the rate at which firms choose to adopt and obtain approvals for new technology. Risk aversion in the industry, then, would also mean laggardly adoption practices for business software, if the diffusion framework were accurate.

Joshi and Krishman (2002) said regulators need to know the full costs of the regulations to determine the best mix of regulations to benefit society as a whole. This is especially true in the case of FDA regulations for computer system validation and Part 11. The researcher sought to discover quantitatively the impact that the regulations have had on the industry.

CHAPTER 3: Methodology

Overview

This quantitative study researched the differences in the mean times for ERP business software adoption between Medical Device companies and non-regulated High Technology firms. It was postulated that computer system validation requirements have caused Medical Device companies to be more conservative in adopting ERP than similar non-regulated companies. An online survey instrument was used to collect empirical data from randomly selected subjects from lists of IT managers.

Restatement of the Problem

Regulatory activity has delayed the adoption of business technology in the Life Sciences industry. This concern was the impetus for the quantitative study; it was important to determine whether laws and regulations delayed progress. Empirical data were collected to answer these research questions:

1. Have medical device companies installed ERP applications later than similar but non-regulated high technology companies?
2. Do Medical Device IT managers familiar with the computer system validation regulations mention compliance with such regulations as a concern in their decision to implement ERP?

This study was conducted at a time when health care costs were spiraling out of control. The ever-increasing burden of aging baby boomers threatens to crush the health care system. Government regulators claimed there would be no economic impact from their regulations on the industry, and Technology Adoption studies ignored the potential affect of compliance on technology diffusion. The convergence of these situations created

a growing challenge. It is a situation that is unlikely to improve the United States' economy or public health, and it may have actually had a deleterious impact on progress in this vital segment of our economy.

Government agencies are required to conduct RIAs if the economic impact of an envisioned regulation will exceed $100 million for the United States economy, not just the industry affected. When an agency can show there will be no such impact, the RIA can be avoided, and mitigating activity ignored.

Separately, technology researchers purport to have developed useful models, which describe characteristics that influence the speed of diffusion for a technology. These constructs include the prospective decision makers' perception of relative advantage, compatibility, complexity, divisibility, and communicability. However, a review of the literature on technology adoption showed that regulatory compliance was not given due consideration as a factor influencing adoption.

In a broad sense, if regulation of a technology inhibited the adoption of such a technology by business, it is a significant problem, but such large-scale issues are in the realm of legalistic-economics (Coase, 1991) and were beyond the modest scope of this study. This research was limited to whether such a phenomenon occurred, in the case of FDA and ERP, and whether the results of empirical data reduced the uncertainty of the effect. Thus, the specific practical problem researched was whether the FDA requirements for CSV, as they pertain to ERP software, delayed ERP adoption rates in the Medical Device segment of the Life Sciences industry. The study compared ERP adoption rates in the industry with those of similar-sized, non-regulated, high technology (NRHT) firms to arrive at a conclusion.

This study addressed this problem for several reasons. The first reason was that if these regulations actually slowed progress, it was contrary to the published determination of impact asserted by FDA in response to the legal requirements for new regulations. Another reason was if these regulations created the sort of perceived complexity diffusion models predict then that would delay the adoption and inherent business benefits of ERP. Another reason was that knowledge of this situation might contribute to a better understanding of the affects of future regulations. Finally, such knowledge can point the way toward mitigating activity, and perhaps even contribute to improving the healthcare delivery infrastructure of Medical Device businesses in the United States.

Statement of Hypotheses

Three variables were selected that could provide insights about the underlying factors. Data were needed to determine if there was a measurable difference in adoption timing of ERP between regulated medical device firms and similar but non-regulated firms. This analysis demanded that a statistically adequate and representative sample of Medical Device IT (MDIT) managers at Medical Device firms be identified and sampled. Similarly, another random sample of IT managers from equivalent but non-regulated firms was identified and participated in the study. These IT managers were from non-regulated High Tech (NRHT) firms.

Another consideration was necessary to determine whether MDIT decision makers were familiar with the regulations that would have influenced the installation of their ERP system so that their decisions were *informed* decisions. This was an important element because if the MDIT decision maker was ignorant of compliance impact to installation cost, schedule, and complexity, he made an adoption decision without

considering this factor. That meant a perception-only decision that may have resulted in IT project failure(s), and thus contributed to even more laggardly adoption(s) in the future.

Finally, it was important to determine whether the MDIT decision makers perceived the regulations as a significant reason to be conservative or laggardly in implementing ERP. If diffusion researchers Bansler, Damsgaard, Scheepers, Havn, and Thommesen (2000), and Brown and Ehlen (2003), are correct, there are a multitude of factors that influence how quickly a given technology is adopted, and then diffuses its perceived benefits throughout the marketplace. *Compliance,* as a factor, fits best in the complexity construct, and as a result, an instrument question related to complexity was developed to capture responses like regulation compliance.

The null hypotheses proposed for the research was as follows:

> **H_{01}** - There is no significant difference between the mean *go-live* dates for ERP in the MDIT segment compared to that for NRHT enterprises. That is, the regulated MDIT departments adopted ERP at the same mean point-in-time as did the NRHT departments.
>
> **H_{02}** - Medical Device IT managers familiar with the computer system validation regulations mention compliance with such regulations as a concern in their decision to implement ERP.

Alternative hypotheses were then:

> **H_{A1}** - There is a significant difference between the mean ERP adoption dates in the regulated Medical Device segment and that for non-regulated

enterprise. That is, MDIT departments adopted ERP later than the mean point-in-time the non-regulated IT departments adopted ERP.

H_{A2} - Medical Device IT managers familiar with the computer system validation regulations do not mention compliance with such regulations as a concern in their decision to implement ERP.

The quantitative analysis that follows allowed the null hypotheses to be rejected or accepted. Variables consisted of:

1. Independent variable – regulation status; either High Tech (not regulated) or Medical Device (regulated). Two classifications.
2. Dependent variable – mean time of go-live of ERP application.

Table 3

Hypotheses with Related Survey Question

Hypothesis	Variable	Related Questions	Analysis
H_{01} There is no difference between the mean ERP start dates in the regulated Medical Device segment compared to that for non-regulated enterprises.	Mean of ERP installation dates	1,12-13	t-test
H_{02} Medical Device IT managers familiar with the computer system validation regulations mention compliance with such regulations as a concern in their decision to implement ERP	Factors mentioned	4-11,14-15	ANOVA with Bonferroni

Table 3.

Hypotheses with Related Survey Question (continued)

Hypothesis	Variable	Related Questions	Analysis
H_{A1} There is a difference in the mean ERP start dates in the regulated Medical Device segment compared to that for non-regulated enterprises.	Mean of ERP installation dates	1-3, 12-13	t-test
H_{A2} Medical Device IT managers familiar with the computer system validation regulations do not mention compliance with such regulations as a concern in their decision to implement ERP	Factors mentioned	4-11,14-15	ANOVA with Bonferroni

Description of Research Design

A quantitative study of several factors was used to accept or reject the null hypotheses. The first factor was a comparison of the mean ERP start time of NRHT versus MDIT firms. Test of the means (t-test) was used for this comparison and an appropriate effect size (Hinkle, Liu, & Cox, 2003). This test was preceded by the determination of sample size.

Based on the researcher's extensive experience in the field of ERP installations, a size effect of less than 6 months (a directional one-tail test) would *not* be indicative of

delayed ERP adoption. The survey instrument measured this level of difference with a probability of better than 50% (power of test greater than 0.50).

The survey instrument collected data from both MDIT and NRHT independent samples sufficient to calculate and plot the mean ERP installation time for both groups. An assumption was made that data from both samples was normally distributed along the time dimension of minus 48 to plus 48 months with *today* being 0 on the plot. This yielded a σ of 1.65 equal to 18 months. The sample size n was then derived as follows:

$$\sigma_{\mu 1} = \sigma_{\mu 2} = \sigma/\sqrt{n}$$

$$\mu_2 = \mu_1 + 1.65(\sigma/\sqrt{n}) = 6 \text{ months} = \mu_1 + 1.65(18 \text{ months} /\sqrt{n})$$

$$\sqrt{n} = 1.65(18)/6 = 4.95, \text{ making}$$

$$n = \sqrt{4.95} \approx \sqrt{5}$$

$$n = 25$$

Thus, the minimum sample size needed in each independent sample to detect a 6 month difference in means with 50% or better probability was 25 responses. Furthermore, the online availability of the instrument meant that dynamic sampling could result in even larger samples that would improve the power of the test.

Therefore, for $\mathbf{H_{01}}$ to be accepted, the acceptance criteria was that the mean ERP start time for MDIT be within 6 months of the mean for NRHT ERP start time. If this was not the case, and the start time for MDIT ERP was more than 6 months later, the null hypothesis could be rejected with confidence.

However, rejecting $\mathbf{H_{01}}$ in this way did not mean that the reason for laggardly adoption had anything to do with the regulatory compliance factor, nor that compliance was even considered by MDIT decision makers in the timing of their adoption decision.

For this element of the study, a separate question was presented to reflect the degree to which (not important, somewhat important, important, critically important, do not know) the compliance requirements affected decisions to adopt ERP.

It was also possible that some MDIT ERP projects were launched as *preventive innovations* (Rogers, 1962, 2003). These projects were adopted early in order to lower the probability of some future event. More specifically, firms adopted Y2K-compatible ERP packages in order to avoid Y2K problems. Firms have also adopted ERP in order to avoid likely FDA citations for older non-compliant systems. For these reasons, accelerating adoption of ERP may have outweighed all other considerations in the decision to change technology. However, studying the weight of decision factors favoring ERP adoption was beyond the scope of this work. Instead, examination of the survey process considered that one question be developed to measure the level of concern MDITs showed toward FDA compliance efforts. As a result, if there was delayed adoption ($\mathbf{H_{A1}}$ is accepted), then there would also be evidence that compliance with regulations was a factor in this type of delay.

Thus, for $\mathbf{H_{02}}$ to be accepted, the acceptance criteria was that a majority of MDIT selected compliance with FDA regulations to describe concerns that were a consideration in the adoption of ERP. This response would need to be selected by 50% or more of the MDIT respondents in order to reject this hypothesis.

In this way, the combined results of the study provided enhanced evidence to demonstrate whether or not regulations have had an affect on industry, and if there was an affect, demonstrated the amount of delay of ERP adoption by MDIT as compared with

NRHT firms. This strengthens the case that FDA was incorrect to claim their regulation would have no impact on industry.

In addition, the responses for ERP installation dates were plotted along a time continuum to create an S curve common in diffusion studies. The curve for medical device respondents was compared to that for non-regulated respondents. If $\mathbf{H_{01}}$ is true, there will be little separation between these curves. However, the greater the separation between the plots of the S curves for diffusion is substantiating evidence that industry differences exist.

Examples of the sort of S curves that were anticipated in this study are shown in Figure 1. Comparing example data, the Medical Device diffusion curve is illustrative of conservative or laggardly adoption relative to non-regulated high tech contemporaries.

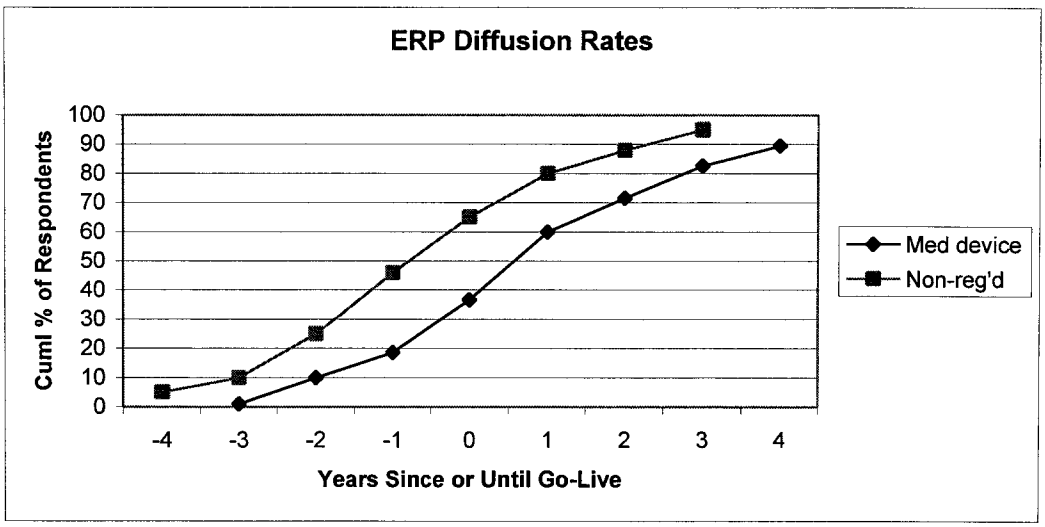

Figure 1. Example of comparative diffusion rates based on timing of ERP *go-live*

Finally, there was a need to measure the extent to which the MDIT decision makers perceived the CSV compliance requirements as a factor influencing his/her decision to either accelerate or delay an ERP adoption. Data on this factor was expected to provide evidence to substantiate a generalization that regulation had slowed ERP

adoption. It would also permit stratification of the decision makers into adopter categories (e.g., Late Majority).

