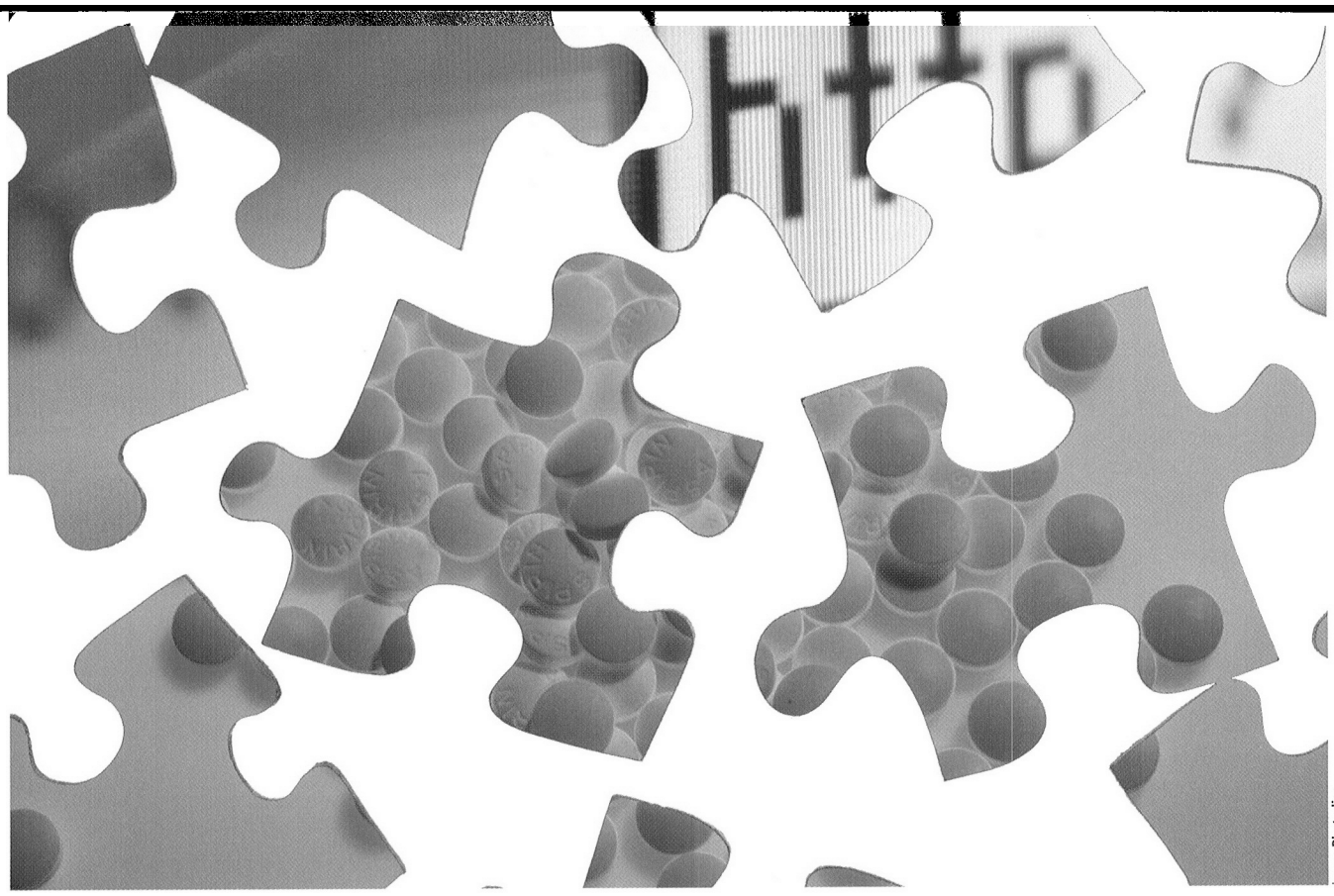

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The Need for **Effective Document Change Management** in the Pharmaceutical Industry

With the advent of regulations such as 21 CFR Part 11 and the introduction of the electronic common technical document, it is becoming increasingly important to be able to enhance and fully utilize data management systems. Document change management is a vital tool in the construction and organization of valuable information, and can play a key role in the all-important process of getting a product to market.

