ASSURX DEVIATION MANAGEMENT FOR THE PHARMACEUTICAL INDUSTRY

# Improve agility and collaboration in the pharma supply chain.

The AssurX Deviation Management solution automates management of the deviation process throughout the product lifecycle as required for Good Manufacturing Processes (GMP) and other regulatory and business requirements.

AssurX provides a single source of truth to capture, investigate, and disposition planned and unplanned deviations. Improve time to resolution and gain insights to help continually improve processes and produce higher quality products.

AssurX Deviation Management enables the comprehensive management of deviations, regardless of source or type. Efficiently find root cause and apply corrective actions to minimize the risk of problem recurrence. Understand and control process deviations to avoid regulatory action, financial loss and compromise to your brand. 21 CFR Part 11, 210, 211, 820, GMPs and ISO Standards.

## REDUCE DEVIATION CYCLE TIME

Eliminate paper and manual work with configurable best-practices workflows that expedite the identification of the deviation source anywhere in the quality value chain. Dashboards, notifications and escalations keep issue management on track and allow efficient collaboration with R&D and suppliers from a single electronic platform.

## CENTRALIZE RECORDS

Deviation Management accommodates any business process that may require more than one type of assessment (GMP, Good Laboratory Practices (GLP), and others). Enable users to track and manage all stages of a deviation from discovery through quarantine, disposition, investigation, corrective actions and changes. All records become inextricably connected and accessible in the AssurX system through powerful query tools.

## INTEGRATE QUALITY PROCESSES

Configurable, best practices workflows capture all deviation information and expedite investigations. Integrating systems eliminates the need for redundant processes and ensures all deviations, regardless of the system in which they occur, are handled in a consistent manner to generate accurate trend data.

Launch CAPAs, and initiate change controls through integration with AssurX Change Management. Attach document records including SOPs and initiate training tasks to maintain and demonstrate audit-ready compliance.

## ENABLE IN-DEPTH ROOT CAUSE ANALYSIS

Conduct a process-driven, step-by-step failure mode and effects analysis to identify all potential causes of a deviation. Prioritize deviations according to severity and follow the appropriate steps to resolve the highest risk deviations first.

Document methods for improving batch output and turn data into actionable information to identify impending quality events and drive informed decisions based on irrefutable data.

## SECURE DEVIATION RECORDS

All AssurX solutions provide role-based security and a full audit trail. Automate your deviation process and create permissions to allow specific records to be viewed by designated users. AssurX enables compliance with industry requirements for FDA 21 CFR Part 11 electronic signatures.

## CONDUCT INVESTIGATIONS ACROSS THE VALUE CHAIN

The Deviation Management investigation portion supports multi-level investigations based on your workflows. Configure a consistent, phased approach from initial report to investigation plan approval, to tracking and recording, actions, dispositions, corrective actions and changes that extends across the value chain. This includes the preliminary investigation, laboratory investigation, manufacturing investigations, and any other type required.

Manage equipment nonconformances, stability testing discrepancies, complaint-triggered findings, production issues, human error, labeling errors, validation, and more from a centralized system.

AssurX supports cross-functional approvals which promotes awareness and aligns agreement of your decision makers. Data collected during the deviation approval process can be used as a facilitator for continuous quality improvement.

## INTEGRATE WITH ENTERPRISE SYSTEMS

Maintain the integrity of information while enhancing horizontal collaboration with others in the quality chain.

Integrate with external enterprise applications including ERP, MES, CRM, and LIMS with a robust, open interface. Exchange information bi-directionally with other functional areas where deviations require input from suppliers, development, and other departments.

## APPLY QUALITY RISK MANAGEMENT

Risk controls should be commensurate with the risk of the deviation or potential deviation. Data entered into the AssurX deviation record generates a risk priority number based on assigned risk factors. Factors can include severity, occurrence and others as determined by your organization.

