GxP Process Management Software

master™ CONTROL

White Paper:

Top Five Ways Automation of Document-Based Processes Can Boost Financial Success

Introduction

In today's global market, innovation and business growth are impossible without the aid of technology. While cutting costs and maintaining operational efficiency remain priorities for businesses, most companies understand that technology not only fuels innovation, but it can help drive business growth.

The majority of CEOs interviewed for the IBM Global CEO Study recognize that "bold, innovative ideas cannot be put into play without technology." The 2006 study surveyed 765 CEOs from different industries worldwide. The insight is relevant within the context of regulated industries, particularly life science companies facing cutthroat global competition, tougher regulatory environment, and dwindling pipelines of new products.

This white paper will focus on how technology—specifically automation of document-based processes—can help life science companies and other regulated industries attain two of the most pressing business goals across the board: lowering costs and realizing profits sooner.

Why the focus on document-based processes? Documentation is the backbone of the operations of life science and other regulated companies. If you are a senior executive in such a company, you must realize that documentation is something you cannot do without. The sooner you recognize it, the better off you are.

Top Five Ways

In the life science industry, as in most businesses, a hit product is the surest route to market success. Think of Pfizer's cholesterol drug, Lipitor, with sales of $2.7 billion in the second half of 2007 alone. The figure is staggering, but it actually marked a 25 percent decline in Lipitor's sales in the U.S. market. In the medical device industry, take the example of Boston Scientific's top-selling implantable cardioverter defibrillator, with sales of $356 million in the fourth quarter of 2006 alone.

However, by its nature, a blockbuster product is rare. Companies cannot rely on an exceptionally popular product alone. They must look at other factors to increase their financial viability. The following are the top five benefits of automating document-based processes, which CEOs, CFOs, and other senior executives should consider in their search for ways to boost financial success:

(1) Reduce internal effort. Processes are increasingly being automated, starting from the concept stage. But the use of technology has not necessarily extended to management of document-based processes.

For example, more and more drug companies are automating their laboratory processes to allow discovery research scientists to test a large number of compounds quickly. Similarly, medical device companies invest in technology to allow their research scientists and engineers to conduct product iterations as rapidly as possible. In both examples, automation from the get-go helps scientists work quickly, which means they also generate huge amounts of data faster.

And yet, many pharmaceutical and medical device companies continue to rely on paper-based processes or use Microsoft Word or basic database software to manage data. Such imbalance in the use of technology affects internal effort as a whole.

By automating document-based processes (preferably from the start), your company will simplify the work of in-house staff, increase productivity and efficiency, perhaps reduce head count, or at least control personnel growth.

If your company is small and your paper-based system has adequately handled moderate amounts of data, there remains the issue of integration. Even when individual departments are efficient, if they work in silos, it still results in inefficiency overall. Life science companies are known to create, albeit unintentionally, internal walls of all kinds: between scientists and marketing specialists, between R&D and commercial teams, between regulatory and manufacturing teams, and so forth and so on. An integrated electronic system will help you promote more effective communication and collaboration.

(2) Reduce external effort. Today there are few life science companies that can develop products entirely from internal expertise and do all the work in-house. Even the largest of companies are increasingly forming joint ventures.

Majority of companies outsource certain functions, from formulating and compounding to manufacturing operations to clinical trials. In addition, there are vendors and consultants who may be involved in different stages of the development and commercialization phases.

Automation of document-based processes can make collaboration between your in-house staff and external parties better and more efficient. This is particularly critical if the contract research organizations (CROs) and suppliers that you deal with are based in different geographical locations.

(3) Accelerate time to market. One could say that time is not on the side of a life science company. The clock begins ticking from the moment such a company receives a patent, which grants exclusive rights to market a product for a period of 20 years. Even the five-year extension in patent life allowed by U.S. law to make up for time spent obtaining Food and Drug Administration (FDA) approval is hardly sufficient for companies to recoup their investment in product development.

It is, therefore, necessary to find ways to accelerate time to market. Any delay that cuts your period of exclusivity is costing you unrealized profits. The sooner you can obtain FDA approval, or a marketing authorization (medicines) or a CE mark (medical devices) in the case of companies entering the European market, the sooner you can realize profits. If you consider the amount of documentation your company must perform from concept stage through commercialization, it makes a lot of business sense to automate all document-based processes to help accelerate time to market.

