

AN INTEGRATED QUALITY SYSTEM SUPPORTING BUSINESS GROWTH

HIGHLY DIVERSE PHARMA USING QUMAS



Challenge:

Disconnected, geographically-dispersed business units; internal and external manufacturing activities; slow manual and disconnected processes and data silos.

Solution:

ENOVIA QUMAS EDMS and EQMS as a single, collaborative, virtual process merging and supporting multiple business lines across the globe.

Results:

- 40% faster FTF, FTM and CMC approval
- 30% cycle time reduction for documentation
- Reduction of SAP role approval from 1 month to 1 day
- Compliance with EU Annex 11 and FDA Part 11, specifically data integrity
- Easy document search and access, e.g., during audits
- Secure and efficient handling of separate CMO CAPA processes
- Cost avoidance through the ability to support growth without increasing staff
- Positive ROI within a few months
- Faster time to market

CUSTOMER:

A MULTINATIONAL PHARMACEUTICAL COMPANY

A multinational pharmaceutical company with world-wide commercial operations develops, manufactures and distributes generic, biosimilar, brand and over-the-counter products. The company provides contract manufacturing, product development and clinical services to third-party customers. It is important for the organization to successfully meet compliance requirements for regulatory agencies worldwide, including FDA, EMA and ANVISA which requires them to set high standards throughout their organization.

CHALLENGE:

DISCONNECTED BUSINESS UNITS WITH SLOW MANUAL PROCESSES

The company has set a high standard for service, quality and innovation, without any FDA-483 citations. But a rapid expansion through acquisitions of different organizations with diverse lines of business led to significant organizational challenges. Geographically-dispersed and disconnected business units demanded virtual collaborations that were not easy to support. In addition, many processes throughout the company were manual and disconnected, further hindering productivity and collaboration. This business environment made it difficult to continue delivering high quality, compliant products in an efficient manner.

SOLUTION:

GLOBALLY IMPLEMENTING INTEGRATED QUALITY PROCESSES AND DOCUMENTATION WITH ENOVIA QUMAS

To support the quality and compliance aspects of their business, the company decided to replace their legacy electronic Common Technical Document (eCTD) system (used in all regions) and to implement a global Quality Management System. The key requirement was to drive standard processes through the implementation of a single solution for the entire global workforce. The solution should provide easy integration and workflow flexibility, an easy-to-use and intuitive user interface, validation-readiness for EU Annex 11 and FDA 21 CFR Part 11, and availability on-premises as well as in the Cloud. The company expected their vendor to provide 24/7 global support and have deep experience with quality, compliance and regulatory requirements.

Originally the solution was required to separately manage data from two different parts of the manufacturing business, the contract manufacturing arm and the company's own products. The subsequent introduction of an open security platform satisfied this requirement.

The required solution capabilities included:

- Bidirectional link to a Learning Management System (LMS, ComplianceWire) for continuously updated Standard Operating Procedures (SOPs)
- Link to SAP for Master Batch Record and Quarantine Materials and release from Quarantine
- Link to eCTD (Lorenz)
- Process support for Auditing, Customer Complaints, Deviations, CAPAs and Change Control

The customer selected the ENOVIA QUMAS EDMS and EQMS solutions for enterprise quality and document management, including all available modules for:

- CAPA
- Change Control
- Deviations
- Audits
- Customer Complaints
- Learning Management
- Submissions
- Electronic Batch Records

The customer adopted a phased approach to deploying the solution because of its required breadth of capabilities and related implementation efforts. They first implemented QUMAS with interfaces to their LMS, SAP and eCTD systems. They then added EQMS with the additional modules including the required interface to SAP for quarantining materials and release

from quarantine. The solution maintains all SAP validation documents, and, in the non-GxP area, it is also used for new employee on-boarding. Implementing CAPA processes required special attention due to the proprietary and CMO aspects of the business. The two CAPA process areas needed to be connected for the personnel tasked with working on them, while at the same time the customer and product specifics remained separate (although this requirement was subsequently lifted).

RESULTS: IMPROVED COMPLIANCE, FASTER PROCESSES, COST AVOIDANCE AND INCREASED REVENUE

The QUMAS solution provides significant value to the customer by helping to improve compliance, speed manufacturing, reduce costs and increase revenue. The compliance improvements are mainly due to the integration of the solution with other systems like SAP, easier validation in accordance with European and US regulations and better regulatory inspections and customer audits. A key benefit is the integrity and security of all data and documents handled within a single globally compliant environment.

The increase in speed is mostly due to the 30% reduction in documentation cycle time and the 40% faster approval processes supporting “First Generics” with First-to-File and First-to-Market status. The solution also speeds manufacturing with digital workflows, standardized processes and naming conventions, use of e-signatures for internal and external customers and easy document access with advanced searching.

With process automation by QUMAS, the customer has avoided the need to hire additional personnel in Quality, Pharmaceutical Development and Operations—supporting the company’s growth in emerging markets. The reduction of paper, printers and supplies through paperless processes has further reduced costs. The solution supports both internal and external manufacturing-related quality processes in a secure, reliant and efficient way.

QUMAS enables the customer to increase revenue by accelerating product launches and gaining revenue earlier than planned. The joint efforts of the teams of the customer and Dassault Systèmes for the deployment of the complete integrated solution took only one year, and the customer was already realizing value after only a few months.

OUTLOOK: FURTHER EXPANSION AND TRULY PAPERLESS PROCESSES

Based on the success of the current implementation and to further leverage the QUMAS solution, the customer is planning to expand the solution into other geographies and other non-GxP processes including SAP role request/approval and contract approval. To achieve further efficiency gains, the customer is planning to go completely paperless and to roll out the QUMAS Electronic Batch Record module on iPads at their manufacturing facilities. The introduction of a Transactional Process Improvement (TPI) Kaizen event should further reduce approval cycles and document creation cycle times.

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