

AUTOMATING DOCUMENT MANAGEMENT FOR EFFICIENCY, VISIBILITY, AND FDA COMPLIANCE

Benefits

Improved efficiency: The document review cycle has gone down by over 50% as the automated workflow takes the documents through the prescribed lifecycle without delays. Email notifications and a task list on the home portal page for user keeps pending tasks on top of the mind, improving responsiveness and proactive participation.

Transparency and analytics: Achieved 100% traceability for all documents. The status of any corrective document is visible across the organization making document management a predictable and transparent process. The ease of accessing and searching documents has increased substantially.

Compliance: Significant reduction in the risk of non-compliance as the quality and regulatory processes are well documented and their change-control process is systematic. cGMP procedural requirements for managing SOPs, batch records, laboratory testing, etc. are easily accessible to concerned units and follow a strict change control mechanism.

Overview

The Customer is a chemistry-based drug discovery and development company, focused on identifying and developing biologically active, small molecules with applications in the drug market. The company conducts R&D projects, collaborates with many leading pharmaceutical, biotechnology and genomics companies, and is developing new chemistry technology for potential pharmaceutical products.

Challenge

Due to its roots in contract-based research and development, the Customer had developed a manual but comprehensive process for document management and control. This manual process was conceived and implemented in the early stages of the company. With the tremendous growth, it was no surprise that the company's operations had far outgrown the manual document management process. With the foray into contract manufacturing, where the demands of FDA regulatory compliance are even higher, the management knew that a manual approach to handling documents would incur higher costs and risks for compliance with cGMP and FDA guidelines.

Convinced that maintaining status quo was not an option, the Validation Manager at the Customer facility built a case for implementing document management automation by highlighting the tangible costs and risks of the current system. The inefficiency of managing document control on spreadsheets, the lack of visibility into status and bottlenecks in the review cycles leading to unpredictable review cycle times, the disparities in the quality practices at various facilities, and the risks and challenges of managing more than one copy of an SOP in a growing organization were easy to demonstrate. It set the Customer on the path to seeking a document management solution.

Solution

Since February 2004, the Customer has been reaping the benefits of MetricStream's Document Management Solution; a proven system for the FDA regulated industry. They have achieved end-to-end automation for management and control for all types of documents such as SOPs, regulatory filings, cGMP and internal quality requirements.

All documents are stored in central repository and with clearly defined lifecycle stages, templates, classification methods, search parameters, numbering schemes, revision control, association and obsolescence rules. The access to the repository is centrally managed with policy-driven rights based on roles and responsibilities.

Employees at the Customer facilities use MetricStream to access, create, modify, review, and approve documents in a controlled manner. The Validation Manager explains, "With paper-based system, there was only one copy of an SOP in a facility, and sometimes, it would not be available to an operator who needed it for a task at hand. With MetricStream, each authorized user always has ready access to an SOP when needed".

The solution also needed to be easy to use to ensure adoption across the organization. "MetricStream has given us a solution that is used across the organization right from the operator on the shop floor all the way to top management", says the Validation Manager.

MetricStream

Why MetricStream

Rich cGMP capabilities with a small footprint

Deep quality management functionality

Multi-site web-based access with central control

Flexibility to meet specific Customer requirements

Low total-cost-of-ownership

MetricStream's understanding of 21CFR Part 11/
cGMP

Each new document or revision of an existing document follows a predefined workflow for creation, review, and approval and the status is visible in real-time making it easy to track documents. And having annotations (electronic redlining) capability has greatly simplified parallel reviews by multiple employees while being able to filter and look at annotations made by a specific user. By enabling email based notifications and alerts, the Customer is able to send reminders and escalations tied to events that need to be attended to and avoid unnecessary delays. "It is a welcome change from the days when we had to walk form desk to desk to find out who has which document and to follow up for reviews and responses", says the Validation Manager.

"The MetricStream professional services organization enabled us to go live with the document management solution in a very smooth manner. We are very happy with our choice of MetricStream and look forward to deploying their CAPA and OOS applications as well to continue to automate our cGMP processes and significantly improve our operational efficiency." says Validation Manager - A global chemistrybased drug discovery, development and manufacturing company.

"With a paper-based manual process," recalls the Validation Manager, "we had no way to measure any metrics or efficiencies like how long it took to approve documents, which stage was taking how much time, etc." Using MetricStream's built-in reporting engine, the Customer now has access to performance metrics across its document control process. Information on audit history, in-process documents, approval cycle times, usage summaries, etc. is available at the click of a button on graphical dashboards or reports that can be exported to standard formats like Excel or PDF.

With MetricStream's robust support for time-stamped audit trails and electronic signatures, the Validation Manager has validated the system to be in compliance with FDA's 21 CFR Part 11 regulation.

For more information, visit
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