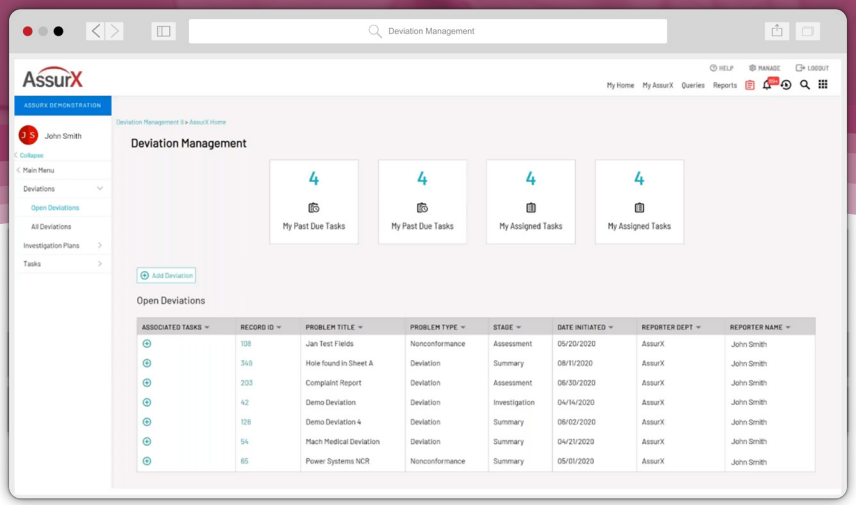
DATASHEET

Deviation Management Solution

AssurX Deviation Management software solution provides a single source of truth to capture, investigate, and correct deviations, regardless of source or type and gain insights to help continually improve processes and produce higher quality products.

Understand and control process deviations to avoid regulatory action, financial loss and compromise to your brand. Maintain compliance with ISO standards and other applicable regulations in your industry



Reduce Deviation Cycle Time

AssurX helps manufacturers expedite the identification and remediation of the deviation source anywhere in the quality value chain.

- Dashboards, notifications and escalations keep issue management on track. Collaborate with R&D, suppliers, and other business areas in a central platform in real-time.
- Utilize root cause tools and apply corrective actions to minimize the risk of problem recurrence.
- Facilitate action plans through an automated process including integrated corrective and preventive actions (CAPA).
- Perform investigation and effectiveness reviews to reduce the risk of recurrence resulting from ineffective CAPAs.

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.
- Conduct data-driven analysis to identify and respond to potential related quality events.

Centralize Records

- Enable users to track and manage all stages of a deviation from discovery through investigation, remediation, disposition, and process changes.
- All records become connected and accessible in the AssurX system through powerful query tools.

Secure Deviation Records

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

Integrate Quality Processes With Other Enterprise Systems

- Enhance horizontal collaboration with others in the quality chain to ensure that all deviations are handled in a consistent manner to generate accurate data.
- Launch CAPAs, initiate change controls, revise SOPs, manage training tasks, and audit quality processes all within a powerful, scalable system and maintain audit-ready compliance.
- Integrate with enterprise applications including ERP, MES, CRM, and LIMS with a robust, open interface for full cycle visibility and collaboration.

Apply Quality Risk Principles

- Through integration with the AssurX Risk Management solution, data entered into the AssurX deviation record automatically generates a risk priority number (RPN) based on assigned risk factors. These factors, such as severity and occurrence, can be customized by your organization.
- 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.