CASE STUDY

CDMO of Specialized Biomedical Polymers and Additives for Medical Device Application

Training Management and Document Management: Building the Foundation of an Enterprise Quality Management System (EQMS)

AssurX

Building Collaborative, Centralized Processes for FDA Compliance and ISO Certification

A leader in custom blending and extrusion of biomedical polymers and additives was sharing a quality system with other corporate divisions that did not require FDA compliance for combination products. Faced with on obsolescing infrastructure, audit risk, and a commitment to quality an innovation, the company knew it had to move to an automated QMS designed for life science industry compliance best practices.



"AssurX met our needs for a configurable system that could meet the rigors of validation, efficient import and indexing of documents, strong process functionality and secure access requirements."

Vice President, Quality and Regulatory

The Problem: Operating Within a Shared System

The company was utilizing a shared quality system for managing quality processes including training management and document management, CAPA and deviations. The shared system was not originally designed for pharmaceutical and medical device grade material manufacturing.

Since the division operates as an independent unit, it is required to comply with FDA 21 CFR Part 210 and Part 211 (CGMPs for combination products) and ISO 13485 standards for a risk-based quality management system that drives continuous improvements of safe, effective products.

To determine which processes should be addressed first, the company performed a detailed gap assessment. Process gaps were found that created inefficiencies and risk. The old system was not in alignment with the company's quality management vision, and could neither not stand up to the rigors of FDA and customer audits, nor meet validation needs.

The AssurX Solution

An automated system was needed to meet the unique and changing needs for GMPs. As a result, the AssurX platform was evaluated by all business areas prior to selection. “Management, IT, QA, Operations and Document Management unanimously agreed that AssurX met our needs for a configurable system that could meet the rigors of validation, efficient import and indexing of documents, strong process functionality and secure access requirements,” explained the Vice President of Quality and Regulatory.

Because significant issues were found with document management and content handling procedures, the company chose to lead its EQMS integration with AssurX Document Management and Training Management solutions. “The [quality] documentation existed," explained the customer, "however, our specialized manufacturing processes and focus on compliance required training and document management to be aligned with FDA pharmaceutical and medical device regulations.”

AssurX Document Management and Training Management led the EQMS implementation to deliver secure, centralized information that interconnects all quality processes.

"Document management and training management are solid first steps towards an integrated QMS. The AssurX system enabled us to easily configure a user-friendly interface that made the employee transition easy, and allows us to integrate unlimited processes."

Vice President, Quality and Regulatory

Document Management

The company implemented AssurX's Document Management solution to support its quality management initiative for data integrity and secure access to documents.

Thousands of documents needed to be imported into AssurX which was simplified by the system's import utility. The customer was able to export all documents from the existing system and upload into AssurX in one weekend. In addition to product life-cycle documents, approximately 700 non-life-cycle documents were imported into AssurX from the shared drives of the existing system.

Training Management

The company automated its training management with AssurX across the entire CGMP manufacturing facility. After the Training Management solution was implemented, the team was re-trained on the materials defined for each user profile. The benefits were two-fold: users had an immersive experience in the new system, and the process reinforced the team's collective knowledge.

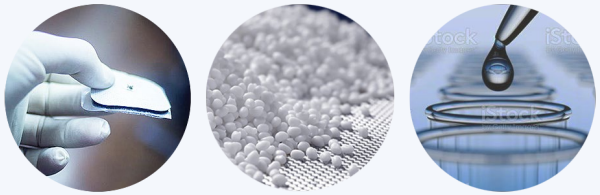
Benefits of AssurX Document Management and Training Management:

- Faster time to task completion with automated routing, escalations and notifications
- Ability to create, store, control, and locate digital documents in a centralized location
- Significant improvement of data integrity
- Elimination of extensive, siloed document searches
- Fulfilled all industry and internal regulatory compliance requirements
- Reduced labor hours spent on document creation and approvals
- Compliance with 21 CFR Part 11 electronic signatures
- Alignment with FDA 21 CFR Part 210 and Part 211 regulations and ISO 13485 certification standards
- Greater management visibility into open issues
- Systematic rule enforcement for all processes
- Immediate insight into employee skill sets, overdue tasks and training certifications
- Training delivered on-time; late tasks are escalated to ensure completion
- Leverages data to validate change request initiation

The Covid-19 Crisis and Remote Audit-Readiness

Centralizing document and training management eliminated compliance concerns by placing all records in a systematic state of control. This became even more significant during the Coronavirus pandemic as travel and social distancing restrictions forced a shift to virtual audits.

Since the implementation of AssurX Document Management and Training Management solutions, **all customer audits have been favorable.**



"Not only have we had excellent audit results, but we can just hand [remote] control over to our customers in Teams™ and guide them to the specific documentation they want."

Vice President, Quality and Regulatory

SEE ASSURX IN ACTION.
Click to schedule a live demonstration.

Since the implementation of the document management and training management solutions, **all client audits have been favorable.** Not only has the company had excellent audit results, but during virtual audits, they can hand control over to auditors in Teams™ and guide them to the specific documentation they want to see. The customer reports very favorable response to document visibility.

Future Plans for the Modernized EQMS

Training management and document management were the foundation of the company's EQMS. But that's just the start. The benefit of AssurX lies in the platform's architecture, which provides the ability to turn up processes as needed without having to purchase individual modules.

"We engage with AssurX for professional services support when needed," the customer explained, "but once you have experience with the system, the workflows are there to use out-of-the-box, or you can easily configure unique workflows with the multitude of built-in features."

While ISO 13485 management system standards certification is not a requirement, the company maintains ISO 13485 certification in the current hybrid environment–***with zero findings.*** The company is in the transitional stage of rolling out the planned EQMS, and will gradually become fully-automated, further streamlining the ISO 13485 certification process in the future.

Future EQMS Plans

The customer's process roll-out in AssurX is based on a logical, phased approach that best aligns with the company's business needs. The company will gradually transition all major quality processes to AssurX including CAPA, change control and temporary change, audit management and deviations/ investigations. In addition, a custom integration for Calibration and Preventive Maintenance (Cal-PM) is also in planning with AssurX professional services. It will have the ability to pull Cal-PM review due dates into master batch records for automating annual product reviews for line clearance.

Conclusion

Document control and training management represented a critical foundation for the manufacturer's EQMS. The transition to an automated system is the starting point of a fully-integrated quality management system that will provide clearly defined, consistent, and controlled processes that are user-friendly. The AssurX platform architecture, which includes all pre-configured core quality processes, will enable the company to design, configure and integrate its system more efficiently than a modular approach to solution add-ons.

AssurX