

A Pharmaceutical Company Implements Pioneering “FDA-Compliant” EDMS



A diversified pharmaceutical/medical device/customer-products company based in the northeastern United States has over 120 years of safely and successfully introducing products to the public. This company has lent its expertise in development and marketing to create some of the most recognizable trademarks on the market.

Introduction of new products to the marketplace is no easy task. For the sake of consumer safety, the Food and Drug Administration (FDA) has established many regulations that govern the development, testing and production of pharmaceuticals, medical devices, over-the-counter drugs, foods and cosmetics. These regulations include: Current Good Manufacturing Practices (CGMP), Good Clinical Practices (GCP) and Quality Systems (QSR).

challenge

To implement and Electronic Document Management System that would offer the efficiency and accuracy of electronic workflow, but still be in compliance with FDA regulations

solution

OIT's DocFinity® Suite of Document Management Software

benefits

The new system provides time, cost, and space saving solutions, while offering the security needed to handle the FDA monitored processes

In 1998, the FDA issued additional regulations entitled Electronic Record/Electronic Signatures. Record keeping requirements within the regulated industry have always been extremely important. Every phase of research and development, manufacture, quality control and product distribution must be thoroughly documented at every phase. These records must be readily available for examination by regulatory authorities. For many years these record keeping processes were conducted on a manual basis – that is, paper and many file cabinets. With the rapid influx of computer and information management technology, many companies realized that this new technology could be used to ease the paperwork burden. However, the ever-present compliance agencies and the need to have accurate, unalterable records raised a flag of caution in both government and within the industry itself.

industry challenge

The challenge for executives at this pharmaceutical giant was to implement an Electronic Document Management System (EDMS) that would offer the efficiency and accuracy of electronic workflow, but still be in compliance with FDA regulations. One innovative aspect of the project would involve the creation of an electronic process that would allow for the circulation and approval of documents that would meet FDA guidelines.

This is where Optical Image Technology, Inc. (OIT), an innovator in the field of EDMS software development, and OIT's Philadelphia-based partner, Doxentric, a leading systems integrator, came into the equation.

The pharmaceutical company formed a team of user and MIS personnel. The team evaluated most of the leading imaging products over nearly a two-year period. The process included review of product functionality, deployment options, and the ability of the VAR-Software Manufacturer team to support the product. The team conducted several site visits to see installed products.

Working together, the team began the task of uncovering the intricacies of the FDA-Compliant development process and integrating that process into the product.

“This is a giant step for the future utilization of electronic document management,” explains Optical Image Technology, Inc. President Scott Buchart. “By operating in a system where FDA guidelines are paramount to a successful operation, OIT technology has proven that innovations such as electronic workflow and electronic signatures can not only be efficient and accurate, but can be applied to business environments where security is mandated.”

the FDA-compliant development process

The main objective of the FDA is to protect the public health by helping safe products reach the market and monitoring them for safety after they are in use. The FDA must respond to the challenges of regulating very complex industries. In order to do this, the FDA has created a comprehensive development process.

The goals of this development process are fundamental and consist of traceability and accountability. Each and every step of the development process, as well as the person responsible for each step, must be stringently documented. These thoroughly recorded documents validate the traceability element of the FDA's goals.

In addition to this, within the system, everything must be audited. Everything that a user does is tracked by the system. To go along with this, the system must be designed so that no one person can compromise the system. These two items represent the accountability portion of the process.

Working in close conjunction with personnel from the firm and officials familiar with FDA regulations, the OIT/ Doxentric team designed and developed a system that would both accomplish the goals set forth by company officials and fit FDA guidelines. The Stelex Corporation was brought in to audit the system for FDA compliance

and found certain minor issues. Those issues were subsequently resolved and a letter of substantial compliance was issued for the system. The customer subsequently released notification to the FDA that electronic documents and signing were certified and in use.

solution

OIT solutions licensed by the pharmaceutical company include: DocFinity® COLD-ERM, DocFinity Imaging, DocFinity Workflow, and DocFinity IntraVIEWER® (Browser Access), OIT's DocFinity Electronic Signature Server is also utilized in the solution.

