

## **The Digital Transformation of Life Science Companies and Processes**

Paper-based processes in life sciences companies have required time consuming indexing, referencing and management in order to comply with federal regulations. Although documentation and retention of information will continue to be an arduous, time intensive process, the US government and International community are now promoting the transition from paper to electronic submission “because we believe that having the information in eCTD [electronic Common Technical Document]...will result in greater efficiency in the future” according to the FDA Guidance for Providing Regulatory Submissions in Electronic Format (April 2006). As early as 1994, the International Conference on Harmonisation (ICH) began developing the Electronic Standards for the Transfer of Regulatory Information (ESTRI) to meet the requirements of both the pharmaceutical companies and regulatory authorities. Although the progress has seemed slow from 1994 to the present day, the change in policy is rapidly heating up and changing the way companies think about internal processes.

According to the International Conference on Harmonisation (ICH), web-based solutions provide the best implementation platform for an eCTD delivery system. The FDA has developed a set of guidance documents to further assist the electronic submission of applications for human pharmaceutical products including new drug applications, biologics license applications, investigational new drug applications, master files, advertising material and promotional labeling.

Most government paperwork is now transitioning to electronic format: applying for a business license and registering your business can be done completely online; submitting tax forms and now, submitting information required in the approval and development processes of biotechnology. These all have shown a great cost and time savings for the government. In 2002/2003, the FDA began a new initiative to improve the state of manufacturing science and the related regulatory processes. The initiative included writing guidelines for culture changes and sharing knowledge. The primary objective is a flexible process that supports the move from a compliance mindset to quality by design thus shortening the development and time to market while mitigating risk through use of innovative technology. The desired outcome is an increase of trust between pharmaceutical companies and the FDA that fosters improved communications and sharing of information.

The efforts on the part of the government to adjust their processes are an encouragement to the pharmaceutical industry to embrace new innovations in information technology. This is analogous of shopping in a retail store only to find the cashier using a 1925 cash register. The cashier tallies the discounts and purchases by hand on small receipts prior to entering the information into the register. Their inventory must be counted by hand on a daily basis if they want daily calculations on sales. Their ability to grow is limited.

Today, inventory can be automatically removed when a purchase is made, thus updating inventory immediately. The warehouse can be notified electronically when stock needs to be replenished and notify the store in minutes regarding tracking and goods arrival schedules. New technology available makes inventory control, financial tracking,

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shipping and accountability so cost effective, successful businesses can't afford to be without it.

Remember the typewriter? Whether it is a manual or electric version, how many errors were there when someone typed on a typewriter? How cumbersome was it to repair these mistakes? The advancement to word processing and other computer software has reduced errors and omissions and improved the speed of delivering documents and information. Today, even a manufacturing defect can be communicated within minutes, many times preventing the release of product before a consumer has access to it, improving the development of the product prior to release. Improved processes, including e-processes have increased customer satisfaction and reduced manufacturer liability as well as corporate productivity.

Technology advances have assisted in reducing errors and omissions, providing instant consumer feedback and improving products and complex distribution systems. The e-initiative also helps to better manage human activity and provides a cost savings in several areas:

- Reduction of valuable personnel time in meetings, reviewing outdated documents and spending time on data retrieval from corporate outposts, providing focus and delivery of mission critical tasks.
- Instant access to the most current data and information available.
- Improvement of document auditing control measures and controlling revision errors that currently require, and waste, an enormous amount of time.
- Communicating revisions, SOP's, changes in product testing, process training, and new product information efficiently and effectively, with an email system that alerts team members and manufacturing line workers of the change in real time.
- Auditing workflow within the entire critical path allows managers to see where bottlenecks and inferior processes may impede critical milestones.
- Effective, meaningful and productive dialogue with external suppliers, potential licensing partners, new personnel hires and senior management using document retrieval systems that provide immediate access to the documents necessary for important meetings.
- Manage out-sourced, off-shore or global distribution workflows using a document system that can keep all key stakeholders up-to-date on all of the information and documentation required to do their jobs effectively and inform team members of changes.

Going back to our previous analogy, can the life science industry continue to perform critical document management tasks with the equivalent of a typewriter to develop an application to the FDA that could be rejected simply because the documents don't tell a clear and compelling story about a product? Or worse, because one small, but critical piece of evidence was omitted from the final submission?

Compliance will not go away. In fact, compliance issues have become more resource burdensome with tighter regulations, an increase in product testing requirements and post launch safety surveillance requirements and Sarbanes-Oxley (SOX). Part of the initiative was "to encourage the early adoption of new technological advances by the

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pharmaceutical industry” and “facilitate industry application of modern quality management techniques” (Pharmaceutical cGMPs for the 21<sup>st</sup> Century – a Risk-Based Approach: Second Progress Report and Implementation Plan, Sept. 3, 2003). This included a review of 21 CFR Part 11 – Electronic Records Requirements.