The study commenced with the development of an online survey instrument designed to measure perceptions of the respondents, identify MDIT and other decision makers as to their role, compare the responding firms' sizes, and then capture actual or planned ERP *go-live* dates. Two distinct but similar instruments were developed. They were identical except that MDIT decision makers were asked an additional question that related specifically to their validation experience with FDA compliance.

Operational Definition of Variables

Variables to be used in the study included:

- Independent variable – being regulated as an MDIT company.
- Dependent variable – month-year of installation of ERP application.
    - The measurement units were the number of months the mean *go-live* date (month-year) for medical device manufacturers differed from that of non-regulated high tech manufacturers. If the means were more than 6 months different, the hypotheses that there is no difference would not be accepted.

Description of Materials and Instruments

A unique instrument was developed for this research and subjects were invited to participate in the survey. Refer to Appendix A for the Invitation to Participate, and Appendix B for the Survey Instrument.

A potential weakness in the study was this use of the unique, untested instrument. To mitigate this situation, two rounds of instrument testing were conducted to remove

ambiguity and to use terminology designed to result in accurate and reliable responses. Tested in this way, the researcher believes the instrument reduced the number of responses which were biased, or which may have had different meanings than respondents intended. Other forms of bias were considered and eliminated. Reviewers were also requested to assess the quality of questions in the instrument as leading questions, loaded questions, expecting too much detail, ambiguity, and their response scale (Wing, 1993, 1997).

The validation tests were conducted by informally administering the questionnaire to four professionals who had been selected based upon their work in the ERP or FDA-compliance consulting business. These individuals were asked to critically review the questions with regard to questioning ambiguity, wording, and ease of understanding the questions. Consideration of their comments resulted in changes to the initial wording, placement, and use of various questions in the questionnaire.

Once the final questions were posted to the chosen online survey site, a second round of testing was conducted before finally releasing the survey for the study. In this round of tests, the online version of the questionnaire was self-administered to several MDITs. The questions as well as the ease of use of the online survey tool were critiqued. These testers were asked to comment upon the ease of using the on-line survey tool and the terminology being used in the questions. At the conclusion of these tests, the instrument was finalized and email invitations sent to individuals in the sample lists.

The final survey instrument itself consisted of up to 15 questions. The number of questions for a given respondent varied depending up on the answers provided to several branching questions. Branching questions permitted the subsequent asking of the same or

a different group of questions. An initial branching question in this instrument was the selection by respondents of their industry. Based on a response as either regulated industry or non-regulated industry, the respondent was branched, but presented with identically worded questions (questions 2 through 6). Question 7 was similar for both respondent groups except that for regulated industry respondents, two additional compliance factors were added to the question (i.e., compliance with 21 CFR Part 11, and compliance with Health Insurance Portability and Accountability Act (HIPAA). Questions 8 through 13 were identical for both groups, and the answer to question 9 revealed if they had actually implemented an ERP application. If no ERP application had been installed, the respondent was branched and asked about intention to install ERP in the future. All branching terminated at the final question (number 15). Regulated industry respondents received question 14 which non-regulated respondents did not see; life science respondents were asked about the validation experiences of ERP decision makers. Such FDA related questions, if addressed to respondents outside of Life Sciences, were judged by reviewers to be inappropriate, and could have led to confusion. This was also a reason for the use of branching in the survey tool.

Responses to several other branching questions resulted in the respondent being routed immediately to the end of the survey. For example, the study sought to learn about the date of ERP implementation, but if the respondent's company never installed ERP, there was no need to collect installation dates from that respondent. The survey tool jumped all branched paths through the instrument to the last question and then thanked the respondent for participating. In this way, respondents were presented with relevant questions, and data were collected only when appropriate to the study requirements.

Thus, the final design of the questionnaire and the self-administering online tool obtained the demographic and comparative data needed to make an analysis and quantitative decisions on the hypotheses.

Selection of Subjects

Subjects were drawn from several sources. First, a list of IT managers compiled by Applied Computer Research (ACR), Inc., filtered the list for manufacturing firms, which was the intended base for the NRHT. Some of these subjects had email addresses, or the company web address could be used as the core email address, but the majority of subjects on that list did not. During the course of the study, it was determined that obtaining email addresses for all of the subjects on this listing would be beyond the research budget, and an alternative source of subjects was sought. Success was achieved in developing a relationship with Technology Evaluation Center (TEC), an online newsletter offering software evaluation services to a broad base of IT professionals in both the regulated and the non-regulated industry. TEC agreed to host a survey link for 2 weeks, and this resulted in an increase in both the number of subjects clicking to visit the survey site. As a result, an improved completion of the survey by subjects was achieved.

The MDIT sample was planned to be drawn from the FDA's published listing of Medical Device Establishments, and 2,715 of the 38,099 listed establishments also provided email addresses. This made the list convenient, but in retrospect, not as complete as planned given the low participation and response rates.

The online survey tool was programmed to preclude multiple responses from the same participant by tracking the computer addresses of respondents. Additionally, the survey included the ability to branch respondents into either the regulated or non-

regulated survey instrument, assuring that both these samples were independent (no invited respondent was in both groups. The TEC subjects and all subjects from both lists with email addresses were solicited and randomly opted to participate in the survey.

As calculated above, a sample size of 25 or more in each group was needed to statistically evaluate results and to justify general conclusions. The actual size of the medical device group was 21 with 6 having installed ERP, 3 projecting installation dates, 9 claiming they would never install and 2 answering "Don't know." The size of the non-regulated high tech group was over 28 and those with ERP installed totaled 22, but 3 projected install dates and 3 claimed they would never install ERP.

Procedures

Following the approval of the study proposal, the researcher conducted a quantitative study of this problem and executed the empirical study.

Specific study steps were:

1. Assembled mailing lists from the various sources.
    - CIO Magazine – would not provide researcher with mailing list email addresses for academic research.
    - Information Week – would not provide researcher with mailing list email addresses for academic research.
    - ACR – provided researcher with academic listing. Web addresses provided could be modified into email addresses.
    - FDA Medical Device Establishments – downloaded public list and email addresses were present in about 7% of the cases.

2. Tested instrument validity improvements using judges. Comments leading to improved understanding and reduced ambiguity were incorporated.
    - Colleagues
    - Local Medical Device volunteers
    - Local High Tech decision maker volunteers
3. Selected Survey Console as the on-line survey Service Provider for delivery vehicle. Question development, refinement, and further testing were implemented as appropriate. Free online survey tools considered:
    - Survey Monkey (not selected because of the name).
    - Survey Console (after the free month, a nominal charge per month was made).
4. Analyze Results - phase included clarifying bias, generalizations.
5. Documented results in the findings chapter of the dissertation.
6. Developed and wrote the conclusions and recommendations chapter of the dissertation.

Discussion of Data Processing

The online survey tool provided statistical data in several formats including MS Excel, which was uploaded into the statistical package, and all data analyses were performed using SPSS™, version 11.0 for Windows™, Student Version. Table 1 shows the type of analysis, t-test, that was performed.

Methodological Assumptions and Limitations

In any study, assumptions are required to make the research feasible within the researcher's time and budget constraints. A major assumption regarding the scope of this study is that no consideration was given to whether the ERP project actually lowered health care costs, promoted public health or contributed to the efficacy of the business.

There was also a potential biasing effect from use of only online survey respondents. Budget factors precluded the use of any mass mailings. However, because the information sought best comes from senior IT experts, it is unlikely that representative numbers of this segment were incapable of Internet use.

In actual practice, all publicly traded firms are regulated since the advent of Sarbanes-Oxley (SOX) regulations, and many other firms must be compliant with other regulatory bodies (e.g., Worker's Compensation, State sales tax regulations). The regulations of specific interest in this study were limited to those in Life Sciences industries and related to computer system validation and 21 CFR Part 11. These are the regulations about which the FDA claimed there would be no impact to the industry. Because the researcher had first-hand knowledge of validation costs at 2 mid-sized firms, which were in excess of $6 million, the FDA's prediction of no impact is a phenomenon that merited further examination.

Another limitation of the study, and one that creates the opportunity for future research, is that many other interesting phenomena could not be studied because of the need to limit the focus of this research. The focus was on actual or planned installation dates, but the executive decision process within these firms was not studied. Further study of the top down, authority decision process, a term that Rogers, (1962, 2003) uses

in the literature would further consider the role of executives in the implementation process.

Ethical Assurances

Prior to administering the survey for this study, approval of the Ethics Application was requested via Dr. Carol Wells, Dissertation Committee Chair from Northcentral University's Ethics Committee. Approval of the study was granted on January 19, 2005.

This study qualified as exempt or minimal risk research because respondents were invited to participate voluntarily in an online survey. They were advised that their responses would remain anonymous. They had the option to receive the study results.

CHAPTER 4: Findings

Overview

This was a quantitative study of manufacturers and the differences in the installation dates for ERP business software adoption between regulated medical device companies and non-regulated high technology firms. In this chapter, the findings are provided that have been derived from the empirical study, the analysis and evaluation of the findings follow, and subsequent to this, a summary is included that highlights the findings.

Using an online survey instrument validated by the researcher, empirical data were collected from 324 respondents, representing a range of industries. These industries included medical device and high technology manufacturing respondents for the purpose of answering these research questions:

1. Have medical device companies installed ERP applications later than similar but non-regulated high technology companies?
2. Did Medical Device IT managers, familiar with the computer system validation regulations, mention compliance with such regulations as a concern in their decision to implement ERP?

Findings

The sample procedure used in the study began with the compilation of several relevant databases. The primary list of potential respondents was from the FDA's published list of worldwide Registered Establishments, which was available and downloaded from the FDA's web site. Mailing addresses, telephone numbers and device filing information were included in the listing for 38,099 medical device companies. A

data field for email address was included in the list, and a total of 2,314 email addresses were available from the list. This list served as the sample frame for regulated medical device companies, and yielded 19 of the 26 medical device manufacturer respondents.

A secondary list of 15,271 named Information Technology (IT) managers and Chief Information Officers (CIOs) was purchased from Applied Computer Research (ACR) to serve as the sample frame for non-regulated high technology companies. This listing provided contact information and mailing addresses, but did not include the email addresses of the named contacts. The list provided company web site addresses from which a general administrative email address was constructed for 170 companies, but this yielded only 1 of the 34 high tech respondents.

A tertiary email address listing of 79 medical device contacts was compiled from contact lists, and Newsletters from American Society of Quality (ASQ) in Southern California. The ASQ list yielded six responses, which included one medical device respondent and one high tech respondent.

Readers of the online newsletter from Technology Evaluation Centers, Inc. (TEC) were invited to participate in the survey during a two-week period, once the survey was underway. About 1,262 TEC readers, generally high tech IT managers, visited the survey site and 221 completed the survey, with 6 medical device and 32 high technology respondents.

A search of the researcher's alumni database uncovered 129 named contacts in both regulated and non-regulated companies to whom the invitation to participate was emailed. Finally, a small business contact listing of 5,836 email addresses including

subjects in both regulated and non-regulated companies was acquired and yielded 57 responses, but no medical device or high tech respondents.

In total, the sample consisted of 420,831 company contacts to whom a sampling of 8,617 email invitations were sent. A random sampling existed because invitations were sent to every company for which an email address was available. The response rate from these groups is shown in the table 4. An overall response rate of 3.8% was achieved. This was a low response rate, but the number of respondents in the two critical industries met or exceeded the size parameters estimated as needed to measure statistical significance, and to determine the difference in the mean installation dates for these two independent samples. There were 25 respondents in each group.

Table 4

Source and Sample Frame for Study

Source of listing	Maximum sample	Actual sample	Viewed Survey (did not complete)	All Respondents (%) w/2 reminders	Med Dev Respondents (%)	High Tech Respondents (%)
FDA List	38,099	2,314	38	29 (1.25%)	19	0
ACR List	15,271	170	0	1 (0.6%)	0	0
TEC respondents	363,050[1]	1,262	1,041	221 (17.5%)	6	32
ASQ List	79	64	1	6 (9.4%)	1	1
Alumni list	129	103	0	10 (9.78%)	0	0
SME List	5,836	4,704	17	57 (1.2%)	0	1
Totals	422,464	8,617	1,097	324 (3.8%)	26	34

[1] TEC eNewsletter demographics, March 31, 2005

The questionnaire used in the survey was developed especially for this study. Because the questionnaire had not been used in any prior studies, validating the survey was necessary. This was accomplished using instrument reviews conducted by judges (experienced professionals known to the researcher) similar to the approach recommended by the literature (Moore & Benbasat, 2001). The first such judge was a highly skilled developer of testing materials for a government agency. His reviews of the question structure, sequenced procedures and wording led to changes in these elements and the elimination of several unnecessary questions, which served to shorten the overall survey in anticipation of more respondents.

Next, the instrument was reviewed by three judges knowledgeable in both ERP installation methods as well as the FDA regulations pertaining to computer system validation. These judges checked the instrument for question ambiguity and for industry terminology that might be confusing to respondents. The suggestions from this set of judges were also incorporated, and the final instrument was posted to the online survey site for further testing.

A final round of instrument testing was conducted by all earlier judges using the online survey process in the same way that respondents would experience the instrument. This included receipt of an email invitation to participate in the survey, as shown in Appendix B, the connection link to the survey web site was activated by clicking on the site address imbedded in the invitation, and finally responding to the questionnaire. Comments and suggestions from the judges were incorporated to create the final self-administered instrument on the web site, and the survey was launched on 7/24/05. Responses were received online for nearly three months.

