DASSAULT SYSTEMES

BIOVIA

SPECIALTY PHARMA CONNECTS CONTENT MANAGEMENT AND REGULATORY COMPLIANCE

SUPPORTING IMPROVED DOCUMENT MANAGEMENT, QUALITY AND COMPLIANCE ACROSS GLOBAL SITES

USE CASE

CUSTOMER: A EUROPEAN SPECIALTY PHARMACEUTICAL COMPANY

A European specialty pharmaceutical business with a commercial presence in all major European markets is focused on the discovery, development, manufacturing and marketing of medicines for specialist disease areas including gastroenterology, hepatology, cancer and both critical and supportive care.

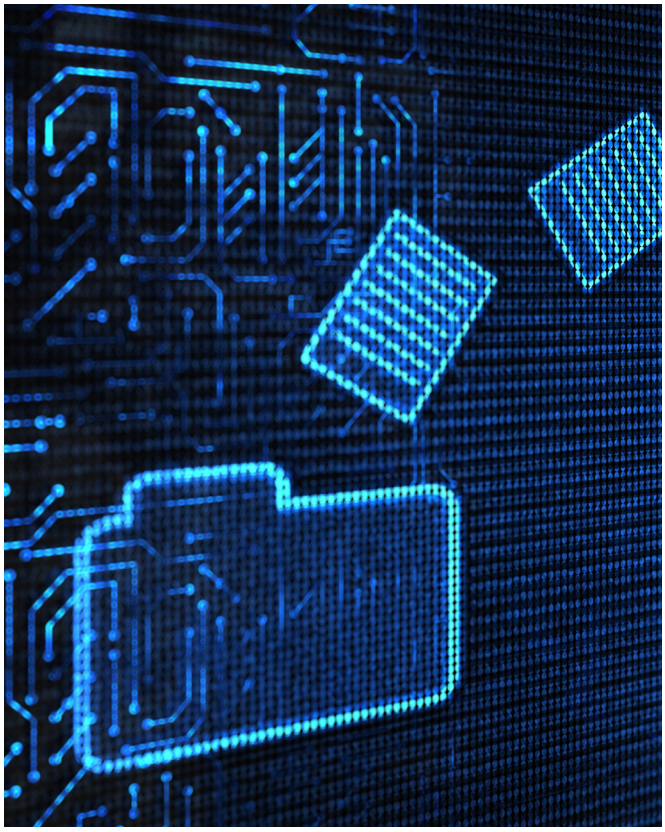
CHALLENGE: IMPLEMENT A COMPLIANT, GLOBAL DOCUMENT & PROCESS MANAGEMENT SYSTEM ACROSS THE ENTERPRISE

Faced with increasing pressure on costs and margins, the company was looking for a more efficient and effective way to manage GxP-controlled documents such as standard operating procedures (SOPs), policies, work instructions, forms and templates. Project challenges included the necessity of rolling the new system out across numerous global sites currently operating with diverse, paper-based document management systems with variable document formats; inconsistent levels of control; no consolidated, end-to-end governance framework for managing metadata; and different ways of handling history data (some documents with up to four previous IDs and version iterations).

With a view to improving regulatory compliance, the company needed to ensure full compliance with 21 CFR Part 11 regulatory requirements. To minimize risk and downtime in ongoing, global manufacturing/supply operations, the company stressed the need for efficient user/operator training. They were also interested in limiting the need to run parallel systems during roll-out to regional commercial units around the world.

SOLUTION: HARMONIZED, COMPLIANT DOCUMENT LIFECYCLE WORKFLOWS IN A COLLABORATIVE ENVIRONMENT

The company selected the DocCompliance and ProcessCompliance solution from Dassault Systèmes to address their needs for unified content management and comprehensive regulatory compliance. System deployment commenced with a pilot program addressing system configuration and validation followed by phased data migration.



> "Our new DocCompliance and ProcessCompliance SOP system provides a more fully harmonized document management system supporting collaborative drug development and continuous improvement."
>
> — Global SOP Manager, Specialty Pharmaceutical Company

Challenge:

Digitizing GxP-controlled document management across numerous global sites; eliminating legacy paper systems; migrating more than 3,500 procedural documents and metadata without jeopardizing ongoing manufacturing/ supply operations.

Solution:

Dassault Systèmes DocCompliance and ProcessCompliance.

Results:

- **Compliance:** Through ability to accurately identify all documents linked to an activity; also supports continuous improvement
- **Quality:** One-stop-shop for procedural documents harmonizes installation, operational and performance qualifications (IQ/OQ/PQ)
- **Collaboration:** Familiar reporting tools generate dashboards and KPIs related to controlled documents
- **Training:** Self-service, online training modules used to implement this system are being extended to other sites and functions across the business

Phase 1 Migration:

This stage comprised 1,400 effective documents involving global functions at the majority of the company's regional sites. Because they were managed by global Quality and IT, these documents had the best level of control. They also offered some degree of metadata harmonization, which further simplified the migration.

Phase 2 Migration:

This stage involved 2,200 effective documents at manufacturing facilities in the UK and France plus their remaining regional sites. These documents had the lowest level of control with little metadata availability, which required greater up-front resources for the migration. To simplify both migrations, the company moved only effective documents to the release library (no previous versions or history). They also migrated documents in accordance with their standard document review cycle. With all effective PDFs available in the system as they hit their defined review date, the company successfully avoided the need to run parallel systems during the deployment.

Training:

All authors attended a classroom demo based on the Validation environment. Reviewers/approvers received a classroom briefing. The vast majority of users (approximately 80%) took advantage of self-service, online training requiring only ten minutes to complete. This targeted, role-based instruction reduced the need for resource-heavy classroom training across global sites.

RESULTS: ENHANCED COMPLIANCE, QUALITY AND COLLABORATION

With the DocCompliance and ProcessCompliance solution, the company has deployed a fully integrated, closed-loop document management system that also addresses the quality and compliance requirements of regulatory bodies. The system drives enterprise-wide control, consistency, and compliance throughout the document lifecycle (create, review, edit, approve, release and distribute). The system also supports FDA initiatives aimed at a risk-based approach to content, compliance and quality management. By accurately identifying all documents linked to an activity, the solution helps drive continuous improvement in the rationalization and harmonization of content—provided that metadata are consistently applied.

The company's Non-GxP functions are beginning to transfer their documents into the system, further establishing the solution as a 'one-stop-shop' for procedural documents across the company.

Scientists are sharing information and collaborating more effectively, while leveraging familiar reporting tools to generate 'dashboard' management information displays and key performance indicators (KPIs) related to controlled documents and processes.

As a single system providing unified electronic workflows supporting content and compliance management, the DocCompliance and ProcessCompliance solution allows tighter control over quality and compliance issues - lowering total cost of ownership, simplifying validation and reducing maintenance costs and complexity throughout the company.

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