Matthew Brown
is director of product management, life sciences at Workshare Technology Ltd, New Loom House, 101 Backchurch Lane, London E1 1LU, UK.
Tel. +44 207 426 0000
Fax +44 207 426 0060
matthew.brown@workshare.com
www.workshare.com

Advances in information technology (IT) and communications technology are beginning to increase productivity and efficiency across a myriad of research and production practices. Technology generally promises much, but is unlikely to remove the common reliance upon peers and colleagues when sharing work. Indeed, the capability to enhance the processes of teamwork and production in the pharmaceutical industry is what technology is increasingly beginning to address. This is nowhere more applicable than in the construction and management of valuable data — in the form of documents and records.

Pushing, pulling and sharing

The commercial pressures that affect pharmaceutical companies are very strong, although the rewards can be lucrative. The simplest economic perspective applies, whereby hours and days are directly quantified in dollars or euros — the crucial determinate of success and survival is the speed at which product reaches the market. Quality can often be pushed and pulled by the constant pressure on costs that hang heaviest on the doorways of research and development (R&D) facilities and marketing departments that are responsible for producing documents of exceptional length, frequency and complexity. These include technical materials, brochures, licensing applications, preclinical report writing and records of research, reviews, investigations, validations and approvals. All of these will be generated as a result of team collaboration, as demonstrated in Figure 1.

Broad knowledge management (BKM) systems have been the technology drivers behind more efficient data sharing. Often with an intranet (or extranet) at its core, the very existence of these

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systems has encouraged users to provide rich content for the greater good of others. The globalization of pharmaceutical companies has thrown working parties together from all over the world and extended communications from a position of 'down the corridor' to 'across the ocean.' This has heightened the existing need to share an awareness of data and to agree on a final position. The data trawl at the heart of the search for the human genome, for example, would not have been successfully undertaken without effective systems that safeguarded against exhausting resource through replication. However, even with an abundance of data to draw upon, the practice of constructing documents (research results, recommendations and analysis reporting, for example) remains the same.

The value of effective document change management

Despite the many benefits that a pharmaceutical organization can reap from the technological advancements made in terms of gathering and processing data, such advancements have also increased the pressure placed upon an organization to increase its productivity, time to market, cost savings, document quality whilst simultaneously reducing its margin of error. Document change management plays a pivotal role in dictating whether a company rises to these challenges or allows itself to be plagued by unnecessary document management problems. In our experience, organizations that have chosen to invest in document change management have approximately a 60% increase in productivity in the document production life cycle. Organizations that choose to ignore this issue will be left to face the following costly problems associated with poorly managed document production:

- inadequate identification of changes and entries to electronic document records
- the inability to compare document versions
- unmanageable levels of document proliferation
- the inability to review documents in parallel
- reduction in document quality and integrity from *ad hoc* methods of sharing and contributing to documents.

Document management systems (DMSs) have been in widespread use for some time as a response to the need for greater document control. Documentum (Pleasanton, California, USA) is arguably the DMS of choice for the pharmaceutical industry — and is generally accepted as the *de facto* standard. Systems such as this provide the data repositories for our documents. Other interconnecting parts that make up the process of document work provide the transport (such as e-mail and notification) and the principal elements of work flow (critical path and job triggering, for example). Together, these constitute a pharmaceutical company's method for developing documents in a safe, structured and efficient way.

In the midst of ever-developing IT solutions for document control, communication and work flow, little attention has been paid by software developers to the matter of identifying physical document change. The responsibility for collating, organizing and recognizing minute changes to documents of all sizes has not been adequately supported by pharmaceutical technology.

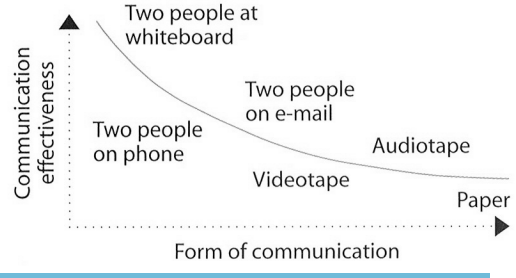
Developing change recognition is the start of providing a comprehensive, accommodating document solution (Figure 2).