At the closing of the online survey on 10/15/05, results for each question were tabulated and these are summarized with an overall comparison provided in Appendix C. This comparison represents the differences between regulated manufacturing respondents, which included pharmaceutical, nutraceutical and medical device industry respondents, and non-regulated respondents who were made up of consumer goods manufacturers as well as high-tech manufacturers. It is beyond the scope of this dissertation study to analyze differences and similarities between these two larger groupings of regulated and non-regulated respondents. The focus is on only the medical device (regulated) and high technology (non-regulated) manufacturers.

Survey question 9 asked respondents whether their company had installed ERP software, and if the response was positive, the month-year of the installation was requested. If no ERP was installed, the survey asked respondents to describe their plans for a future installation of ERP. The resulting planned installation data were reconfigured, and was considered in the final analysis. The researcher was justified in including the planned installation periods because as claimed by Waarts, "intention is a fairly good predictor of self-reported usage behavior, and actual behaviors," (Waarts, 2002, p. 418).

Amongst the high technology respondents, 18% (6 out of 34) stated they were unlikely to ever implement an ERP solution, and 58% (15 of 26) of the medical device respondents claimed they too were unlikely to ever adopt ERP. The researcher believed it was appropriate to include these "unlikely to install" responses in the analysis because in the longer term, viable businesses will need the benefits of ERP to help them grow. However, an install date was assumed to be 60 months in the future and both groups were

treated in the same way. The resulting month-year installation data is provided in Appendix D.

Analysis and Evaluation of Findings

In this section, the explanation for each finding is discussed along with a statistical assessment of the significance of the results. Only responses from the two relevant industries were further analyzed.

A comparative analysis of the later responses to earlier responses was conducted to determine if the late responses differed materially from the majority so that non-response bias, if not reduced, was at least noted in the final study results. Table 5 demonstrates that there were differences between early and late responders in a broad sense. However, this can be explained by the fact that medical device participants were invited to participate in the survey several weeks earlier than the other respondents because email addresses for that list were available earlier.

Table 5

Response Timing Bias

	Response Timing		
Categories	Early	Late	Total
Industry	30	30	60
High Tech	8	26	34
Med Dev	22	4	26
ERP	8	21	29
Yes-HT	3	19	22
Yes-MD	5	2	7

Another concern related to bias was the uncertainty associated with Y2K inspired installations. That concern prior to 2000 may have been viewed as a decision impetus, which carried more weight at the time than the FDA regulations or any other diffusion-influencing factors. This type of decision process influenced many companies prior to 2000. As a result, the responses of those subjects who implemented ERP prior to 2000 were scrutinized for evidence of this type of bias. There were 2 medical device respondents with systems installed prior to Y2K. Their responses to question 7i (Y2K compliant) regarding importance were inconclusive. One responded that the initial installation had viewed Y2K as somewhat important, while the other respondent skipped that question altogether.

Table 6

Pre-Y2K Installations by Industry Respondent

	Total
Pre-Y2K	5
HT	3
MD	2

The survey instrument responses were numeric but ordinal rather than scaled, and so a nonparametric analysis, such as Spearman's rho was judged to best represent both the meaningful and statistically significant relationships between the variables demonstrating significance. Analysis of data from the medical device and high technology industries yielded extensive correlation data, which is shown in full in Appendix E, with the resulting significant nonparametric correlations summarized in Figure 2. These consisted of Industry (either Medical Device or High Tech), Founding

(age of firm), Employees (a proxy for the size of the firm), Timing (the self-judged adopter category) and the dependent variable of ERP (installed or not).

Correlations

			Industry	Founding	Employees	Timing	ERP Y=1	Install duration	CSV Knowledge
Spearman's rho	Industry	Correlation Coefficient	1.000	-.212	-.452*	.280*	.370*	-.201	.
		Sig. (1-tailed)	.	.052	.000	.017	.003	.220	.
		N	60	60	60	57	54	17	5
	Founding	Correlation Coefficient	-.212	1.000	.527*	-.048	-.409*	-.131	.000
		Sig. (1-tailed)	.052	.	.000	.361	.001	.308	.500
		N	60	60	60	57	54	17	5
	Employees	Correlation Coefficient	-.452*	.527*	1.000	-.057	-.494*	.345	-.574
		Sig. (1-tailed)	.000	.000	.	.337	.000	.088	.156
		N	60	60	60	57	54	17	5
	Timing	Correlation Coefficient	.280*	-.048	-.057	1.000	.437*	-.011	-.354
		Sig. (1-tailed)	.017	.361	.337	.	.001	.483	.280
		N	57	57	57	57	53	17	5
	ERP Y=1	Correlation Coefficient	.370*	-.409*	-.494*	.437*	1.000	.	.
		Sig. (1-tailed)	.003	.001	.000	.001	.	.	.
		N	54	54	54	53	54	17	5
	Install duration	Correlation Coefficient	-.201	-.131	.345	-.011	.	1.000	-.816
		Sig. (1-tailed)	.220	.308	.088	.483	.	.	.092
		N	17	17	17	17	17	17	4
	CSV Knowledge	Correlation Coefficient	.	.000	-.574	-.354	.	-.816	1.000
		Sig. (1-tailed)	.	.500	.156	.280	.	.092	.
		N	5	5	5	5	5	4	5

**. Correlation is significant at the .01 level (1-tailed).

*. Correlation is significant at the .05 level (1-tailed).

Figure 2. Nonparametric correlations: medical device and high technology

The variable labels in the table merit further explanation. "Industry" as coded in survey results had a value of 1 for high tech respondents and 6 for medical device. "Founding" represented the age of the firm, with low values being younger and high value responses being older firms. "Employees" represented the size of the firm, again with low values being smaller firms and high values larger enterprises. "Timing" was a

representation of the respondent's Adopter Category expressed in a range between 1 as early adopter to 6 being laggards. Finally, "ERP" values are 1 if installed and 2 if not installed. Higher numbered responses included other choices.

As described in Hinkle (2003 p. 109), interpreting correlations depends on the size of the correlation, with the following as guidelines:

.90 – 1.00	Very high correlation
.70 - .90	High correlation
.50 - .70	Moderate correlation
.30 - .50	Low correlation
.00 - .30	Little to any correlation

Given the above guidelines, it becomes clear that there is a low correlation between Industry (.370) and installation of ERP, with high tech firms more likely to have installed ERP than medical device firms to have installed ERP. This finding becomes clearer in the subsequent comparison of actual installation and projected installation month-year data in the sections that follow.

The data further showed a low negative correlation between the age of the firms (-.409) and the size of the firm (-.494) to having installed ERP, but the negative direction in the table correlation can be explained by the response values in the survey instrument (i.e., a smaller instead of larger value representing the installation of ERP). Thus, this finding is not out of line with earlier technology adoption research showing that a firm's age and size positive influence early adoption of technology (Thong, 1995; Al-Qirim, 2001).

Especially interesting is the correlation is between Timing, the self-assessed description of respondents' Adopter Category as relates to the adoption of business software technology, and the installation of ERP. The data shows a low correlation between Early Adoption (.437) and installed ERP, validating the claimed adoption practices of respondents to actual behavior (at least as far as ERP adoption practices). Likewise, there is some correlation, albeit small, between Industry and Timing (.280). This leads to a finding that medical device respondents are more laggardly than their high tech cohorts. A further comparison of the mean ERP installation dates added support to this finding.

Analysis of the raw data from the 34 High Tech and 26 Medical Device respondents benefited from reconfiguring the raw ERP installation date data. This was because only 28 High Tech and 21 Medical Device manufacturers responded to the full set of questions related to ERP installed or planned. Respondents generally recalled the year of installation, but were less sure of the month in that year. Incomplete responses were reconfigured in the following way. If no installation year was given, it was assumed that the installation was an old install and a date of minus 72 months (October 1999) was used. This was reasonable because ERP packages were not available before 1995, and many old-install firms had rushed to beat the Y2K threat by installing ERP in 1999.

If no install month was given, the mid-point of the given install year was assumed. For respondents in either group, claiming not to have installed ERP, their plans for a future installation were queried, and this data were added to the time scale data in the following way. Plans to install within 6 months were posted as April, 2006 (6 months from the October, 2005 date of survey). Plans to install between 6 to 12 months were

posted at a 9-month mid-point, in September, 2006. April, 2007, an 18-month mid-point was used to post planned installs between 12 and 24 months in the future. Plans more than 24 months in the future were posted as October, 2007, 2 years from the survey month.

Responses of "unlikely to ever install ERP" were posted as 60 months in the future for both groups. Responses of "don't know" were not posted to the reconfigured installation time scale and not used in the further analysis of the data. These adjustments resulted in 28 useable data points for High Tech and 22 for medical device respondents as shown in Appendix D.

An assumption of a normal distribution was critical for the decision to rely on the t-test for differences in the mean of two independent samples. As demonstrated in the following histogram and a normalized curve from the data, this assumption appears reasonable for the high tech respondents.

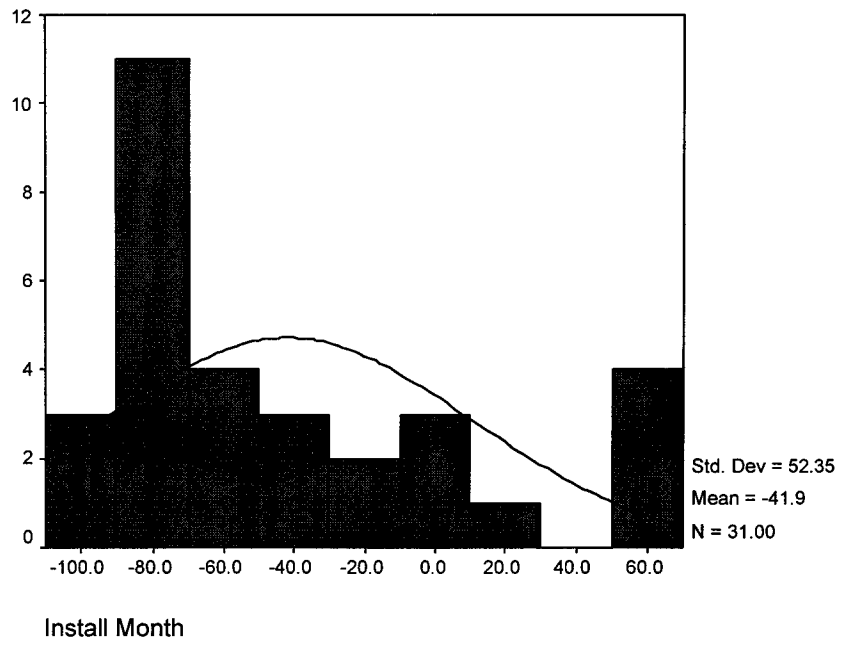

Figure 3. Normalized go-live month of high tech respondents

ERP installation date data from 22 Medical Device manufacturers were likewise reconfigured along a month-year scale and are shown in Appendix D, Table D-2. Again, the assumption of a normal distribution appears reasonable, even though the shape of the two different curves varies. As described above, the data for both high tech and medical device respondents include both actual month-year as well as the adjustments for future periods for respondents planning to install ERP.

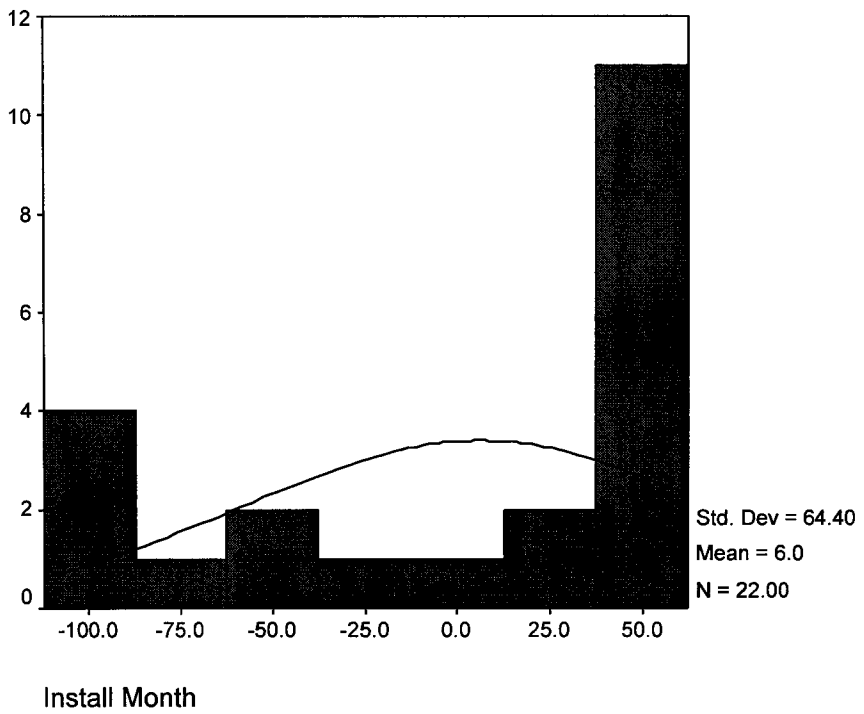

Figure 4. Normalized go-live *m*onth of medical device respondents.