(4) Increase product quality. Your product is what will bring in profits. The higher the quality of your product, the better chances you have of succeeding in the market. The FDA, the European Medicines Agency (EMEA), and individual drug or medical device agencies in Europe all incorporate quality in regulations to ensure product quality and safety. ISO standards exist for the same reason.

Outside of compliance, quality also has a direct impact on a company's bottom line. For example, the recall of Guidant's defective implantable defibrillators in 2005 cost the company $195 million to settle more than 4,000 lawsuits. In the blood industry, the FDA imposed a $4.2 million fine against the American Red Cross in 2006 due to blood safety violations stemming from poor quality assurance. As these examples show, poor quality can be costly.

The strict documentation required of life science companies is necessary to ensure quality. Through documentation, companies are essentially proving the quality of their products and providing accountability every step of the production process. So it is not enough that you produce high-quality products, you also must prove it through documentation. Automating your document-based processes increases the quality of your documentation by standardizing and simplifying the procedure, reducing the possibility of errors, and making it easier to revise documents.

(5) Enhance risk management. The life science industry is regulated because of inherent risks that permeate the business. A medicine or vaccine or medical device may save lives, but unfortunately, they can sometimes harm patients. Such was the case with Vioxx, a popular pain medication that alleviated arthritis and joint pain in millions of patients, but may have caused heart attacks in thousands of others. Merck voluntarily recalled Vioxx in 2004.

In the face of such risks, the FDA, the European Commission (EC), other regulatory agencies, as well as ISO standards incorporate risk management in compliance. Risk management principles can be found in the FDA's "Q9 Quality Risk Management" guidance (for pharmaceutical companies), ISO 14971 (for medical device firms), and the EMEA's "Guideline on Risk Management Systems for Medicinal Products for Human Use," just to name a few.

Within the context of document-based processes, the most critical risks for life science companies are:

- **Noncompliance Risk:** Document control, change control, corrective and preventive action (CAPA), quality audit, and customer complaints are but a few document-based processes where effective data management could help reduce noncompliance. By automating such processes, you can increase efficiency and also integrate them with training. Any substantial change in a document or procedure that affects product quality will automatically trigger training tasks for all affected personnel, which will help reduce the risk of an unsafe product, and the risk of noncompliance in training requirements.

After your product enters the global market, the need for an automated system is greater, in terms of documenting, processing, managing, and resolving consumer complaints and field reports, all of which could affect your post-market vigilance and compliance efforts.

- **Security Risk:** Hard copy documents—ranging from compliance records to documentation of proprietary procedures and trade secrets—stored in filing cabinets or store rooms can be easily misplaced, or photo copied, or stolen. Storing them in electronic directories may only partly mitigate the risk; you still need to be able to track any revisions or detect any record tampering. Your security considerations should include access to documents based on user roles and rights, as well as FDA requirements such as user authentication, record retention, and audit trail.

The MasterControl Solution

The MasterControl™ GxP process and document management software was designed to effectively automate and manage your manual or partially electronic document-based processes. Below are some of the software's features that are critical in optimizing document and process management, and in helping you attain the twin goals of lowering costs and realizing profits sooner.

Reduce Internal Effort and Accelerate Time to Market

- **Automatic Routing:** MasterControl reduces document cycle time by automating routing, notification and follow-up, escalation, and approval. A MasterControl customer reported cutting down its throughput process by 45 percent, from 11.5 days to 6.3 days. Cycle time was reduced by 37 percent from 14 hours to 8.8 hours.

- **Electronic Approval:** The capability to review and approve documents electronically speeds up the approval process significantly. Electronic signature manifestation (name, date, time, and meaning of e-signature) can be appended automatically to each document as required by 21 CFR Part 11.

- **Template Formatting:** By implementing submission-formatted document templates early in the product development phase, the time it takes for assembling documents required for submissions can be greatly accelerated.

