

ASSURX SOLUTION CASE STUDY

GLOBAL QUALITY MANAGEMENT SYSTEM

Multi-plant Pharmaceutical
& Chemical Manufacturer

Automating QMS Eliminates Paper
Processes; Brings Compliance
Up-to-Speed



GLOBAL QUALITY MANAGEMENT SYSTEM

A Pharmaceutical & Chemical Manufacturing Case Study

An international multi-plant company bogged down by labor-intensive manual processes implements the AssurX platform to streamline Adverse Event/Defect Handling, CAPA, Complaint Management, Supplier Quality and Audit Management—saving more than 10,500 personnel hours per year.



ASSURX QMS SOLUTIONS IMPLEMENTED:

- + Manufacturing Quality: Deviations/Adverse Events
- + CAPA Management
- + Complaint Handling
- + Supplier Quality Management
- + Audit Management
- + Disposal Management
- + Laboratory Incidents
- + Environmental Health & Safety Compliance Management

Initial State: Defect/Deviation & Corrective Action Process

A multi-national, multi-plant pharmaceutical and chemical company used a conglomeration of hand-written reports, Excel spreadsheets and Microsoft Word documents to report and track their adverse events which included defects, deviations, issues with supplied materials and laboratory incidents. Daily one-hour meetings with an average of 12 representatives from quality, compliance, engineering, logistics and production were held to review and determine/disposition all adverse events.

Often, attendees were not aware of incidents prior to meetings, so time was spent bringing the group up to speed on adverse events before any resolution discussions could begin. Generally, only events that occurred more than 48 hours prior were addressed; not all of the prior day's issues were known and multiple meetings were needed to discuss each event before corrective actions could begin.

Within Days of the AssurX Implementation

Daily one-hour meetings were reduced to 10 minutes with all attendees aware of the events to be addressed prior to the meeting. The number of participants was reduced because only staff from departments affected by the events were required to attend. Because all events were known and detailed information was readily available to all departments prior to meetings, immediate determination/disposition could be completed for the majority of the adverse events and CAPAs could be assigned to avoid recurrence. Within 2 weeks, more than 400 onsite users were fully engaged working in the system without needing administrator support.

AssurX Implementation +90 Days

DAILY MEETINGS NO LONGER REQUIRED

Instead of having daily conversations about defects, meetings were only scheduled for critical events needing additional discussion. AssurX Adverse Event and CAPA Management software was used across operations and dispositions and corrective actions were initiated and processed through the automated system.

INSTANT INFORMATION AND STREAMLINED PROCESSING FOR EVERY INCIDENT

Up-to-the-minute status and details of all defects were available at the click of a button, ensuring every issue could be addressed quickly and easily, and nothing fell through the cracks. AssurX kept the processing of reported defects and corrective actions on track by automatically sending reminders to staff advising of pending tasks and auto-escalating any late items to the appropriate personnel.

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TIME SAVINGS ACHIEVED WITH ASSURX:

- + 800 hours eliminated PER AUDIT
- + 1,400 personnel-hours eliminated for manual information gathering
- + 2,100 personnel-hours eliminated in manually logging and entering defects
- + 3,000 personnel-hours eliminated for deviation/disposition meetings
- + 1.5 full-time employees reallocated to other projects

QUALITY RESOURCES SAVED AND REALLOCATED TO MORE VALUE-ADDED ACTIVITIES

In addition to the significant time savings from eliminating meetings, AssurX also eliminated the need for staff to perform a variety of administrative activities such as scheduling, communications, locating lost documents and duplicate tasks which saved another approximately 65 personnel-hours per week. The combined savings allowed the company to reallocate 1.5 full-time Quality personnel to the production floor to monitor and improve production systems.

One Year After Implementation

AUDIT MANAGEMENT

A year after going live with Adverse Event and CAPA handling, Audit Management was integrated into the AssurX system to streamline preparation for regulatory audits. Pre-AssurX, a substantial number of personnel-hours were required to prepare for each audit to locate outstanding defects and related documents. After implementing the solution, regulatory audit preparation time was reduced significantly and overtime was reduced (and in some cases eliminated) because the built-in data collection, document handling, task escalation and notification features ensured Defect Reports (and related CAPAs) were closed properly and on schedule.

SUPPLIER QUALITY MANAGEMENT

The system was expanded to include supplier defects management. When raw materials (supplier) or packaging (sub-contractor) defects are entered into AssurX, supplier or sub-contractor details are automatically pulled into AssurX from the ERP. Based on the defect type, tasks are automatically created to follow-up on each defect reported.

ENVIRONMENTAL HEALTH & SAFETY COMPLIANCE

Additionally, chemical or pharmaceutical defects are automatically evaluated for EH&S impact and material disposal requirements. If either applies, tasks are automatically generated to ensure environmental impacts are minimized and regulatory requirements are met. Prior to AssurX, the paper-based system for tracking EH&S and material disposal was especially fragmented. Since implementing AssurX traceability has vastly improved, detailed information is immediately accessible throughout the enterprise, and material disposal times have been reduced.

Moving Forward: Broader Use of AssurX Solutions

Rollout of the AssurX system has been completed throughout South America, Western Europe, Eastern Europe and Asia Pacific totalling 8 countries and 5 languages. The system has expanded to include Complaint Handling and Disposal Management solutions. Additional worldwide implementation of other integrated solutions including expanding Audit Management for managing internal audits and Change Control is planned.

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FUTURE ASSURX IMPLEMENTATIONS:

- + Change Management
- + Internal Audit Management
- + Rollout to Additional International Facilities

Net Results

ANNUAL TIME & PERSONNEL SAVINGS:

- + More than 2,100 personnel-hours saved in reporting defects. Reporting initially consisted of the defect being logged manually (handwritten) and then entered into Excel spreadsheets. Now defect data is entered onto a single AssurX report screen. Any related document or information is electronically attached to the defect record.
- + 800 personnel-hours saved in following paperwork, determining the problem and/ or status of defects, and making follow-up telephone calls to resolve issues.
- + 3,000 personnel-hours saved by eliminating regular meetings to discuss events and defects.
- + More than 45 minutes daily, annualized to 1,400 personnel-hours saved because staff no longer has to interpret handwritten descriptions, collect reports or documents, or track down information throughout the concern.
- + Quality Assurance estimates 800 personnel-hours PER AUDIT (3,200 hours annually) saved in regulatory audit preparation time as a result of AssurX's automated reporting, notification and escalation features.
- + One and a half (1.5) full-time Quality personnel reallocated from performing administrative activities to more value-added responsibilities.

About AssurX

AssurX, Inc. provides a unique Quality Management and Regulatory Compliance System that helps FDA regulated businesses do more of what they need to do faster, better and easier. AssurX is a highly versatile software platform used to maintain quality and regulatory compliance, streamline workflow, control risk and better manage any enterprise. Our incredibly configurable software applications and deep understanding of users' needs produce a system that easily adapts as your business evolves. AssurX is an ideal partner for life science companies looking for better operational control and efficiency while staying compliant.