The study data further compared these reconfigured ERP installation month-year data for regulated Medical Device and non-regulated High Technology respondents using an "S" curve graphic. This is the usual practice to contrast technology diffusion rates. The Medical Device respondents' diffusion curve is illustrative of conservative or laggardly adoption relative to their non-regulated high tech contemporaries.

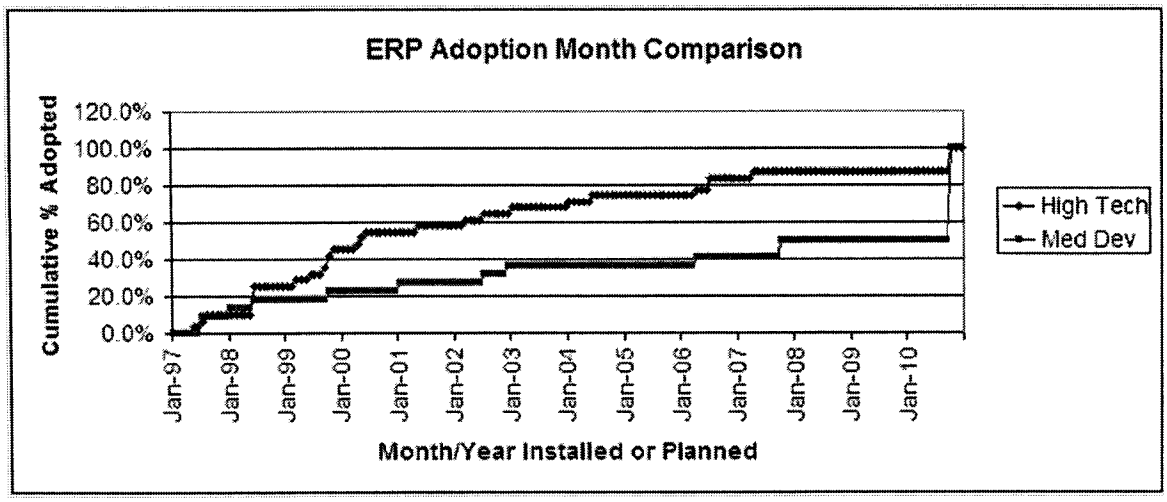

Figure 5. Study results comparative diffusion rates based on timing of ERP go-live.

Analysis of the empirical data from Appendix D is shown below for the t-test figures and supports the rejection of the researcher's primary null hypothesis proposed prior to the research. Stratifying the collected data from survey questions and using SPSS™(2001) t-test for Equality of Means, it was determined that High Tech, non-regulated had a mean ERP installation or planned installation month of -42, equating to roughly April 2002. In contrast, the mean of ERP installation or planned installation month for Medical Device respondents was 6, equating to roughly April 2006, a 48 month difference, and later than the high technology respondents. The planned installation month-year for both groups was obtained from the results on survey question 10 as reconfigured, and is included in the calculation of the means. These means are 48 months apart. The researcher stipulated that a 6 months difference would be sufficient to claim delayed ERP adoption by medical device companies. The actual difference is much greater and as demonstrated below in the t-test, is also statistically significant.

Group Statistics

	Group	N	Mean	Std. Deviation	Std. Error Mean
Install Month	High Tech	31	-41.90	52.349	9.402
	Med Dev	22	6.05	64.398	13.730

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Install Month	Equal variances assumed	3.174	.081	-2.985	51	.004	-47.95	16.062	-80.194	-15.703
	Equal variances not assumed			-2.881	39.269	.006	-47.95	16.640	-81.600	-14.298

Figure 6. Comparison of install month means for high tech and medical device

To determine whether this 48-month difference was statistically significant, and "too great to be attributed only to chance fluctuations in sampling," a t-test was performed (Hinkle, 2003, p.182).

In the t-test for Equality of Means, "Sig (2-tailed)" above is α, the risk of rejecting a hypothesis when it is true. In this case, α at .004 is less than 0.05. This means it can be claimed with greater than 95% confidence that the difference between the means at 48 months is meaningful and the null hypothesis can be rejected.

The researcher sought to empirically determine whether $\mathbf{H_{01}}$ could be rejected with confidence. The study demonstrated that $\mathbf{H_{01}}$ can be rejected and $\mathbf{H_{A1}}$ accepted.

Null Hypothesis is rejected:

> $\mathbf{H_{01}}$ - There is no significant difference between the mean *go-live* dates for ERP in the MDIT segment compared to that for NRHT enterprises. That is, the regulated MDIT departments adopted ERP at the same mean point-in-time as did the NRHT departments.

Alternative Hypothesis is accepted:

> **H_{A1}** - There is a significant difference between the mean ERP adoption dates in the regulated Medical Device segment and that for non-regulated enterprise. That is, MDIT departments adopted ERP later than the mean point-in-time the non-regulated IT departments adopted ERP.

For **H_{02}** to be accepted, the acceptance criteria was that a majority of MDIT selected compliance with FDA regulations to describe concerns that were a consideration in the adoption of ERP. This response would need to be selected by 50% or more of the MDIT respondents in order not to reject this hypothesis. Fifteen out of 26, or 57.7% of the medical device respondents claimed that compliance with FDA regulations was important or critically important to their decision regarding ERP installation. Of the 7 respondents claiming to have ERP installed, 85.7% responded that compliance was important or critically important. Three of the respondents claimed to be serving in the role of Quality Executive, and only one of them responded that compliance was somewhat important as compared to being critically important to the other two Quality Executives. In expanding the analysis to respondents with ERP installed as well as those planning to install ERP, 61.9% responded that compliance was important or critically important.

Survey questions 7a Sarbanes-Oxley Act 7g; 21 CFR Part 11; 7h HIPAA sought to measure the relative importance of regulatory compliance to respondents. While only medical device respondents even saw the Part 11 and HIPAA questions related to FDA regulations, both industries responded to the compliance query about Sarbanes-Oxley Act. The questions that related to 21 CFR Part 11 and HIPAA only appeared in the

branched survey for regulated respondents because these questions were unlikely to be understood by non-regulated respondents.

The collected data on the importance of Sarbanes-Oxley Act compliance to the independent samples, using the ANOVA test along with the Bonferroni post hoc analysis are shown in the following tables. In this one instance multiple results are compared making use of ANOVA appropriate.

Descriptives

SOX Comply

	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
					Lower Bound	Upper Bound		
High Tech	31	3.32	1.351	.243	2.83	3.82	1	5
Genl Mfgr	35	2.40	1.376	.233	1.93	2.87	1	5
Retailing	25	3.12	1.641	.328	2.44	3.80	1	5
Pharma Mfgr	6	3.17	1.602	.654	1.49	4.85	1	5
Biotech Mfgr	2	3.00	.000	.000	3.00	3.00	3	3
Med Dev	23	3.61	1.438	.300	2.99	4.23	1	5
Total	122	3.06	1.484	.134	2.79	3.32	1	5

ANOVA

SOX Comply

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	24.473	5	4.895	2.345	.046
Within Groups	242.126	116	2.087		
Total	266.598	121			

Figure 7. Comparison of means for SOX compliance

The means in this case, where 1 = Not important, reflect a level of importance at between important and critically important for all industries, with the medical device respondents at a slightly higher mean level of importance. However, using ANOVA with post hoc Bonferroni analysis the only significant difference was between General Manufacturing and Medical Device, not with the High Tech industry. Thus the difference cannot be considered significant, and the responses must be concluded to be about the same between the two industries of focus.

Multiple Comparisons

Dependent Variable: SOX Comply

Bonferroni

(I) Industry	(J) Industry	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
High Tech	High Tech					
	Genl Mfgr	.92	.356	.163	-.15	1.99
	Retailing	.20	.388	1.000	-.96	1.37
	Pharma Mfgr	.16	.644	1.000	-1.78	2.09
	Biotech Mfgr	.32	1.054	1.000	-2.84	3.48
	Med Dev	-.29	.398	1.000	-1.48	.91
Genl Mfgr	High Tech	-.92	.356	.163	-1.99	.15
	Genl Mfgr					
	Retailing	-.72	.378	.893	-1.85	.41
	Pharma Mfgr	-.77	.638	1.000	-2.68	1.15
	Biotech Mfgr	-.60	1.050	1.000	-3.75	2.55
	Med Dev	-1.21*	.388	.035	-2.37	-.05
Retailing	High Tech	-.20	.388	1.000	-1.37	.96
	Genl Mfgr	.72	.378	.893	-.41	1.85
	Retailing					
	Pharma Mfgr	-.05	.657	1.000	-2.02	1.92
	Biotech Mfgr	.12	1.062	1.000	-3.06	3.30
	Med Dev	-.49	.417	1.000	-1.74	.76
Pharma Mfgr	High Tech	-.16	.644	1.000	-2.09	1.78
	Genl Mfgr	.77	.638	1.000	-1.15	2.68
	Retailing	.05	.657	1.000	-1.92	2.02
	Pharma Mfgr					
	Biotech Mfgr	.17	1.180	1.000	-3.37	3.70
	Med Dev	-.44	.662	1.000	-2.43	1.54
Biotech Mfgr	High Tech	-.32	1.054	1.000	-3.48	2.84
	Genl Mfgr	.60	1.050	1.000	-2.55	3.75
	Retailing	-.12	1.062	1.000	-3.30	3.06
	Pharma Mfgr	-.17	1.180	1.000	-3.70	3.37
	Biotech Mfgr					
	Med Dev	-.61	1.065	1.000	-3.80	2.58
Med Dev	High Tech	.29	.398	1.000	-.91	1.48
	Genl Mfgr	1.21*	.388	.035	.05	2.37
	Retailing	.49	.417	1.000	-.76	1.74
	Pharma Mfgr	.44	.662	1.000	-1.54	2.43
	Biotech Mfgr	.61	1.065	1.000	-2.58	3.80
	Med Dev					

*. The mean difference is significant at the .05 level.

Figure 8. Bonferroni Comparison of multiple means for SOX compliance

By itself, this data were sufficient to address the second hypothesis, but further analysis was of interest. Observing the way in which the medical device participants responded to the 21CFR11 and HIPAA questions confirmed that regulatory compliance was important to critically important (means of 3.5 and 3.18) in their decisions regarding business software technology adoption. It was also noteworthy that 18% of the medical device respondents (4 of 22) claimed they did not know how important 21CFR Part 11 compliance was to the original decision makers, and 27% of these claimed the same regarding HIPAA.

Statistics

		7aSARBOX	7g 21CFR11	7h HIPPA
N	Valid	54	22	22
	Missing	6	38	38
Mean		3.44	3.50	3.18
Std. Error of Mean		.188	.226	.320
Median		4.00	3.50	3.00
Mode		5	3	5
Std. Deviation		1.383	1.058	1.500
Variance		1.912	1.119	2.251
Skewness		-.503	-.398	-.154
Std. Error of Skewness		.325	.491	.491
Kurtosis		-.875	.082	-1.407
Std. Error of Kurtosis		.639	.953	.953
Range		4	4	4
Minimum		1	1	1
Maximum		5	5	5
Sum		186	77	70

Figure 9. Means for compliance importance.

Finally, survey question 16 sought to measure the regulatory knowledge level of ERP decision makers at the time of the ERP technology adoption. This question was only asked of regulated respondents. Those in the medical device industry responding to the question (n = 5) claimed on average that decision makers were not fully aware of the requirements (1= Very knowledgeable). Said another way, no more than 20% of the

decision makers were considered knowledgeable of Computer System Validation requirements at the time of the first ERP installation.

Statistics

16 Knowledge

N	Valid	5
	Missing	55
Mean		3.8000
Std. Error of Mean		.48990
Median		4.0000
Mode		4.00
Std. Deviation		1.09545
Variance		1.20000
Skewness		-1.293
Std. Error of Skewness		.913
Kurtosis		2.917
Std. Error of Kurtosis		2.000
Range		3.00
Minimum		2.00
Maximum		5.00
Sum		19.00

16 Knowledge

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	2.00	1	1.7	20.0	20.0
	4.00	3	5.0	60.0	80.0
	5.00	1	1.7	20.0	100.0
	Total	5	8.3	100.0	
Missing	System	55	91.7		
Total		60	100.0		

Figure 10. Level of CSV knowledge by decision makers

Thus, observed in totality, the empirical data demonstrated that the second hypothesis $\mathbf{H_{02}}$ cannot be rejected, and thus $\mathbf{H_{A2}}$ cannot be accepted.

$\mathbf{H_{02}}$ - Medical Device IT managers familiar with the computer system validation regulations mention compliance with such regulations as a concern in their decision to implement ERP.

H_{A2} - Medical Device IT managers familiar with the computer system validation regulations do not mention compliance with such regulations as a concern in their decision to implement ERP.

A third area of interest, although not a hypothesis, was the empirical data regarding the actual length of time for the ERP installation. Question 15 asked about the number of months required to actually install the ERP (1 = Fewer than 6 months). Contrasting the two industries, the data showed no significant difference in the installation durations between medical device and non-regulated high technology respondents.

Group Statistics

	Industry	N	Mean	Std. Deviation	Std. Error Mean
Install duration	High Tech	13	2.23	1.013	.281
	Medical Device	4	1.75	.500	.250

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Install duration	Equal variances assumed	1.658	.217	.901	15	.382	.48	.533	-.656	1.618
	Equal variances not assumed			1.279	10.980	.227	.48	.376	-.347	1.309

Figure 11. Installation duration differences.

