

Manufacturing Document Control for Major Pharmaceutical Company

Six manufacturing sites around the world on the right page every time

The Organization

Leading international research-driven pharmaceutical company, publicly traded on the New York Stock Exchange. The company, with 20,000 employees, is ranked among the world's 100 best-managed companies and has six manufacturing plants around the world.

The Business Challenge

There were no uniform manufacturing documentation standards at the six manufacturing sites and no way to ensure corporate control. Each of the plants relied on their own set of documentation standards. There were also signature problems when they wanted to move the manufacture of a particular drug from one plant to another across the world. The industry is highly regulated and has to meet the stringent standards of various regulatory bodies, including the FDA.

The Burntsand Solution

The solution was put together using Documentum document management solutions. Key functionalities are dynamic watermarking that imprints the document's attribute information without the need for a watermarking server; and document creation process enhancements that link together authoring tools like MS Word, Visio, ChemDraw, Powerpoint, AutoCAD, and others.

Project Background

This leading pharmaceutical company, heavily committed to R&D, manufactures drugs and medical devices or delivery mechanisms at six major facilities around the world. This is a highly regulated and competitive industry and documentation of the manufacturing process is critical, especially where plants in different countries manufacture the same drug and must meet the stringent requirements of various regulatory bodies, including the Food and Drug Administration (FDA).

Historically, each of the geographically dispersed manufacturing facilities relied on a unique set of documentation standards. From a corporate perspective, the lack of worldwide standards impeded the ability to relocate efficiently or expand certain manufacturing processes. In addition, staff familiar with one approach had difficulty 'converting' to other site standards.

Burntsand proposed to implement worldwide standards for document control covering the entire lifecycle of the manufacturing-related documentation and to enforce corporate standards and procedures, including authoring tools, templates, numbering schemes, and review and approval processes. These standards were implemented through a web-based document management system that would ensure uniform standards at all times at all the company's manufacturing sites around the world.

Burntsand was chosen to undertake the project because of its experience with Documentum document management solutions and its knowledge of the requirements of the pharmaceutical industry. The development of the solution took about a year, followed by eight months to roll it out.

Security

"This was a challenging job because the security model was so complex," says the project implementation manager for Burntsand. "There were a lot of scenarios that had not been considered in the initial design of the system. We defined seven roles (writer, reviewer, signer, approver, clerk, printer, and viewer) that can be applied by document type. Users are given only the access they should have."

Documents are categorized by a type and sub-type. Since many sites are decentralized, users may have different roles for specific document types. For instance, a user who can write Administrative Procedure may only have the ability to view Manufacturing Orders. Groups are defined for each combination of role and sub-type, and users are assigned to the groups corresponding to their responsibilities.



ABOUT BURNTSAND

Burntsand is a technology consulting firm specializing in integrating content, processes and data. For more than a decade, Burntsand has been a respected EMC Documentum partner with proven expertise in Enterprise Content Management. Leading organizations have trusted Burntsand to deliver results-oriented business solutions including document management and scanning, digital asset management, web and portal publishing, publications automation, and records retention. Burntsand delivers optimum time to value and unrivaled customer experience whether delivering an Enterprise Content Management Roadmap, complex integration or product installation. Our consultants work hard to ensure that accountability, leadership, teamwork and trust are the guiding principles of every engagement. With additional expertise in .NET development, Burntsand can help you create intelligent solutions that integrate seamlessly with your business.

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Documents go through a lifecycle that moves from WIP (Work in Progress) to a final state of either Approved or Cancelled. Documents are reviewed and approved at various stages. Reviewers can attach comments in the form of electronic "stickynotes." The progress and response of each reviewer is stored in a log that generates a report that can be reviewed during and after the review process. The company requires hard copy signatures that are stored in an external file.

A key part of Burntsand's Documentum solution functionality is dynamic watermarking. The PD5 watermark is portable and does not need a watermarking server. Effective documents are watermarked, with their status, effective date and document number clearly labelled on each hard copy for production use. This ensures that everybody is reading from the right page at all times and manufacturing instructions are the same no matter where the manufacturing facility is in the world. The watermarking technology is also used to print batch sheets with incremental batch sheet numbering.

Documentum can store documents of any format and manage the viewing and editing of document formats. The editing application can be launched from a command line. This enables authors to mix and match the output of various authoring tools (MS Word, Excel, Powerpoint, PDF, AutoCAD, Visio, and ChemDraw), so that they can organize document components as needed. The system renders documents to PDF, links the documents together, and imprints the appropriate watermarks for a uniform look and feel.

Competitive benefits

The benefits of the new system are enormous. It ensures corporation-wide standardization of documentation far more cost-effectively than before. It guarantees that only effective documents are presented to the plant operators. It promotes ease of audit by any regulatory body and enhances regulatory compliance. And it allows for multi-site collaboration and enhances batch sheet printing.

In addition, individual plants can now create and manage their own portfolio of documents. They can transfer documents to other plants, confident that only approved new documents or versions will automatically be transmitted. They can use the documents as is or apply them as templates for the creation of new documents.

“Quality assurance in the manufacturing process is paramount and the level of tolerance is low.”