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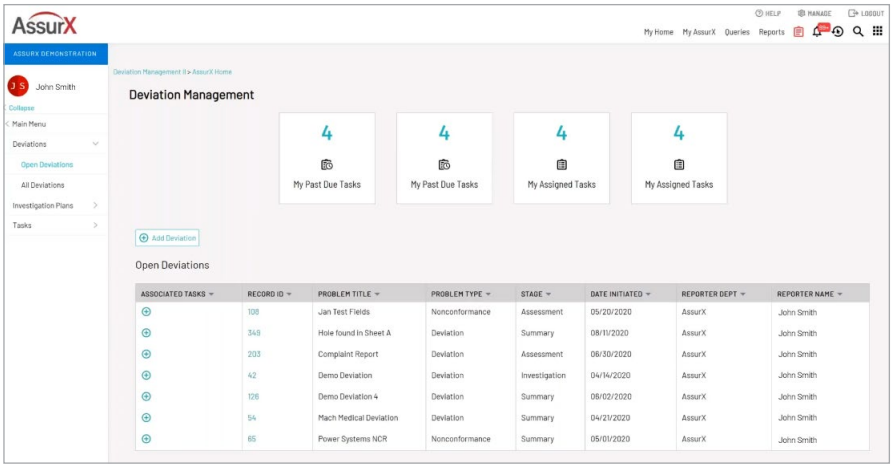
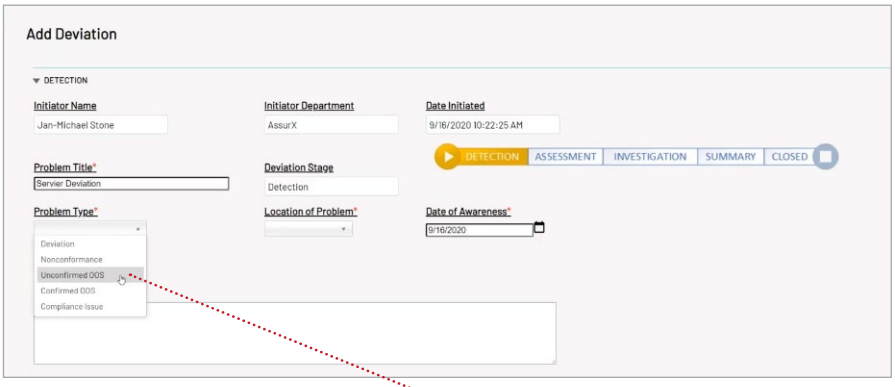
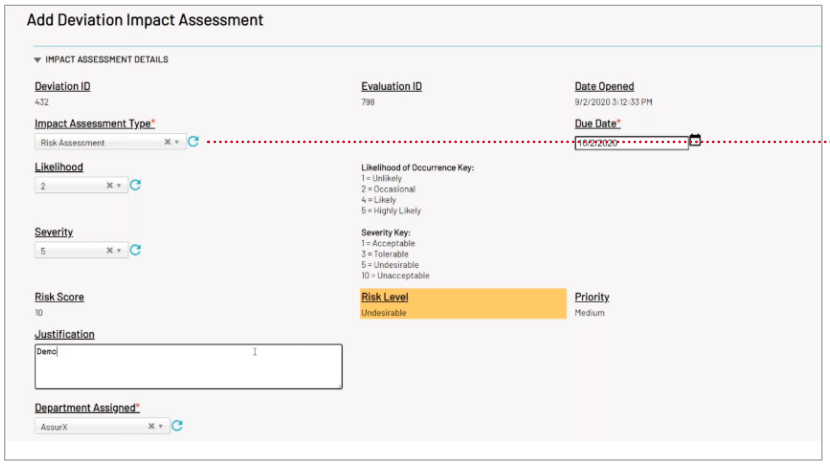
Demonstrate a structured, repeatable method to identify product defects or changes in product quality and all activities performed to eliminate the issue. Integrate CAPA, effectiveness reviews and process audits to drive continual improvement within your quality ecosystem.




Dashboards allow users to view open investigations and drill down to each record from dashboard cards, which can be configured to display the details that are relevant to each user.




Add deviations by multiple problem type selections if desired to conduct more granular investigations and problem-specific trending.




Add multiple impact assessments based on the type(s) required. AssurX creates the impact assessment record based on the type of information required and rolls all assessments into the master deviation record.

## BENEFITS AT A GLANCE:

- Demonstrate consistency in the deviation management process.
- Manage risk by routing tasks in terms of criticality.
- Increase visibility with dashboards that display the status of open deviations in real-time.
- Increase enterprise-wide accountability through a clear workflow of tasks, reminders, and escalations.
- Link root cause to CAPAs.
- Route records for electronic, time-stamped approval.
- Integrate with other systems for full cycle visibility and collaboration.
- Track deviation and incident information by lot, part, ingredient, batch number or any other criteria.
- Cross-functional approvals promote awareness and facilitates continuous quality improvement.

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