The mean of 2.2 for high technology respondents equates to between 6 and 24 months, while that for the medical device respondents was 1.75, or less than 12 months. However, comparing the means, with Significance of 0.382, is not less than 0.05, so there is insufficient support to claim that this difference is accountable for more than statistical sampling differences. Therefore, the results did not demonstrate a difference in ERP installation durations.

The survey instrument captured additional interesting data, but its further analysis was determined to be beyond the limited objective of this dissertation study.

Summary

This section summarizes the major findings of the study, which were supported by the empirical data collected from the researcher's online survey. These findings were that medical device companies installed or plan to install ERP systems at a delayed rate, as much as 48 months later than their non-regulated high technology cohorts.

Findings also demonstrated that compliance with regulations was an important consideration in the decision to install ERP at medical device companies. As a factor, compliance was no more important to regulated companies than it appeared to be for non-regulated firms when compliance to the Sarbanes-Oxley Act was considered across both groups.

The survey further showed that fewer than 20% of ERP decision makers were believed to be knowledgeable about compliance regulations at the time it was decided to implement ERP. Finally, there was no significant difference in the installation durations of ERP implementations the sample studied. For all respondents, approximately 6-12 months were required to install ERP.

CHAPTER 5: Summary, Conclusions & Recommendations

Summary

An existing body of research has attempted to describe the multitude of factors that either impede or encourage technology adoption by individuals and businesses. The literature reviewed revealed a gap in such research related to empirical evidence showing the influence of government regulation on technology adoption. The FDA in 1997 confidently claimed that its computer system validation (CSV) requirements and the related 21 CFR Part 11 regulation would have no impact on industry. However, they made their claim without reliance on technology adoption research, because the impact of regulations on technology adoption had not been measured.

The researcher sought to empirically determine if a statistically significant impact could be detected by asking managers in both regulated medical device and non-regulated high tech companies about their ERP installations. The results showed that there have been, and continue to be, significant delays in ERP adoption in the regulated medical device industry. However, the study did not attempt to determine whether regulation actually caused the laggardly adoption of ERP in medical device industry. Even so, these findings fill the gap heretofore extant in the research, that government regulation has impeded ERP technology adoption by regulated medical device companies as compared to their non-regulated cohorts.

Of added interest, only 27% (7 of 26) of the sampled medical device companies have actually installed ERP technology, and 58% (15 of 26) claimed they are unlikely to *ever* adopt ERP.

Conclusions

This was a quantitative study of the differences in the mean install dates for ERP business software adoption between medical device companies and non-regulated high technology firms. Empirical data were collected that provided these research results:

1. Medical device companies have installed or plan to install ERP applications about 48 months later than similar, but non-regulated high technology companies.
2. Medical device IT managers familiar with the computer system validation regulations, mention compliance with regulations as an important concern in their decision to implement ERP.

There are important implications in these results because the health care enterprise in the United States continues to be in crisis. Meanwhile, the regulations meant to protect public health, at least in terms of business software, have impeded progress. This situation in the United States may also mean that our medical device businesses are at a competitive disadvantage worldwide because in Europe, according to the research:

> In terms of Rogers' adoption categories, we observe that the innovators and early adopters have already adopted ERP software, whereas the early-majority are planning to follow soon. Before the year 2001, more than half (57%) of the medium-sized firms in Europe are expected to have ERP software installed in one or more functional areas. (Waarts, 2002, p. 418)

Generalizations that are justified by statistical inference in this study are that medical device manufacturers are more risk averse than other high tech manufacturers, and a larger mix of medical device firms than high tech firms believe they will never

adopt ERP to help them run their businesses. In addition, relative to ERP purchasers, fewer than 20% of the medical device ERP decision makers were knowledgeable about the regulatory compliance issues for their ERP systems when purchased.

Except for the mean install date difference, there was no statistical difference between the perceived levels of importance in the various adoption factors mentioned in the survey instrument, and as a result, the two groups can be considered to be homogeneous in regard to factors influencing purchase decisions. This was clear when both groups cited regulatory compliance to the Sarbanes-Oxley requirements at a similarly high level of importance.

There were some limitations to recognize in the study. The assumptions of independent and randomly sampled respondents were necessary in order to accept the statistical significance of the data in this study, and using a self-administered online survey has proved to be no guarantee of achieving either randomness or independent samples. Likewise, the researcher's choice of test criteria values may have biased results, but it did not influence responses or the result. Another limitation in the survey results derives from the study methodology, and the results did not definitively demonstrate that the regulations caused the laggardly adoption of ERP technology, even if the hypotheses went the suspected way. Finally, a mathematical demonstration that the sample is representative of the entire population is not included herein because there is no rigorous method of excluding the possibility of self-selection sampling bias. This is commonly the case when collecting data on sensitive issues without the authority to compel a response or even to guarantee anonymity. It is hoped that this initial foray will open a dialogue which will lead to more and better data.

Another conclusion drawn from the research relates to the efficacy of future online research in an era where spam and computer viruses abound. Conceptually, an online survey offered the prospect of economical and speedy research. Unfortunately, the especially low response rates of this study, which used an online survey, give cause to question the statistical relevance of the many other studies the public is bombarded with daily in the press or other media. This emphasizes the need for innovative Internet-age techniques to boost access and cooperation.

Recommendations

Based on the research, a number of recommendations emerge. First, the FDA's claim in 1997 that no impact would result from their computer system validation regulation has been unseated. This would recommend that such future claims be supported with empirical data, much as Coase (1991) had recommended in his Nobel prize acceptance speech, "....collect the data from managers."

Further, regulated firms need to be made aware of their delayed adoption of business technology, such as ERP software, as compared to their counterparts in the United States, and in Europe. Their risk aversity gives their enterprises a competitive disadvantage, and weak businesses cannot yield the sort of improvements our nation's public health demands.

In terms of future research, it would be interesting to determine if these survey results can be replicated with alternative approaches to the study methodology. This research was self-funded and required a resourcefulness from which an externally funded study might be spared. Mandatory responses, as in Malhotra (1999, p. 28), where students were required to participate before leaving a class, if feasible in a free enterprise

environment would surely deliver more precise results. However, in light of the continuing public concern, and certainly the wariness within the IT Management community about computer viruses and the anti-spam legislation of 2004, it is unlikely that any other online survey approach will achieve a different level of response by IT management.

Similarly, with 58% of the medical device respondents claiming they would never install ERP, further research would be helpful to clarify organizational motivations in this regard. There can be conjecture that start-up medical device firms with highly successful products simply plan to be *bought out* by larger businesses long before the nascent business is large enough to require the benefits of ERP, but further research is advisable.

This study focused on the FDA regulations, but with the passage of Sarbanes-Oxley (SOX), computer regulatory compliance has expanded beyond the FDA concerns for end-product efficacy. Now, more public firms have become regulated. Future research to gather empirical data from managers regarding the influence of SOX is recommended so that the economic implications of such politically inspired regulations can be known. Such results would be unlikely to stem a *rush to regulate*, but certainly in the small business segment at least, there is still a burden on regulators to seek a means of mitigating impact. In the medical device field, this could result in regulations that actually promote public health by making medical device manufacturers healthier businesses, and for FDA regulators to fulfill their full charter to, "protect and promote public health."

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APPENDICES

Appendix A

List of Abbreviations

ACR Applied Computer Research, Inc.

ASQ American Society of Quality

CAD Computer Aided Design

CEO Chief Executive Officer

CES Center for Economic Studies, Census Bureau

CFR Code of Federal Regulations

CIO Chief Information Officer

COTS Commercial Off The Shelf (software)

CSV Computer System Validation

EDI Electronic Data Interchange

EO Executive Order

ERP Enterprise Resource Planning

FDA Food and Drug Administration

GAMP Good Automated Manufacturing Practices

GAO General Accounting Office

HIPAA Health Insurance Portability and Accountability Act

IT Information Technology

MDIT Medical Device IT

NRHT Non-regulated High Technology

OMB Office of Management and Budget

REH Rational Expectations Hypothesis

RFA Regulatory Flexibility Act

RIA Regulatory Impact Analysis

SBA Small Business Administration

SMT Survey of Manufacturing Technology

SOX Sarbanes-Oxley Act

TAI Technology Adoption Indicators

TAM Technology Adoption Model, Technology Acceptance Model

TEC Technology Evaluation Center

UTIP Utilization of Technology and Individual Performance

XML Extensible Markup Language

Y2K Year 2000

Appendix B

Invitation Letter

Dear IT Professional:

The researcher is a doctoral candidate affiliated with Northcentral University in Prescott, Arizona and is conducting an empirical research study to learn more about the technology diffusion rates for Enterprise Requirements Planning (ERP) business software.

You have been selected to participate in this study because of your recognized status as a distinguished member of the IT community. Your participation will be especially helpful in measuring the rates of technology diffusion for ERP, and in clarifying any perceived impediments to implementation decisions for ERP.

We invite you to participate in this important industry study. You can be assured that all participants in the study will remain anonymous. Company specific data and individual respondents will not be identified in any reports.

You will only be contacted afterwards to be provided a free copy of the survey results, and then only if you wish to receive your copy of the relevant and strategically significant findings. Your free copy of the final research report will be sent via email during the Winter of 2005-6.

The survey is designed to require fewer than 15 minutes of your time and your accurate responses are critically important to the study results. To complete the brief survey, please click on the following URL:

http://survey.xxxxxx.com/ITappdiffusionstudy

If you have any questions about the study, or need assistance in completing the questionnaire, please call 555-555-5555 x555, or send an email to:

surveyinfo@xxxxx.com

Thank you for your participation.

Sincerely,

Jim Farkas

Researcher, NCU

Appendix C

Survey Instrument

The author is conducting a quantitative research study that plots the installation dates of companies' ERP software in order to learn more about technology adoption rates in various industries. Your responses will be very helpful in comparing these adoption rates and may lead to a better understanding of the impact of various factors on technology adoption. Your responses are strictly confidential. You might wish to recall and write down the month and year your company installed its first ERP application. Thank you for participating in this survey.

1- Which of the following best describes your company's primary industry?

   a. Consumer products – High Tech Manufacturing
   b. Consumer products – General Manufacturing
   c. Consumer products – Retailing
   d. Life Sciences – Pharma Manufacturing
   e. Life Sciences – Biotech Manufacturing
   f. Life Sciences – Medical Device Manufacturing
   g. Other (fill-in) _____

2- Which of the following best describes when your company was founded?

   a. Founded within the past 1 year
   b. Founded between 1-3 years ago
   c. Founded between 3-10 years ago
   d. Founded more than 10 years ago

3- Which of the following best describes the number of *worldwide* employees in your company?

a. Less than 50 employees
b. Between 50 – 150
c. Between 151 – 500
d. Over 500 employees

4- How long have you worked at your current company? (Select only one)

a. Less than 1 year
b. Between 1-3 years
c. Between 3-5 years
d. Between 5-10 years
e. More than 10 years

5- Which of the following best describes your current role in the company? (Select only one)

a. IT management
b. CIO/IT executive
c. Financial management
d. CFO/Finance executive
e. Quality/Validation management
f. Quality/Validation executive

g. Other (fill-in) _____

6- Please tell us which of the following best describes your company's sense of urgency toward the installation of business software applications.

a. We invest in business software applications as soon as it becomes available and before anybody else in our industry.

b. We invest in business software applications before most competitors, but only after a few references are available from other users.

c. We wait to see numerous, very well established references before investing in business software applications.

d. We invest in business software applications only after it becomes an established standard in the market, well tested and accompanied by full support.

e. We avoid investing in business software applications for as long as possible.

f. Do not know.

7- For each of the factors listed below, place a check mark or X within the box to describe its level of importance to your company's initial purchase decision for business software applications:

Factor	Not important	Somewhat important	Important	Critically Important	Do not know
System compliance with Sarbanes-Oxley Act					
System					

Factor	Not important	Somewhat important	Important	Critically Important	Do not know
compliance with 21 CFR 11					
System compliance with HIPAA					
Licensing costs					
Software vs. Consulting cost ratios					
Brand name of software					
Sponsoring Executive's preference					
Having an industry standard					

8- Which of the following best describes where your products are manufactured?

a. Completely in-house.

b. Mostly in-house and some outside.

c. About half and half.

d. Some in-house and mostly outside.

e. Totally outside (e.g., vendors, contract manufacturers).

9- Enterprise Resource Planning (ERP) software automates business transactions for more than one department (e.g., Manufacturing, Finance, Operations, Sales, etc.).

Does your company have an ERP software application installed and in use by more than one department?

a. Yes

b. No

c. Do not know

d. Other.

10- Which of the following best describes your role in the *most recent* decision to install a business software application? (Select only one)

a. Not involved in adoption decision

b. Provided advice to decision maker(s)

c. Was member of decision making team

d. Made final decision

e. Choose not to say

11- In how many ERP implementations have you been personally involved, at this company and at any previous companies? (Select only one)

a. None

b. Only 1

c. 2 or 3

d. More than 3

12- Knowing the accurate month and year of your ERP installation is critically important to the results of this survey. Please be as accurate as possible and feel free to check records if necessary. In what calendar YEAR did the ERP application first *go-live?*

a. [Select from pull down listing 2005 through 1995]

13- Knowing the accurate month and year of you ERP installation is critically important to the results of this survey. Please be as accurate as possible and feel free to check records if necessary. In what calendar MONTH did the ERP application first *go-live*?

a. [Select from pull down listing JAN. through DEC.]