DMSs have evolved to the point where they almost seek to provide one-stop solutions for the document construction and review process. For the most part, this evolution has been driven by business demand for content management, the electronic manifestation of knowledge management (KM). This demand has led to a focus on the higher level aspects of the document construction process, particularly organizational and communications channels. This has been at the expense of lower level aspects, such as actually working with reviewers' changes and comments. The result of this is that the development of programs that can work with such granular elements as individual reviewers' changes has been comparatively slow. Nevertheless, the efficiency gains among the higher level processes is leading increasingly to a demand to clear out bottlenecks among the lower level processes.

Inadequacy of current solutions

The most prevalent document comparison/collaboration tool that addresses change identification can be found in the toolbars of *Microsoft (MS) Word*. The 'Track Changes' option enables a user to simply indicate areas of text that should be deleted from a document, and which should be added. A novel function. Yet, within the type of professional environment outlined above, this proves to be woefully inadequate on a number of counts. The tool can only be employed on a one-to-one basis, therefore, it does not allow for parallel review because of its linear person to person nature. With extra participants, the shortcomings of A's document being amended by B, and going back via C and D are clear; complexities add up, and the process of re-review is very problematic and time-consuming. Continued amendment of the same document often results in corruption, with different metadata and text/font styles adding confusion. The need to maintain the integrity of an original document through ownership by a managing author, and the need to open up collaboration among multiple contributors both go

Figure 1 The efficiency of working together.



At the user end, systems have to be extremely easy to use — largely because scientists have developed a reputation for being generally uncomfortable with IT

unanswered. There is also no integration with an existing DMS or enterprise content management (ECM) system.

The publishing tool, *Adobe*, has a 'collaboration feature' that is more advanced but shares the same shortcomings concerning document integrity and effective multiple collaboration. Time inefficiencies are not overcome by either of these tools, despite the basic ability to recognize change in some way.

End to end collaboration

Document change management (DCM) is the process of enabling various contributors to quickly and accurately communicate and report change on a document — no matter how complex. In most document writing, when a number of parties are involved, there is a very strict hierarchy among the authors. Theoretically, one author will create a document and be ultimately responsible for its final form. All others who contribute to it only have the right to make suggestions. In the pre-Internet age, this system would probably be implemented simply through the use of paper faxes. The originating author would keep the original document and send out faxed copies to contributors. Contributors could then only mark suggestions on their fax copy, in ink — thus forever protecting the original. In the likely event of dealing with a highly complex 300 page document, however, the major drawbacks to this are obvious. E-mail communication has revolutionized these outmoded practices, and offers far more flexibility and ease of access for users.

The restrictions of e-mail document collaboration, however, also become immediately apparent. Despite the capability to e-mail a document to literally any recipient in the world, the practice of collaboration can only effectively be managed on a one-to-one basis. Not only that, the original document is also open to corruption from imported styles and metadata. Persistent changing of a large document with imported material or among more than two correspondents often generates one of three outcomes: a mess, a corrupt file or a massively inefficient use of time.

Today, DCM software provides the solution to these difficulties. By working alongside a DMS or ECM, the security of a document is ensured. The process of keeping track of proposed changes from multiple parties is automated into a single interface. Working on documents with people is no longer an arduous process. Document content collaboration becomes a manageable task that actually inspires people to work together.

The originating author of a given document uses the DCM software to send a replica of their original document to all contributors — but not the document itself. By doing this, the author maintains complete control, as the document never leaves the security of the document management system. Additionally, there is no danger of hidden metadata or the inclusion of unwanted macros or foreign styles into the original document, as the DCM software strips all of this away.