Transforming to electronic format may not currently be an absolute requirement, but it can provide increased profitability, improved workflow processes, smoother regulatory audits, tighter accountability and faster speed-to-market results. Risk and costs are mitigated via the use of electronic tools to better manage resources, improving profitability. Better cross-functional team collaboration and communication can reduce errors, invigorate product strategies and increase the capacity of the company as a whole. Regulatory audits are faster and communication between agents and company managers are more meaningful using secure, electronic Document Management Systems (eDMS). Senior managers, line managers and team members in both Regulatory and Quality can quickly perform periodic audits to assure important milestones are met as well as compliance to agencies and policies. All of these changes within the organization can improve the speed in which new life science products get to a waiting market.

Challenges Life Sciences currently face include:

- Substantial increases in filing fees
- Increased testing requirements and surveillance
- Sarbanes-Oxley compliance
- Compliance reduction in regulatory approvals for new products
- New patent legislation that can effectively shorten product life
- Lower margins due to increased development costs and shorter patent protection
- Loss of older, more experienced workforce nearing retirement
- The need for cross-functional teams requiring expertise in multiple areas
- An increasingly mobile and sometimes remote workforce

A properly managed eDMS can provide security, accessibility and redundancy to prevent loss of data. Redundancy provides protection against loss of data better than a paper-based system. Instead of scanning in or copying all documents to maintain an electronic copy or an additional physical hardcopy of the actual documents, electronic copies, configuration control and revision information can all be easily copied to another secured drive at pre-defined times.

Paper also means signatures. All key personnel must be physically present in order to sign documentation for a project/product. In today’s high speed, high intensity world, that isn’t always possible. Waiting for the return of a key manager in order to complete signoff and approval of a project can create inadvertent bottlenecks and become another process that requires management. With electronic signature compliance per 21 CFR Part 11 Guidelines, secured remote access and time stamps enable individuals who must review documents and provide signoff approval to access all necessary information and securely sign from just about any location.

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Document sharing is also difficult with paper-based projects. Scanning can sometimes produce illegible content and is not searchable—a requirement the FDA has now encouraged in their guidelines for submissions. Where possible, all documents should be adequately bookmarked with an equivalent table of contents for all electronically filed documents. This is best done when developing your final document from already organized files and data.

Building trust between the FDA and life sciences companies is important to the development of good products. The goal of both is to develop a quality product that can be brought to market for the benefit of the community as quickly as possible. Clinical standards are evolving and competition is increasing. Being able to provide adequate and timely documentation is part of building that trust and streamlining the approval process, which shortens the time to market. Providing important documents in a format that is easily read and searched improves that trust and decreases the time for review and inspection. Providing outside vendors with timely, accurate information helps to speed their actions which helps bring the desired results as well.

To move to an electronic system may seem expensive and even a little imposing. The initial cost of adequate software and hardware to store and manage the documents varies from one vendor to the other. Options in collaboration tools and compliance management are factors that must be considered when reviewing the available products. Web-based delivery systems have been recommended internationally as the most compatible and accessible.

Some of the available products for GxP and ISO-based quality processes include:

- Audit management
- SOX
- Process automation
- Integrated quality management solutions
- Change control
- Complaint handling and tracking
- Design History Files
- Clinical Trial Master Files
- Corrective Action Preventive Action (CAPA)
- Deviation management
- Statistical Process Control (SPC)
- And more....

With all of the valuable benefits of moving to an electronic system, many companies have been challenged by the decision to move forward. Without an understanding of how processes can be improved within various departments, how decisions to incorporate a new system should be made and when the incorporation of that program will enhance workflow, managers cannot make the best decisions and commitments regarding a system.

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The process of moving forward can be more easily managed by:

- Developing a team of critical functional areas most involved with regulatory documents: product development, manufacturing, regulatory and quality and create a short list of document management “must have’s.”
- Bringing the new eDMS online early in the development process and grow the company’s acumen as the product moves through the phases of development. This will help you build your submission.
- Begin with an out-of-the-box solution and add components as you need them. There will be a steep learning curve and adjustment as you recognize the power of eDMS. Buying an expensive customized work suite will slow down internal workflows during the design and testing stages, leaving personnel frustrated and disinterested so beginning slowly and adapting the processes as the product develops may be the best solution.
- For companies with products already being manufactured, start at either end and work towards the middle. Incorporate eDMS in manufacturing and distribution immediately and use the system to track early stage products at the same time. Once the processes are clear and have been incorporated into the company culture, integrate the system into emerging products.
- Although bringing in a system and sticking with it is important in order to best manage resources and training issues, don’t buy the Cadillac yet. Buy an affordable system that will get used.
- Don’t wait until you’ve faced a regulatory audit or get a non-approvable letter from the FDA to incorporate an eDMS, do it now. Think of it like putting on a seatbelt before the accident happens. When development and manufacturing issues and changes arrive, and they will, you’ll feel better about the safety net you’ve created for your company by using important new innovation.
- Use the system to create email alerts, training and regulatory audits. Get personnel used to using the system and they will soon grasp its power.