14- In how many **ERP computer system validation** projects (for FDA regulated companies) have you participated directly or indirectly, at this company, and at any previous companies?

Do not know that term, or None.

a. Only 1

2 to 3

b. 4 to 6

c. More than 6 ERP system *validations*

15- In what industry did you work just prior to joining your present company?

a. Consumer products – High Tech Manufacturing

b. Consumer products – General Manufacturing

c. Consumer products – Retailing

d. Life Sciences – Pharma Manufacturing

e. Life Sciences – Biotech Manufacturing

f. Life Sciences – Medical Device Manufacturing

That concludes the survey. Thank you very much for participating. If you are interested in having a copy of survey results, feel free to email the author at jfarkas@isp.com. Final results will be available in the November or December time frame.

Appendix D

List of Figures and Survey Results

Figure D22. Question 14 Month of implementation

Figure D23. Question 15 Duration of ERP implementation

Figure D24. Question 16 Knowledge of compliance requirements

Figure D25. Question 17

At the closing of the online survey on 10/15/05, results on each question were as follows:

Which of the following best describes your company's primary industry?

1	Consumer or Industrial Products - High Tech Manufacturing	34	12.83%
2	Consumer or Industrial Products - General Manufacturing	49	18.49%
3	Consumer or Industrial Products – Retailing	30	11.32%
4	Life Sciences - Pharma Manufacturing	10	3.77%
5	Life Sciences - Biotech Manufacturing	2	0.75%
6	Life Sciences - Medical Device Manufacturing	26	9.81%
7	Life Sciences – Nutraceuticals Manufacturing	0	0.00%
8	Other	114	43.02%
Total		**265**	

Mean	5.06
Standard Dev.	2.86
Variance	8.21
Mean Percentile	49.29%

Figure D1. Question 1 Industry

Which of the following best describes when your company was founded?		Regulated		Non-regulated	
1	Founded within the past 1 year	2	5.26%	2	1.80%
2	Founded between 1-3 years ago	3	7.89%	8	7.21%
3	Founded between 3-10 years ago	10	26.32%	15	13.51%
4	Founded between 10-20 years ago	12	31.58%	27	24.32%
5	Founded more than 20 years ago	10	26.32%	58	52.25%
6	Other	1	2.63%	1	0.90%
Total		**38**		**111**	
	Mean		3.74		4.21
	Standard Dev.		1.18		1.05
	Variance		1.39		1.11
	Mean Percentile		54.39%		46.55%

Figure D2. Question 2 Founding

Which of the following best describes the number of worldwide employees in your company?		Regulated		Non-regulated	
1	Less than 50 employees	16	42.11%	16	14.81%
2	Between 50-150	6	15.79%	21	19.44%
3	Between 151-500	7	18.42%	23	21.30%
4	Over 500 employees	9	23.68%	48	44.44%
Total		**38**		**108**	
	Mean		2.24		2.95
	Standard Dev.		1.24		1.11
	Variance		1.54		1.24
	Mean Percentile		69.08%		51.16%

Figure D3. Question 3 Employees

How long have you worked at your current company? (Select only one)		Regulated		Non-regulated	
1	Less than 1 year	3	7.89%	9	8.49%
2	Between 1-3 years	9	23.68%	22	20.75%
3	Between 3-5 years	9	23.68%	26	24.53%
4	Between 5-10 years	10	26.32%	23	21.70%
5	More than 10 years	7	18.42%	26	24.53%
Total		**38**		**106**	
	Mean		3.24		3.33
	Standard Dev.		1.24		1.29
	Variance		1.54		1.65
	Mean Percentile		*55.26%*		*53.40%*

Figure D4. Question 4 Longevity

Which of the following best describes your current role in the company? (Select only one)		Regulated		Non-regulated	
1	IT management	6	16.22%	40	37.74%
2	CIO/IT executive	5	13.51%	12	11.32%
3	Financial management	0	0.00%	8	7.55%
4	CFO/Finance executive	3	8.11%	6	5.66%
5	Quality management	1	2.70%	4	3.77%
6	Quality executive	3	8.11%	6	5.66%
7	Other	19	51.35%	30	28.30%
Total		**37**		**106**	
	Mean		4.97		3.57
	Standard Dev.		2.49		2.57
	Variance		6.19		6.61
	Mean Percentile		43.24%		63.34%

Figure D5. Question 5 Current Roles

Please tell us which of the following best describes your company's timing and strategy as regards the installation of business software applications.

Generally, our timing for business software applications is to install it:		Regulated		Non-regulated	
1	As soon as it becomes available and before anyone else in our industry	1	2.78%	4	4.00%
2	Before most competitors, but only after a few references from other users are available	4	11.11%	14	14.00%
3	After we see numerous, very well established references from other users before investing in business software applications.	11	30.56%	37	37.00%
4	Only after it becomes an established standard in the market, well tested and accompanied by full support.	11	30.56%	34	34.00%
5	Only as a last resort.	2	5.56%	6	6.00%
6	Don't know.	2	5.56%	5	5.00%
7	Other (Fill-in)	5	13.89%	0	0.00%
Total		**36**		**100**	
	Mean		3.97		3.39
	Standard Dev.		1.61		1.09
	Variance		2.60		1.19
	Mean Percentile		57.54%		65.86%

Figure D6. Question 6 Adopter Categories

For each of the factors listed below, click the button to describe its level of importance to your company's initial purchase decision for business software applications:

7a

A System compliant with Sarbanes-Oxley Act		Regulated		Non-regulated	
1	Not Important	4	12.90%	24	26.37%
2	Somewhat Important	3	9.68%	14	15.38%
3	Important	9	29.03%	17	18.68%
4	Critically Important	4	12.90%	18	19.78%
5	Don't Know	11	35.48%	18	19.78%
Total		**31**		**91**	
	Mean		3.48		2.91
	Standard Dev.		1.41		1.49
	Variance		1.99		2.21
	Mean Percentile		50.32%		61.76%

Figure D7. Question 7a Sarbanes-Oxley compliance

Licensing costs		Regulated		Non-regulated	
1	Not Important	1	3.23%	2	2.17%
2	Somewhat Important	4	12.90%	15	16.30%
3	Important	10	32.26%	29	31.52%
4	Critically Important	13	41.94%	45	48.91%
5	Don't Know	3	9.68%	1	1.09%
Total		**31**		**92**	
	Mean		3.42		3.30
	Standard Dev.		0.96		0.84
	Variance		0.92		0.70
	Mean Percentile		51.61%		53.91%

Figure D8. Question 7b Licensing costs

Software versus Consulting cost ratio		Regulated		Non-regulated	
1	Not Important	1	3.13%	8	8.42%
2	Somewhat Important	6	18.75%	14	14.74%
3	Important	6	18.75%	42	44.21%
4	Critically Important	13	40.63%	24	25.26%
5	Don't Know	6	18.75%	7	7.37%
Total		**32**		**95**	
	Mean		3.53		3.08
	Standard Dev.		1.11		1.02
	Variance		1.22		1.04
	Mean Percentile		49.38%		58.32%

Figure D9. Question 7c Software versus consulting cost ratio

Brand name of software		Regulated		Non-regulated	
1	Not Important	3	9.68%	15	15.96%
2	Somewhat Important	11	35.48%	31	32.98%
3	Important	12	38.71%	38	40.43%
4	Critically Important	2	6.45%	8	8.51%
5	Don't Know	3	9.68%	2	2.13%
Total		**31**		**94**	
	Mean		2.71		2.48
	Standard Dev.		1.07		0.94
	Variance		1.15		0.88
	Mean Percentile		65.81%		70.43%

Figure D10. Question 7d Brand name of software

Sponsoring Executives preference		Regulated		Non-regulated	
1	Not Important	8	25.00%	14	14.74%
2	Somewhat Important	6	18.75%	24	25.26%
3	Important	12	37.50%	32	33.68%
4	Critical Important	2	6.25%	17	17.89%
5	Don't Know	4	12.50%	8	8.42%
Total		**32**		**95**	
	Mean		2.63		2.80
	Standard Dev.		1.29		1.15
	Variance		1.66		1.33
	Mean Percentile		67.50%		64.00%

Figure D11. Question 7e Sponsoring executive's preference

Having an industry standard		Regulated		Non-regulated	
1	Not Important	1	3.13%	4	4.21%
2	Somewhat Important	6	18.75%	13	13.68%
3	Important	14	43.75%	42	44.21%
4	Critical Important	6	18.75%	33	34.74%
5	Don't Know	5	15.63%	3	3.16%
Total		**32**		**95**	
	Mean		3.25		3.19
	Standard Dev.		1.05		0.87
	Variance		1.10		0.75
	Mean Percentile		*55.00%*		*56.21%*

Figure D12. Question 7f Industry standard

System compliance with 21 CFR Part 11		Regulated		Non-regulated
1	Not Important	2	6.45%	
2	Somewhat Important	3	9.68%	
3	Important	11	35.48%	
4	Critical Important	10	32.26%	
5	Don't Know	5	16.13%	
Total		**31**		
	Mean		3.42	
	Standard Dev.		1.09	
	Variance		1.18	
	Mean Percentile		51.61%	

Figure D13. Question 7g Compliance with 21 CFR Part 11

System compliance with HIPAA		Regulated		Non-regulated
1	Not Important	5	16.13%	
2	Somewhat Important	5	16.13%	
3	Important	7	22.58%	
4	Critically Important	7	22.58%	
5	Don't Know	7	22.58%	
Total		**31**		
	Mean		3.19	
	Standard Dev.		1.40	
	Variance		1.96	
	Mean Percentile		56.13%	

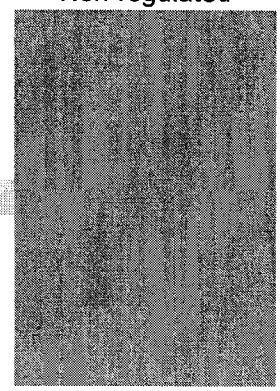

Figure D14. Question 7h Compliance with HIPAA

Concern with non-Y2K compliant programs		Regulated		Non-regulated	
1	Not Important	8	25.81%	38	40.43%
2	Somewhat Important	6	19.35%	19	20.21%
3	Important	8	25.81%	21	22.34%
4	Critically Important	2	6.45%	8	8.51%
5	Don't Know	7	22.58%	8	8.51%
Total		**31**		**94**	
	Mean		2.81		2.24
	Standard Dev.		1.49		1.30
	Variance		2.23		1.69
	Mean Percentile		63.87%		75.11%

Figure D15. Question 7i Y2K compliant

Which of the following best describes where your products are manufactured?		Regulated		Non-regulated	
1	Totally in-house	5	15.63%	18	18.37%
2	Mostly in-house and some outside	11	34.38%	36	36.73%
3	About half and half	7	21.88%	16	16.33%
4	Some in-house and mostly outside	3	9.38%	14	14.29%
5	Totally outside (e.g. vendors and contract manufacturers)	6	18.75%	14	14.29%
Total		**32**		**98**	
	Mean		2.81		2.69
	Standard Dev.		1.35		1.32
	Variance		1.83		1.74
	Mean Percentile		63.75%		66.12%

Figure D16. Question 8 Manufacturing

Enterprise Resource Planning (ERP) software automates business transactions for more than one department (e.g. Manufacturing and Finance and Operations, etc.).

