Case Study: Regulatory Compliance & Document Management System for Pharmaceuticals

Industry
Pharmaceutical

Overview

The Pharmaceutical Industry has rigorous compliance requirements. Coupled with that, it also has very high confidentiality requirements for pharmaceutical documents such as formulations, product specification documents, product development reports and so on.

A powerfully configured and tailor made compliance management solution on a secure DMS facilitates efficient management of information and meeting the regulatory requirements. A central repository helps the organization to achieve their goals and shorten their time to market.

Client

A multinational pharmaceutical company headquartered in Mumbai, India with revenues over US $ 1.3 bn. It is one of the largest manufacturer and seller of pharmaceutical formulations and active pharmaceutical ingredients.

Business needs

- High confidentiality of pharmaceutical formulations and compliance with various regulatory requirements along with high security in terms of authorization and access
- Centralized repository for huge volumes of data generated at diverse locations
- A single enterprise class DMS in order to maintain a standard workflow for all departments

Challenges

- Archiving and managing confidential pharmaceutical formulations or product related documents from various sources in a web-accessible central repository
- Defining a standard automated process for publishing and submission of product specific documents for more than 11,000 employees spread over numerous departments
- Designing a workflow capable of ensuring the compliance of regulatory norms at all stages of review and approval

Datamatics’ Solution

After a rigorous analysis of the client’s landscape, Documentum D2 was identified as the best fit for the client’s needs. Datamatics’ experts developed a web based document management and business process management system on Documentum D2. A central repository was set up for all documents including product identification form, product specification (master formula), chemical formulations, product development report, clinical study, litigation and so on. A compliance management solution was developed; that streamlined the publishing and submission process and helped enforcing the compliance and regulatory rules through the review and approval stages of the document lifecycle. This solution effectively archived and managed vital documents which were easily searchable based on attributes, metadata or content.
Datamatics’ enterprise wide solution ensured end-to-end management of vital information in the client’s content value chain. Automation of business processes in this secured environment especially facilitated the legal and R&D departments with easy access and location-independent retrieval of data drastically reduced their time to market.

**Approach**

A team of experts was deployed at the client’s premises to gather requirements and study their entire work process. Datamatics incorporated the best practices suggested by EMC on Documentum implementation. Agile methodology was adopted to give a better visibility and transparency during the complete implementation process. In order to lower the risk and minimize defect density, the solution was developed for one department first and then replicated for other departments. To achieve better customer satisfaction after each deployment user acceptance testing was conducted and learning extracted from this rollout was applied to the subsequent rollouts in the lifecycle of development.

**Benefits**

- The solution was established on Documentum D2 as an enterprise-wide DMS

**Process**

Scan / Input of Documents → Optimal Taxonomy → Secured Storage → DMS → Publishing / Approval of Workflow → Published / In-force → Format Transformation into PDF → Watermark / e-Signature → Regulatory Submission [Virtual Documents] → Print Control → Retrieved → Archival

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**Result**

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