The benefits of an electronic system will soon outweigh the concerns of switching:

- **Built-in redundancy**—if you install your system correctly, your IT department should include a backup feature so the information held in the electronic system is regularly archived in a safe, secure location. With an electronic system, this can be automated and verified on a regular basis.
- **Easy access** from any location with secured login. Traveling management can access and follow the development of the product while they are on the road. They can also participate fully in the development steps and sign from a remote location for timely processing of any and all product filings.
- **International and multiple teams** across the US can use a web-based system to review documents, provide feedback, and approve changes within minutes of the changes occurring. No need to wait for processes to move forward. Some teams can even work real-time on a project with everyone viewing the results as they happen. No more waiting for team "a" to develop part "a" of the project to deliver their results—the results, and their progress, are available immediately.

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- With electronic tracking of all documents, there is more **control over revisions** as well as knowledge of the “**who, what, where and when**” of changes.
- **Senior management has more access** 24-hours a day to all company activities and developments enabling them to be more informed and better able to assure compliance.
- **Better communication** is facilitated between **marketing** and **development** when product issues and design questions arise. All functional departments can more fully participate in the decisions.
- **Time for filing is reduced and streamlined.** No more waiting and wondering if the paper based documents arrived at their location on time; more time for development to assure their information is clear, concise and correct for any and all FDA regulations.
- Electronic filing allows **easier access for the government agencies** involved in approving applications. Later steps referencing earlier documentation take less time to track down the prior documentation, thus reducing the time for approvals and presenting the company in a better light.

Electronic filings provide easier access of information and compliance review to both the company and the FDA at all stages of development. This access provides greater clarity and communication of new life science products. This is critical to the development and evaluation of innovations that provide revenues to the company's bottom line. As product approvals are more difficult to get and manufacturing delays can cause companies millions in lost revenue, this alone is a compelling reason to move into an electronic solution.

Despite the challenges, switching from a paper-based system to an electronic system for document management is inevitable. Companies seeking a strong relationship with the FDA, a reduction in time spent on redundant processes and a workforce committed to collaboration to improve products and customer relations will do it now rather than wait. The time of paper-based companies and submissions will soon be as the lore of hand written sales receipts and typewriters. Reviewing history tells us that the fast pace of technological change in all areas of 21<sup>st</sup> Century life can be embraced and quickly integrated into everyday processes while transforming our experiences. This change will provide greater opportunities as the life science industry moves forward.

Organic benefits to consider are:

- **Reviving earlier innovations:** Rather than boxing up lab notebooks and early versions of designs not advanced, companies can revisit these documents effortlessly both to learn from and potentially refine and use.
- **On-line collaboration:** Scientists, engineers, and internal medical teams can collaborate on important product development and communication issues in real time with experts from around the globe. Inputs can be given on current scientific and medical knowledge making “what if,” “what is.”
- **Expansion of capabilities:** eDMS can enhance publication planning, the development of product monographs and presentations, due diligence review,

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- improved patent development, investor presentations, and enable stronger co-promote and other industry partnerships.
- **Expansion of corporate knowledge:** Cross-functional teams will be able to view more documents and provide careful, thought provoking ideas and product solutions to team members outside of their department. New innovations, product improvements, and better processes can come from this.
  - **Rapid response:** External stakeholders such as Principal Investigators, contracted providers, and hospitals can quickly inform the company of problems, to be quickly managed and avoid issues with product uncertainty, liability, and customer satisfaction.

Let's return to our 1925 cash register. You are still standing at the counter waiting for the store clerk to calculate your discount and write it down before he enters the final cost into the register. Then he has to be sure to remember to write down the items you bought so he can add them to the list of items sold for the day. There are three people behind you—will he get to doing that before the end of the day? Will he remember?

As the world accepted new innovations in the cash register and progressed from the typewriter of yesteryear to the word processor and computer software of today, the world became more accessible to everyone. Electronic developments have opened the doors of communication and accessibility of information to everyone including the Sciences. This global growth has enabled greater development of medications, quicker acceptance and availability of new developments as well as greater awareness of new diseases and their treatments.

As International standards develop, the harmonizing of regulatory standards that are accepted worldwide will increase acceptance of products globally thus increasing the market. Time to complete clinical trials can be reduced. Costs associated can be reduced significantly and increase competitiveness. Other research will become available quicker and collaboration can contribute to better drug development and quicker resolution of any problems. Implementing an eDMS is the first step in beginning a journey to greater awareness and advancement of life science technology as well.

Using an eDMS helps to bring your company out of the early 20<sup>th</sup> Century and into the 21<sup>st</sup> and beyond. Government compliance is moving toward all electronic, secured submission while paper-based processes are steadily being recognized as stifling and burdensome. As you transition from paper to electronic, support your personnel and help them discover the value it brings to their contributions. Start with an out-of-the-box, web-based solution that is easily managed in both resources and technology. Maintain regulatory compliance without sacrificing the critical skills within your teams by their performing mundane tasks. The time saved will stimulate new innovations, provide more accurate results and improve your company's bottom line profitability by shortening the release of new products to the consumer and reducing errors and omissions that can be costly.