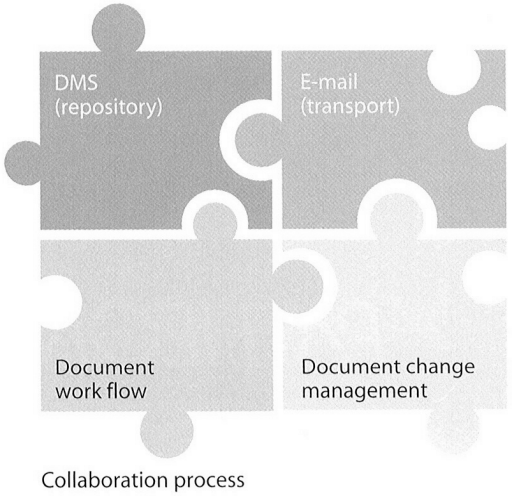
21 CFR Part 11, e-CTD and other standards

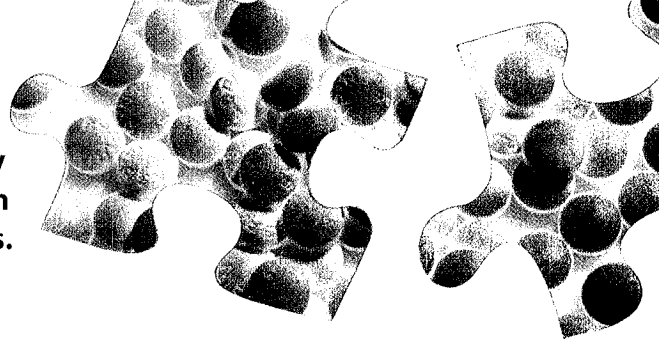
The benefits of DCM are particularly applicable to the pharmaceutical industry, when considered in the light of electronic data and submission regulations. The introduction of the 1997 US Food and Drug Administration (FDA) regulation, 21 CFR Part 11, for how pharmaceutical companies needed to set up their computer systems and processes had a major impact on the demand for technological solutions and a technical awareness across the three principal markets of Europe, Japan and the US. The move from drawer to desktop has not only been introduced — it is practically enforced. Equally, the rapidly approaching common technical document (CTD) and e-CTD regulations are certain to have a profound effect on these issues.

CTD is a global standard for the format and structure of regulatory submission. This defines a directory structure for what are often extremely large documents. e-CTD is the electronic equivalent and is expected to accelerate the process of submission across the different parts of the world. Where previously, physical pallets of paper were sent to regulators as part of the submission process, now document collaboration solutions can deliver these electronically, offering time efficiencies and content integrity.

A solution specific to the European pharmaceutical landscape, jointly endorsed by the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the European Medicines Evaluation Agency (EMEA) is in the process of being developed for product information management (PIM). The PIM solution will be the first simple production system supporting the electronic submission and management of product information (summary of product characteristics [SPC], label and package leaflet) in the European regulatory procedures. The implementation of this technology will support the establishment of improved business processes, which will improve information quality and reduce duplication and rework in industry and agencies, creating more efficient and faster work processes. It is hoped

Figure 2 The last piece of the document jigsaw.





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that this will prove extremely useful in the event of resubmissions.

Document democracy, not dictatorship

At the user end, systems have to be extremely easy to use — largely because scientists have developed a reputation for being generally uncomfortable with IT. The most successful DCM systems will empower, motivate and inspire users to maximize their technology's potential and work with each other. The establishment of user groups by software companies has been ensuring the successful development of user interfaces (UI) for many years. This is crucial with a DCM solution, as its whole raison d'etre is to simplify the complex and present it comprehensively, enhancing existing infrastructure while adhering to strict regulatory requirements. An effective pharmaceutical-specific DCM solution will enable the user to

- increase efficiency/productivity — providing instant return on investment
- gain competitive advantage
- maintain comprehensive audit trails
- leverage existing infrastructure
- formulate concise audit trails
- facilitate electronic documentation formatting
- enjoy ease of use (UI)
- ensure document security — encryption/stripping of metadata.

Peer-to-peer document teamworking

The latest advances in DCM allow contributors to view one another's suggestions. This extends the capability of the managing author to control the life cycle of the document and encourages up-to-the-minute debate and deliberation regarding salient points. In a strong peer environment (such as pharmaceutical, legal, financial or other consultancy) where discussion often reaches academic levels, this is crucial.

"The strength of a team is more than the sum of its parts," it has been said. In that case, not only is the quality of documents produced by a company of professionals a lasting testament to its proficiency — so is its speed at being completed and used. ■

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Tel. +44 1244 393 419
Fax +44 1244 383 356
smcquair@advanstar.com