Does your company have an ERP software application installed and in use by more than one department?		Regulated		Non-regulated	
1	Yes	14	42.42%	64	65.31%
2	No	16	48.48%	30	30.61%
3	Don't know	2	6.06%	2	2.04%
4	Other	1	3.03%	2	2.04%
Total		**33**		**98**	
	Mean		1.70		1.41
	Standard Dev.		0.73		0.64
	Variance		0.53		0.41
	Mean Percentile		82.58%		89.80%

Figure D17. Question 9 ERP installed

Since you have not implemented ERP yet, which of the following best describes your plans regarding ERP?		Regulated		Non-regulated	
1	Unlikely we will ever implement ERP.	9	50.00%	15	50.00%
2	Plan to implement within 6 months.	1	5.56%	2	6.67%
3	Plan to implement between 6 to 12 months.	1	5.56%	5	16.67%
4	Plan to implement between 12 to 24 months.	1	5.56%	6	20.00%
5	Plan to implement more than 24 months from now.	3	16.67%	1	3.33%
6	Other	3	16.67%	1	3.33%
Total		**18**		**30**	
	Mean		2.83		2.30
	Standard Dev.		2.12		1.51
	Variance		4.50		2.29
	Mean Percentile		69.44%		78.33%

Figure D18. Question 10 Plans if no ERP installed

Which of the following best describes your role in the decision to first install an ERP software application in your current company? (Select only one)		Regulated		Non-regulated	
1	Not involved in adoption decision	3	25.00%	27	43.55%
2	Provided advice to decision maker(s)	4	33.33%	17	27.42%
3	Was member of decision making team	4	33.33%	15	24.19%
4	Made final decision	1	8.33%	3	4.84%
5	Choose not to say	0	0.00%	0	0.00%
6	Other	0	0.00%	0	0.00%
Total		**12**		**62**	
	Mean		2.25		1.90
	Standard Dev.		0.97		0.94
	Variance		0.93		0.88
	Mean Percentile		79.17%		84.95%

Figure D19. Question 11 Decision role in ERP

In how many ERP implementations have you been personally involved, at this company and at any previous companies? (Select only one)		Regulated		Non-regulated	
1	None	1	8.33%	14	22.58%
2	Only 1	2	16.67%	13	20.97%
3	2 or 3	5	41.67%	17	27.42%
4	More than 3	4	33.33%	18	29.03%
Total		**12**		**62**	
	Mean		3.00		2.63
	Standard Dev.		0.95		1.13
	Variance		0.91		1.29
	Mean Percentile		50.00%		59.27%

Figure D20. Question 12 Number of ERP implementations

In what calendar YEAR did the first ERP installation at your company first go-live?		Regulated		Non-regulated	
1	2005	0	0.00%	1	1.72%
2	2004	0	0.00%	5	8.62%
3	2003	1	7.69%	7	12.07%
4	2002	2	15.38%	5	8.62%
5	2001	2	15.38%	3	5.17%
6	2000	1	7.69%	5	8.62%
7	1999	0	0.00%	8	13.79%
8	1998	1	7.69%	5	8.62%
9	1997 or earlier	5	38.46%	12	20.69%
10	Don't know	1	7.69%	7	12.07%
Total		**13**		**58**	
	Mean		6.92		6.40
	Standard Dev.		2.47		2.75
	Variance		6.08		7.54
	Mean Percentile		*40.77%*		*46.03%*

Figure D21. Question 13 Calendar year of implementation

In what MONTH of the year did the first ERP installation at your company first go-live?		Regulated		Non-regulated	
1	JAN	1	9.09%	6	12.00%
2	FEB	1	9.09%	0	0.00%
3	MAR	0	0.00%	6	12.00%
4	APR	1	9.09%	1	2.00%
5	MAY	0	0.00%	4	8.00%
6	JUN	1	9.09%	2	4.00%
7	JUL	2	18.18%	5	10.00%
8	AUG	1	9.09%	4	8.00%
9	SEP	0	0.00%	3	6.00%
10	OCT	0	0.00%	5	10.00%
11	NOV	0	0.00%	3	6.00%
12	DEC	1	9.09%	0	0.00%
13	Don't Know	3	27.27%	11	22.00%
Total		**11**		**50**	
	Mean		7.82		7.60
	Standard Dev.		4.45		4.11
	Variance		19.76		16.86
	Mean Percentile		47.55%		49.23%

Figure D22. Question 14 Month of implementation

For this first ERP implementation, how many months did the project require from the start of project until successful go-live?		Regulated		Non-regulated	
1	Fewer than 6 months.	3	27.27%	6	15.00%
2	Between 6 months to 12 months.	5	45.45%	16	40.00%
3	More than 12 months to 24 months.	0	0.00%	10	25.00%
4	More than 24 months to 36 months.	2	18.18%	5	12.50%
5	More than 36 months.	0	0.00%	3	7.50%
6	Other	1	9.09%	0	0.00%
Total		**11**		**40**	
	Mean		2.45		2.58
	Standard Dev.		1.57		1.13
	Variance		2.47		1.28
	Mean Percentile		75.76%		73.75%

Figure D23. Question 15 Duration of ERP implementation

With regard to the first ERP installation at your company, how knowledgeable were decision makers about the FDAs computer system validation requirements for that ERP system?		Regulated		Non-regulated
1	Very knowledgeable	2	16.67%	
2	Knowledgeable	2	16.67%	
3	Aware of requirements but not knowledgeable	1	8.33%	
4	Unaware of requirements	4	33.33%	
5	Do not know	3	25.00%	
6	Other	0	0.00%	
Total		**12**		
Mean		3.33		
Standard Dev.		1.50		
Variance		2.24		
Mean Percentile		61.11%		

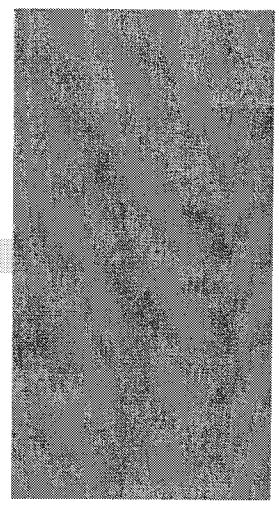

Figure D24. Question 16 Knowledge of compliance requirements

In what industry did you work just prior to joining your present company?

1	Consumer Products - High Tech Manufacturing	17	7.39%
2	Consumer Products – General Manufacturing	38	16.52%
3	Consumer Products – Retailing	24	10.43%
4	Life Sciences - Pharma Manufacturing	10	4.35%
5	Life Sciences - Biotech Manufacturing	3	1.30%
6	Life Sciences - Medical Device Manufacturing	18	7.83%
7	Life Sciences – Nutraceuticals Manufacturing	0	0.00%
8	Other (Fill-in)	120	52.17%
Total		**230**	

Mean	5.60
Standard Dev.	2.75
Variance	7.58
Mean Percentile	42.50%

Figure D25. Question 17

Appendix E

Tabulation of ERP Installation Survey Results

Table E-1

High Tech Responses

Responses (N=34, n=31)		Assumptions
-101	1	
-99	1	
-98	1	
-88	5	
-79	1	
-76	1	
-73	1	
-72	1	Installed but install date blank; -72 months
-72	1	Installed but not being used; -72 months
-71	1	
-66	1	
-65	1	
-64	1	
-53	1	
-43	1	
-39	1	
-33	1	
-21	1	

Table E-1

High Tech Responses (*continued*)

Responses (N=34, n=31)		Assumptions
-16	1	
6	1	Being implemented now; assume 6 months
9	2	Projected (3 = 6-12 months)
18	1	Projected (4= 12-24 months)
60	3	Unlikely to ever install ERP; +60 months
60	1	No ERP, plans blank; +60 months
	3	ERP blank, not used
	34	

Table E-2

Medical Device Response

Responses (N=26, n=22)		Assumptions
-99	2	
-93	1	
-88	1	
-72	1	Installed but install date blank; -72 months
-57	1	
-39	1	
-34	1	
6	1	Projected (2= within 6 months)
24	2	Projected (5= >24 months)
60	9	Unlikely to ever install ERP; +60 months
60	2	No ERP, did not know plans; +60 months
	3	ERP blank; data not used
	1	Not a manufacturer; not used.
	26	

Appendix F

Correlation Results

Figure F1. Correlation results.

Four pages explain the correlation results.

Spearman's rho		Industry	Founding	Employees	Timing	ERP Y=1	Install duration	CSV Knowledge	Longevity
Industry	Correlation Coefficient	1	-0.212	-0.452	0.280	0.370	-0.201	.	0.006
	Sig. (1-tailed)	.	0.052	0.000	0.017	0.003	0.220	.	0.481
	N	60	60	60	57	54	17	5	59
Founding	Correlation Coefficient	-0.212	1	0.527	-0.048	-0.409	-0.131	0.000	0.136
	Sig. (1-tailed)	0.052	.	0.000	0.361	0.001	0.308	0.500	0.152
	N	60	60	60	57	54	17	5	59
Employees	Correlation Coefficient	-0.452	0.527	1	-0.057	-0.494	0.345	-0.574	-0.143
	Sig. (1-tailed)	0.000	0.000	.	0.337	0.000	0.088	0.156	0.140
	N	60	60	60	57	54	17	5	59
Timing	Correlation Coefficient	0.280	-0.048	-0.057	1	0.437	-0.011	-0.354	0.026
	Sig. (1-tailed)	0.017	0.361	0.337	.	0.001	0.483	0.280	0.423
	N	57	57	57	57	53	17	5	57
ERP Y=1	Correlation Coefficient	0.370	-0.409	-0.494	0.437	1	.	.	-0.087
	Sig. (1-tailed)	0.003	0.001	0.000	0.001	.	.	.	0.266
	N	54	54	54	53	54	17	5	54
Install duration	Correlation Coefficient	-0.201	-0.131	0.345	-0.011	.	1	-0.816	-0.078
	Sig. (1-tailed)	0.220	0.308	0.088	0.483	.	.	0.092	0.384
	N	17	17	17	17	17	17	4	17
CSV Knowledge	Correlation Coefficient	.	0.000	-0.574	-0.354	.	-0.816	1	-0.791
	Sig. (1-tailed)	.	0.500	0.156	0.280	.	0.092	.	0.056
	N	5	5	5	5	5	4	5	5
Longevity	Correlation Coefficient	0.006	0.136	-0.143	0.026	-0.087	-0.078	-0.791	1
	Sig. (1-tailed)	0.481	0.152	0.140	0.423	0.266	0.384	0.056	.
	N	59	59	59	57	54	17	5	59
Role	Correlation Coefficient	0.339	-0.149	-0.215	0.207	0.433	0.044	-0.500	-0.007
	Sig. (1-tailed)	0.005	0.132	0.052	0.062	0.001	0.433	0.196	0.480
	N	58	58	58	57	54	17	5	58
Compl SOX	Correlation Coefficient	0.119	0.104	0.043	-0.006	-0.002	0.027	-0.707	0.082
	Sig. (1-tailed)	0.196	0.227	0.377	0.482	0.494	0.460	0.091	0.278
	N	54	54	54	53	53	17	5	54
License Cost	Correlation Coefficient	0.031	-0.176	-0.030	-0.074	-0.010	-0.041	0.825	-0.163
	Sig. (1-tailed)	0.415	0.105	0.417	0.302	0.472	0.440	0.043	0.124
	N	52	52	52	51	51	16	5	52
Sftwr v Cnsltg	Correlation Coefficient	0.273	-0.187	-0.191	0.138	0.055	-0.153	0.574	0.010
	Sig. (1-tailed)	0.023	0.088	0.083	0.162	0.349	0.279	0.156	0.473
	N	54	54	54	53	53	17	5	54
Brand Sftwr	Correlation Coefficient	0.016	-0.031	0.081	-0.017	-0.043	0.384	-0.344	-0.317
	Sig. (1-tailed)	0.453	0.411	0.279	0.453	0.380	0.064	0.285	0.010
	N	54	54	54	53	53	17	5	54

Figure F1. Correlation results

Spearman's rho		Industry	Founding	Employees	Timing	ERP Y=1	Install duration	CSV Knowledge	Longevity
	Correlation								
Exec's Pref	Coefficient	-0.143	-0.069	0.044	0.008	-0.054	0.409	0	-0.097
	Sig. (1-tailed)	0.153	0.311	0.376	0.479	0.352	0.052	0.500	0.246
	N	53	53	53	52	52	17	5	53
	Correlation								
Ind. Std	Coefficient	-0.033	-0.180	-0.102	0.110	0.189	0.134	0.354	-0.147
	Sig. (1-tailed)	0.407	0.096	0.232	0.217	0.087	0.304	0.280	0.145
	N	54	54	54	53	53	17	5	54
	Correlation								
Compl P-11	Coefficient	.	-0.263	-0.089	0.014	0.169	0.000	-0.471	-0.239
	Sig. (1-tailed)	.	0.118	0.346	0.476	0.232	0.500	0.211	0.142
	N	22	22	22	22	21	4	5	22
	Correlation								
Compl HIPAA	Coefficient	.	-0.312	0.020	0.050	-0.092	0.775	-0.949	-0.109
	Sig. (1-tailed)	.	0.079	0.464	0.413	0.346	0.113	0.026	0.314
	N	22	22	22	22	21	4	4	22
	Correlation								
Compl Y2K	Coefficient	0.052	-0.091	0.102	0.146	-0.080	0.416	0.000	-0.154
	Sig. (1-tailed)	0.357	0.259	0.233	0.151	0.286	0.048	0.500	0.135
	N	53	53	53	52	52	17	4	53
Manu-	Correlation								
facturing	Coefficient	0.108	0.110	0.114	0.015	-0.124	0.407	-0.471	-0.188
	Sig. (1-tailed)	0.219	0.215	0.207	0.457	0.190	0.052	0.211	0.087
	N	54	54	54	53	52	17	5	54
	Correlation								
Future ERP	Coefficient	0.029	-0.002	-0.095	-0.081	0.369	.	.	-0.129
	Sig. (1-tailed)	0.450	0.497	0.340	0.363	0.050	.	.	0.289
	N	21	21	21	21	21	0	0	21
	Correlation								
Decision role	Coefficient	0.298	-0.007	-0.392	-0.380	.	-0.321	0.632	0.276
	Sig. (1-tailed)	0.065	0.486	0.022	0.025	.	0.105	0.184	0.082
	N	27	27	27	27	27	17	4	27
Implemen-	Correlation								
tations	Coefficient	0.353	-0.316	-0.288	-0.094	.	0.027	-0.500	-0.045
	Sig. (1-tailed)	0.033	0.051	0.068	0.318	.	0.460	0.196	0.409
	N	28	28	28	28	28	17	5	28
	Correlation								
Year ERP	Coefficient	-0.023	0.143	0.364	0.489	.	-0.200	-0.707	0.080
	Sig. (1-tailed)	0.454	0.239	0.031	0.005	.	0.220	0.091	0.346
	N	27	27	27	27	27	17	5	27
	Correlation								
Month ERP	Coefficient	0.131	-0.231	0.055	0.236	.	-0.299	-0.258	-0.033
	Sig. (1-tailed)	0.291	0.164	0.409	0.158	.	0.130	0.371	0.444
	N	20	20	20	20	20	16	4	20
	Correlation								
Prev. Industry	Coefficient	0.323	0.170	0.066	0.339	-0.118	0.162	0.791	-0.143
	Sig. (1-tailed)	0.011	0.119	0.325	0.009	0.208	0.267	0.056	0.160
	N	50	50	50	49	50	17	5	50