- **Centralized Repository:** All records and documents, from the discovery stage through the post-market phase, can reside in a centralized electronic repository that can be accessed only by authorized users. This will make it easier to update, and to search and retrieve documents. Although the system is centralized, every department can compile documents separately using the Organizer, a MasterControl tool similar to Windows Explorer, which helps users find documents quickly.

- **Automatic Revision Control:** With a paper-based system, making sure that all documents are current requires extra vigilance. There is no mechanism to stop a user from inadvertently using obsolete or unapproved documents. With MasterControl, revision control is automatic, so only approved documents are released. Outdated documents are automatically archived, and documents in the process of revision are locked.

- **Integration with Existing Systems:** You can save a lot of time and training effort by leveraging existing systems such as ERP, PDM, and PLM, and integrating them with MasterControl without expensive custom coding.

- **Integration with E-Submission Tools:** MasterControl can be integrated with leading e-submission tools to improve and accelerate the electronic submission process.

Reduce External Effort and Accelerate Time to Market

- **Web-Based Platform:** MasterControl is Web-based, making distance and time zone differences less of an obstacle. Employees, CROs, suppliers, consultants, and other authorized users outside of the company can have system access regardless of location. Access will be based on the extent of their roles in any document-based process.

- **Virtual Workspace:** Collaboration between internal staff and external parties is easier through a virtual workspace, accelerating completion of tasks such as cross-functional review and document approval. The system automates tasks pertaining to collaborative projects, including routing, follow-up, escalation, and approval.

- **Electronic Compliance Environment:** By automating your compliance environment, you are increasing your audit- and inspection-readiness. It also means you will be reducing the time and effort spent by third parties during inspections. An FDA investigator said that a routine GMP inspection typically lasts a week, but sometimes it can last up to five weeks. When that happens, he said an electronic record-keeping system could make all the difference in speeding up the inspection process.

Enhance Risk Management

- **Integrated System:** MasterControl connects all document-based processes such as document control, CAPA, quality audit, change control, customer complaints, deviation handling, nonconformance disposition, and training. An integrated system will help you see the overall picture of your operations. For example, when there is a customer complaint serious enough to require a CAPA, it will be automatically escalated to the CAPA process. Any document change resulting from an approved CAPA will automatically trigger training tasks on the revised document for all affected employees.

- **Automatic Life Cycle Management:** Virtual vaults provide automatic management of a document's life cycle to reduce the risk of using obsolete or unapproved documents. A document being revised will stay in the "draft" vault until it is approved. Once approved, it will be automatically released and then reside in the "released" vault. When a released document is updated, the original document will automatically move to the "archive" vault.

- **Audit Trail:** MasterControl provides a time-stamped audit trail of all changes made to a document as required by the FDA. The system will show the document's history, including who approved it and when.

- **Advanced Analytics:** MasterControl's advanced reporting capability enhances risk management by increasing your ability to monitor product quality/safety issues. The system provides standard and customized reports.

- **Retention Control:** You don't need to keep sensitive records longer than you need to. This feature allows you to retain records according to your company policy and regulatory requirements, anywhere from 24 hours to several years or longer. Retention can be configured by document type.

- **Best Practices:** Industry best practices are incorporated in critical processes (e.g., CAPA, nonconformance disposition, EBR management, quality audit, change control) to enhance risk management. Best-practice workflows can be used as is or customized.

Conclusion

Life science companies are typically on the cutting edge of technology when it comes to product development. They must extend their technological savvy into the area of data and process management. As this white paper has shown you, choosing the right software to automate your document-based processes can bring long-term benefits that are critical to your overall financial success.

About MasterControl

MasterControl Inc. is a global provider of GxP process and document management software solutions for life science companies. The MasterControl™ suite is easy to use, easy to deploy, easy to validate, and easy to maintain. It incorporates industry best practices for automating and connecting every stage of the product development cycle, while facilitating regulatory compliance. By combining an integrated platform with a continuum of risk-based software validation products and services, MasterControl drives down the total cost of ownership and enables customers to extend their investment across the enterprise. Hundreds of companies worldwide use MasterControl for easier compliance, faster validation, and better process management. For more information, visit www.mastercontrol.com, or call 800-825-9117.