CUSTOMER CASE STUDY

DIAGNOSTIC IMAGING AGENT MANUFACTURER

Reducing Costs and Centralizing Quality and Compliance Control with a Single Platform

AssurX

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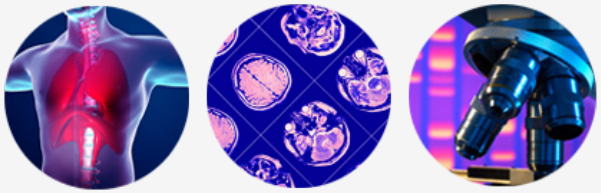
Imaging solutions and products used to detect the onset, severity and cause of illnesses are critical to treating the aging population as well as keeping pace with the preventive care movement. Innovations in accuracy, safety and reliability of diagnostic solutions are the key factors to gaining a competitive edge in next-gen solutions. A global manufacturer of medical diagnostic imaging agents knew that their quality and processes needed to change in order to stave off increasing costs and inefficiencies that could impact quality and compliance.



16 PROCESSES IMPLEMENTED IN ASSURX:

+ Audit Schedules (Internal and External)
+ Corrective and Preventive Actions (CAPA)
+ Change Control
+ Complaints Handling
+ Control Printing
+ Deviations
+ Document Management
+ Internal Audits
+ Investigations
+ Material Review Board (MRB)
+ Records Management
+ Supplier Change Notifications
+ Supplier Audits and Scheduling
+ Supplier Surveys
+ Training Management
+ Temporary Changes

Mounting Complexities with Multiple Quality Systems

The pharmaceutical manufacturer of agents and products for diagnosing conditions affecting the heart, lungs, brain and other organs faced several challenges often accompanying rapid growth and decentralized processes.

Legacy Applications: The company was struggling to support four different quality management applications. While several quality processes were automated, there was little to no integration. The applications were becoming unstable due to compatibility issues with current operating systems, web browsers and a lack of programming experience. In addition, some processes still incorporated paper-based records and data.

Aging Infrastructure and High Support Costs: An extensive hardware and IT investment was required to support the systems. Applications resided on **18 servers**, and support costs were escalating for hardware and software updates. In many cases, hardware was reaching end of life. Users had multiple logins, and system administrators and the IT department had to frequently retrieve user names and passwords. Downtime stalled data input and ultimately impeded the ability to identify areas of risk and concern on a timely basis.

Lack of Integration: Quality management applications were decentralized and running in multiple relational databases. Each application collected data and automated quality processes, but the data was siloed with little integration. System administrators spent considerable time comparing data, reports and KPI metrics between the different quality management systems. Contradictory reports and duplications were often identified and required additional work to fix the inconsistencies.

Non-Compliance: Several processes did not meet current compliance requirements. CAPAs were missing critical effectiveness checks. In addition to not meeting industry best practices, users were creating undocumented manual workarounds to process simple tasks.

Furthermore, the company had not yet automated electronic FDA regulatory filing processes that left non-compliance constantly looming as well, including Supplier Corrective Action Request (SCARs), Annual Product Quality Review (APQRs), and Management Oversight Committee (MOC).

Taking a best practice approach to quality management system implementation, the pharmaceutical manufacturer prioritized and deployed **16 processes** based on the most urgent needs first.

"We knew data extraction was going to be a matter of trial and error. Our biggest challenge was our document management and training history records. The AssurX system proved to be highly intuitive and the extraction and migration of metadata into AssurX was easy to execute... We migrated approximately **20,000 Lifecycle Documents** and close to 1**00,000 Training History Records."**

- Sr. Director, Quality Systems

A Phased Approach to AssurX Implementation

Working with a single, methodical approach to new system deployment enabled the company to move all seven existing quality processes and sub-processes to the AssurX platform as well as integrate nine additional processes.

PHASE 1: REASSESS AND REBUILD

Each process was assigned a **process team** that was responsible for the migration/implementation of their respective process(es). Five process teams were tasked with:

(1) Revisiting and documenting current processes
(2) Redeveloping the processes based on company and regulatory requirements
(3) Migrating data to the new system if necessary
(4) Quality assurance testing
(5) Go live (production)
(6) Auditing the new process

One of the most important practices in any QMS implementation is process documentation. Process teams streamlined existing processes by breaking each down to the minimal workflow steps required to insure effectiveness and compliance. Decision matrices were simplified to keep processes moving while obtaining the right signatures.

The Quality Systems-led teams engaged AssurX Professional Services in a consultative role when required. One area where this proved particularly helpful was data migration. With some initial consultation from AssurX, the company's IT staff performed the extraction and migration of metadata. With so much data residing across the quality systems, each process team made the decision to archive or migrate data based on how critical the data was in terms of utilization and compliance.

PHASE 2: NEW PROCESS INTEGRATION

Phase 2 followed the same methodology as Phase 1. New processes were designed based on company and regulatory requirements and each new process was integrated into the AssurX system in order of importance.

To create consistency across similar events for accurate trending, the company created **standard terminology** for tools and terms used across the system so information would remain consistent as it continued downstream.

PHASE 3: TRAIN AND RETRAIN

With an investment made in AssurX professional training, Quality staff and IT co-designed the internal AssurX training program. The company's training program is available for all employees based on their AssurX usage and in accordance with GMP guidelines. The company invested in AssurX training for a dozen heavy touch users. "The return on investment was realized by the impact on smooth migration, ease of validation and the structured knowledge transfer through the online training system," noted the quality assurance director. Training for new users or as a reference is available 24/7 in the AssurX Training Management system.

The AssurX platform replaced disparate quality systems on 18 servers, reducing first year infrastructure maintenance and support costs by **65%.**

The medical diagnostic imaging agent manufacturer approached their new QMS implementation with a focus on building a culture of compliance. AssurX enables all system users and managers to have visibility into the entire quality ecosystem and understand their role and responsibilities to achieve quality and compliance objectives.

Embracing Change

The director of quality knew that centralizing and automating the enterprise quality system would result in greater end user satisfaction, but the short-term perception of change could be daunting. "It's a change thing," he stated. "You can either change the wording on a piece of paper or spreadsheet, or you can implement an automated process. We wanted our users to get to their work with one or two clicks."

As part of their ongoing initiatives to build a culture of compliance, the company supported its users' adoption of the new AssurX system. Users rapidly adopted the technology changes—they were able to fully visualize how they contributed to the overall process by viewing open tasks in real time, prioritizing critical issues and drawing insights from trends and analysis.

AssurX Implementation Results

The costs associated with supporting the infrastructure, manual hours and the potential costs on non-compliance were not only a continual burden but a risk as well. The company knew that it had to consolidate processes and infrastructure.

Prior to AssurX implementation, the company's support costs alone exceeded $443,000.00. This included server maintenance, licensing multiple systems, database support training and extended operating system support. Additional costs included labor hours to meet and prepare reports and documentation and end-user administration.

Despite more than **doubling their number of quality processes**, the company realized **significant cost savings** and **increased user efficiency**.

Server maintenance costs reduced
65%

Licensing costs reduced
90%

Personnel hours reduced
3,072

Total first year hard cost savings
$266,000

Conclusion

With many life science manufacturers merging and acquiring other companies within the life science industry, leadership is often faced with the impact of separate legacy quality management systems. As illustrated in this case study, by unifying all quality management processes in the core AssurX quality management software platform, the life science manufacturer enjoyed tremendous cost savings, reduction in personnel hours and the ability to draw key insights from linked systems. These benefits allowed the life science manufacturer to dedicate additional resources to increasing the quality and effectiveness of its various products.

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