The system runs on NT Servers using MS SQL Server 7 and 6.5 for the OIT security, document management and workflow tables and for the storage repositories. Storage is handled by a 300-gig RAID array.

Browser access has been tested using MS Internet Information Server while awaiting security upgrades in the customer's data communications network. Principal access is currently via desktop PC's and notebooks authenticated on the customer's inter-connected LAN's.

The architecture is n-Tier, client server using OIT Encryption Server, Workflow Server, and central program library (file server) from NT Server platforms, in addition to MS SQL Server. Workflow notification is done via a MAPI interface with MS Exchange Server via an Exchange Mail Client.

phase one

OIT's DocFinity Suite of Document Management Solutions was first implemented in the company's Internal Procedures Division. The Internal Procedures Division works directly with the FDA guidelines.

With 250 users on the system, the Internal Procedures Division distributes approximately 2,000,000 documents per year, including FDA supporting documents, which can contain thousands of pages each.

To comply with FDA regulations, OSHA and other regulatory agencies' rules on electronic distribution of files, OIT developed a system that utilized its DocFinity WorkFlow and e-Signature Server modules that could:

- Integrated workflow with Exchange, E-Mail notification.
- Protect electronic signatures from tampering through an innovative electronic signature token system.
- Retain all copies and comments made throughout the process.
- Encrypt each revision in a separate "signed document" vault.
- Tight integration with networked NT servers, NT security, and MS Word Change Control and Protection, so that the overall package provides four levels of security to protect storage vaults, documents and provide audit trails of changes and document versions.
- Unique workflow administration controls that dynamically track documents in process, providing details about date/time received and sent and actions.
- A history log that tracks actions on documents at the individual user level.
- The ability to produce SOP (Standard Operating Procedure) print-outs containing an FDA Batch Control Number overlay and the complete revision history of the SOP.
- The ability to search the revision history of an SOP since its inception and retrieve and view the documents. This feature has many uses like research scientists who are developing changes to products using other computerized systems, who can have the whole product history available.

- The ability to include, add and approve attachments to SOP's, such as Packaging Specifications, using full color PDF's.
- Automated mainframe archive and import engines to move COLD/ERM reports into the document stores and document meta-data into the databases.
- Processes which were previously handled manually, such as distributing product changes among technical writers and editors or circulating graphic art materials for approval from relevant divisions, now are completed electronically in less time and with less chance of mishandling.

"We can now complete a task in a few days that once took months," said one company official familiar with the project, "But there is no loss of quality assurance, in fact there is an improvement in this area, as well."

The significant reduction in task time and man-hours will produce a quick return on investment for the company. Executives from the pharmaceutical firm expect the system to pay for itself within 3-5 years.

phase two

Impressed with the solutions created in the Internal Procedure Divisions, the company also wanted to apply the same timesaving and money-saving document management solutions to other areas within the company.

The Customer Service Division was one such segment and was the focus of the second installation phase of OIT technology.

Customer Service handles about 500 pieces of paper per day. These pieces included purchase orders, invoices, etc. COLD/ERM (computer-generated) and imaged data is included in the mix. This division has approximately 38 users.

DocFinity Imaging and DocFinity COLD-ERM were utilized in the Customer Service Division solution.

The response time has been cut significantly by the new technology, according to company officials and this has led to other benefits.

The officials report that in the Customer Service Division, the implementing OIT technology continues to provide tangible and quantifiable benefits such as increasing productivity and improving response time. This, in turn, enhances those important, but somewhat intangible business areas such as customer satisfaction and customer relationship management.

Customer service representatives are now able to rapidly and efficiently respond to the needs of customers. Improved customer service leads to customer retention and that adds up to improved profitability.

Even as customer satisfaction ratings climb higher, fewer personnel are needed in the division, also, allowing the company to reallocate labor within the company.

In summary, the effects of this project are rippling throughout the company. It appears that there are other benefits from clarifying the firm's organizational responsibilities, to affecting the start-up of other efficiency projects. In addition, new projects are being evaluated to extend electronic documents into other divisions and operating units.

Optical Image Technology, Inc.
www.docfinity.com