Figure F1. Correlation results *(continued)*

Spearman's rho	Role	Compl SOX	License Cost	Sftwr v Cnsltg	Brand Sftwr	Exec's Pref	Ind. Std	Compl P-11	Compl HIPAA
Industry	0.339	0.119	0.031	0.273	0.016	-0.143	-0.033	.	.
	0.005	0.196	0.415	0.023	0.453	0.153	0.407	.	.
	58	54	52	54	54	53	54	22	22
Founding	0.149	0.104	-0.176	-0.187	-0.031	-0.069	-0.180	-0.263	-0.312
	0.132	0.227	0.105	0.088	0.411	0.311	0.096	0.118	0.079
	58	54	52	54	54	53	54	22	22
Employees	0.215	0.043	-0.030	-0.191	0.081	0.044	-0.102	-0.089	0.020
	0.052	0.377	0.417	0.083	0.279	0.376	0.232	0.346	0.464
	58	54	52	54	54	53	54	22	22
Timing	0.207	-0.006	-0.074	0.138	-0.017	0.008	0.110	0.014	0.050
	0.062	0.482	0.302	0.162	0.453	0.479	0.217	0.476	0.413
	57	53	51	53	53	52	53	22	22
ERP Y=1	0.433	-0.002	-0.010	0.055	-0.043	-0.054	0.189	0.169	-0.092
	0.001	0.494	0.472	0.349	0.380	0.352	0.087	0.232	0.346
	54	53	51	53	53	52	53	21	21
Install duration	0.044	0.027	-0.041	-0.153	0.384	0.409	0.134	0.000	0.775
	0.433	0.460	0.440	0.279	0.064	0.052	0.304	0.500	0.113
	17	17	16	17	17	17	17	4	4
CSV Knowledge	0.500	-0.707	0.825	0.574	-0.344	0.000	0.354	-0.471	-0.949
	0.196	0.091	0.043	0.156	0.285	0.500	0.280	0.211	0.026
	5	5	5	5	5	5	5	5	4
Longevity	0.007	0.082	-0.163	0.010	-0.317	-0.097	-0.147	-0.239	-0.109
	0.480	0.278	0.124	0.473	0.010	0.246	0.145	0.142	0.314
	58	54	52	54	54	53	54	22	22
Role	1	-0.032	0.135	0.129	0.111	0.077	0.028	0.079	0.183
	.	0.410	0.169	0.176	0.212	0.292	0.420	0.363	0.207
	58	54	52	54	54	53	54	22	22
Compl SOX	0.032	1	0.097	0.214	0.375	0.083	0.037	0.504	0.344
	0.410	.	0.248	0.060	0.003	0.277	0.395	0.008	0.059
	54	54	52	54	54	53	54	22	22
License Cost	0.135	0.097	1	0.098	0.239	0.426	0.239	-0.165	-0.017
	0.169	0.248	.	0.245	0.044	0.001	0.044	0.232	0.470
	52	52	52	52	52	51	52	22	22
Sftwr v Cnsltg	0.129	0.214	0.098	1	0.346	0.327	0.392	0.416	0.358
	0.176	0.060	0.245	.	0.005	0.008	0.002	0.027	0.051
	54	54	52	54	54	53	54	22	22
Brand Sftwr	0.111	0.375	0.239	0.346	1	0.541	0.142	0.515	0.208
	0.212	0.003	0.044	0.005	.	0.000	0.152	0.007	0.177
	54	54	52	54	54	53	54	22	22

Figure F1. Correlation results *(continued)*

Spearman's rho	Role	Compl SOX	License Cost	Sftwr v Cnsltg	Brand Sftwr	Exec's Pref	Ind. Std	Compl P-11	Compl HIPAA
Exec's Pref	0.077	0.083	0.426	0.327	0.541	1	0.274	0.161	0.072
	0.292	0.277	0.001	0.008	0.000	.	0.023	0.238	0.375
	53	53	51	53	53	53	53	22	22
Ind. Std	0.028	0.037	0.239	0.392	0.142	0.274	1	0.466	0.417
	0.420	0.395	0.044	0.002	0.152	0.023	.	0.014	0.027
	54	54	52	54	54	53	54	22	22
Compl P-11	0.079	0.504	-0.165	0.416	0.515	0.161	0.466	1	0.799
	0.363	0.008	0.232	0.027	0.007	0.238	0.014	.	0.000
	22	22	22	22	22	22	22	22	21
Compl HIPAA	0.183	0.344	-0.017	0.358	0.208	0.072	0.417	0.799	1
	0.207	0.059	0.470	0.051	0.177	0.375	0.027	0.000	.
	22	22	22	22	22	22	22	21	22
Compl Y2K	0.158	0.487	0.126	0.341	0.403	0.271	0.172	0.616	0.380
	0.129	0.000	0.189	0.006	0.001	0.026	0.110	0.001	0.040
	53	53	51	53	53	52	53	21	22
Manu-facturing	0.213	0.184	0.072	0.205	0.276	0.079	0.033	0.447	0.351
	0.061	0.096	0.309	0.073	0.024	0.291	0.408	0.024	0.064
	54	52	50	52	52	51	52	20	20
Future ERP	0.271	0.417	-0.056	0.003	0.280	-0.169	0.016	0.109	-0.146
	0.117	0.034	0.407	0.496	0.116	0.238	0.473	0.362	0.309
	21	20	20	20	20	20	20	13	14
Decision role	0.104	-0.415	-0.084	-0.020	-0.416	-0.473	0.124	-0.229	-0.289
	0.303	0.016	0.344	0.461	0.015	0.007	0.269	0.355	0.318
	27	27	25	27	27	26	27	5	5
Implemen-tations	0.130	-0.192	-0.258	-0.324	-0.116	-0.274	-0.210	-0.365	0.344
	0.254	0.164	0.102	0.046	0.278	0.084	0.142	0.238	0.285
	28	28	26	28	28	27	28	6	5
Year ERP	0.010	0.213	-0.018	-0.122	0.158	0.018	-0.310	0.381	0.263
	0.479	0.143	0.466	0.272	0.215	0.465	0.058	0.228	0.334
	27	27	25	27	27	27	27	6	5
Month ERP	0.413	-0.033	-0.333	-0.021	-0.310	-0.095	-0.286	0.949	0.500
	0.035	0.445	0.082	0.466	0.092	0.346	0.111	0.026	0.333
	20	20	19	20	20	20	20	4	3
Prev. Industry	0.075	0.018	0.004	0.165	0.174	0.084	-0.176	-0.030	-0.164
	0.303	0.451	0.489	0.129	0.116	0.284	0.113	0.449	0.244
	50	49	47	49	49	49	49	20	20

Figure F1. Correlation results *(continued)*

Spearman's rho	Compl Y2K	Manu-facturing	Future ERP	Decision role	Implemen-tations	Year ERP	Month ERP	Prev. Industry
Industry	0.052	0.108	0.029	0.298	0.353	-0.023	0.131	0.323
	0.357	0.219	0.450	0.065	0.033	0.454	0.291	0.011
	53	54	21	27	28	27	20	50
Founding	-0.091	0.110	-0.002	-0.007	-0.316	0.143	-0.231	0.170
	0.259	0.215	0.497	0.486	0.051	0.239	0.164	0.119
	53	54	21	27	28	27	20	50
Employees	0.102	0.114	-0.095	-0.392	-0.288	0.364	0.055	0.066
	0.233	0.207	0.340	0.022	0.068	0.031	0.409	0.325
	53	54	21	27	28	27	20	50
Timing	0.146	0.015	-0.081	-0.380	-0.094	0.489	0.236	0.339
	0.151	0.457	0.363	0.025	0.318	0.005	0.158	0.009
	52	53	21	27	28	27	20	49
ERP Y=1	-0.080	-0.124	0.369	.	.	.	.	-0.118
	0.286	0.190	0.050	.	.	.	.	0.208
	52	52	21	27	28	27	20	50
Install duration	0.416	0.407	.	-0.321	0.027	-0.200	-0.299	0.162
	0.048	0.052	.	0.105	0.460	0.220	0.130	0.267
	17	17	0	17	17	17	16	17
CSV Knowledge	0.000	-0.471	.	0.632	-0.500	-0.707	-0.258	0.791
	0.500	0.211	.	0.184	0.196	0.091	0.371	0.056
	4	5	0	4	5	5	4	5
Longevity	-0.154	-0.188	-0.129	0.276	-0.045	0.080	-0.033	-0.143
	0.135	0.087	0.289	0.082	0.409	0.346	0.444	0.160
	53	54	21	27	28	27	20	50
Role	-0.158	-0.213	-0.271	-0.104	-0.130	0.010	-0.413	0.075
	0.129	0.061	0.117	0.303	0.254	0.479	0.035	0.303
	53	54	21	27	28	27	20	50
Compl SOX	0.487	0.184	0.417	-0.415	-0.192	0.213	-0.033	0.018
	0.000	0.096	0.034	0.016	0.164	0.143	0.445	0.451
	53	52	20	27	28	27	20	49
License Cost	0.126	0.072	-0.056	-0.084	-0.258	-0.018	-0.333	0.004
	0.189	0.309	0.407	0.344	0.102	0.466	0.082	0.489
	51	50	20	25	26	25	19	47
Sftwr v Cnsltg	0.341	0.205	0.003	-0.020	-0.324	-0.122	-0.021	0.165
	0.006	0.073	0.496	0.461	0.046	0.272	0.466	0.129
	53	52	20	27	28	27	20	49
Brand Sftwr	0.403	0.276	0.280	-0.416	-0.116	0.158	-0.310	0.174
	0.001	0.024	0.116	0.015	0.278	0.215	0.092	0.116
	53	52	20	27	28	27	20	49

Figure F1. Correlation results *(continued)*

Spearman's rho	Compl Y2K	Manu-facturing	Future ERP	Decision role	Implemen-tations	Year ERP	Month ERP	Prev. Industry
Exec's Pref	0.271	0.079	-0.169	-0.473	-0.274	0.018	-0.095	0.084
	0.026	0.291	0.238	0.007	0.084	0.465	0.346	0.284
	52	51	20	26	27	27	20	49
Ind. Std	0.172	0.033	0.016	0.124	-0.210	-0.310	-0.286	-0.176
	0.110	0.408	0.473	0.269	0.142	0.058	0.111	0.113
	53	52	20	27	28	27	20	49
Compl P-11	0.616	0.447	0.109	-0.229	-0.365	0.381	0.949	-0.030
	0.001	0.024	0.362	0.355	0.238	0.228	0.026	0.449
	21	20	13	5	6	6	4	20
Compl HIPAA	0.380	0.351	-0.146	-0.289	0.344	0.263	0.500	-0.164
	0.040	0.064	0.309	0.318	0.285	0.334	0.333	0.244
	22	20	14	5	5	5	3	20
Compl Y2K	1	0.182	0.221	-0.561	-0.329	0.180	0.370	0.219
	.	0.101	0.174	0.001	0.047	0.189	0.060	0.067
	53	51	20	27	27	26	19	48
Manu-facturing	0.182	1	0.031	-0.271	0.011	-0.254	-0.312	0.264
	0.101	.	0.448	0.086	0.478	0.101	0.090	0.035
	51	54	20	27	28	27	20	48
Future ERP	0.221	0.031	1	.	.	.	.	0.021
	0.174	0.448	.	.	.	.	.	0.464
	20	20	21	0	0	0	0	21
Decision role	-0.561	-0.271	.	1	0.514	-0.477	-0.184	-0.229
	0.001	0.086	.	.	0.003	0.007	0.225	0.135
	27	27	0	27	27	26	19	25
Implemen-tations	-0.329	0.011	.	0.514	1	-0.299	-0.102	-0.328
	0.047	0.478	.	0.003	.	0.065	0.335	0.051
	27	28	0	27	28	27	20	26
Year ERP	0.180	-0.254	.	-0.477	-0.299	1	0.379	0.045
	0.189	0.101	.	0.007	0.065	.	0.049	0.415
	26	27	0	26	27	27	20	26
Month ERP	0.370	-0.312	.	-0.184	-0.102	0.379	1	-0.041
	0.060	0.090	.	0.225	0.335	0.049	.	0.431
	19	20	0	19	20	20	20	20
Prev. Industry	0.219	0.264	0.021	-0.229	-0.328	0.045	-0.041	1
	0.067	0.035	0.464	0.135	0.051	0.415	0.431	.
	48	48	21	25	26	26	20	50

Correlation is significant at the .01 level (1-tailed).

Correlation is significant at the .05 level (1-tailed).

Figure F1. Correlation results *(continued)*