DEVIATION MANAGEMENT FOR MANUFACTURING INDUSTRIES

AssurX SOLUTIONS

AssurX provides a single source of truth to capture, investigate, and correct deviations, regardless of source or type. AssurX workflows are highly configurable to adapt to the specific needs of your organization.

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.
- Utilize root cause tools to 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

AssurX Deviation Management software accommodates any business process that may require more than one type of assessment.

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

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 21 CFR Part 11 electronic signatures.

INTEGRATE QUALITY PROCESSES FOR GREATER QUALITY ASSURANCE

Integrating quality processes within the AssurX platform ensures that all deviations, regardless of the system in which they occur, 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. Maintain and demonstrate audit-ready compliance - all from a single source of truth.

CONNECT WITH ENTERPRISE SYSTEMS

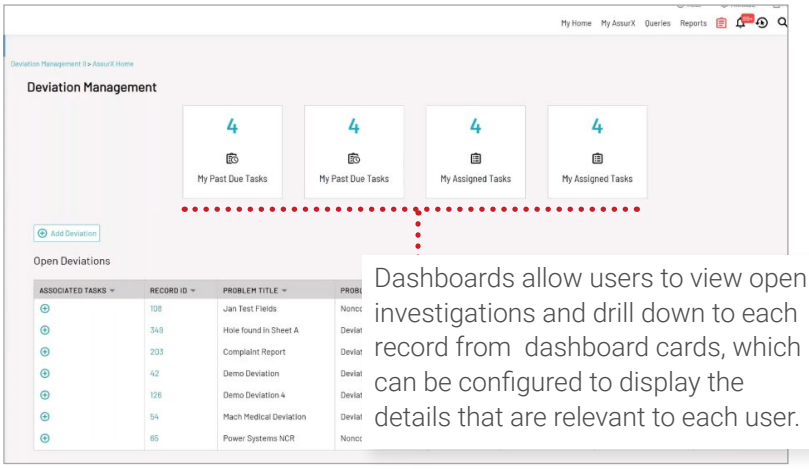
Maintain the integrity of enterprise information while enhancing horizontal collaboration with others in the quality chain.

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.

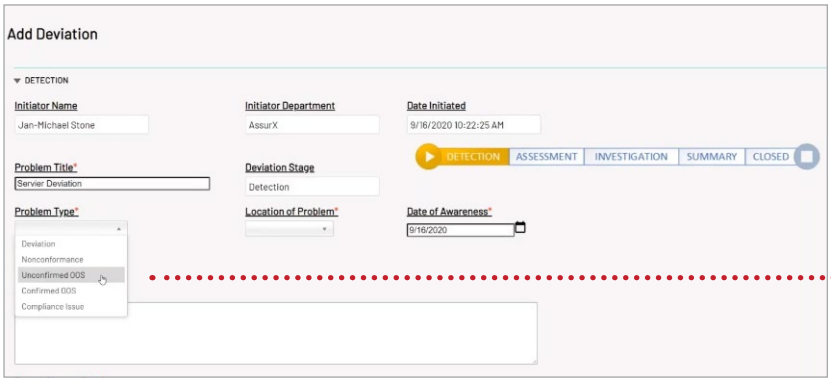
APPLY QUALITY RISK PRINCIPLES

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 (RPN) based on assigned risk factors. Factors can include severity, occurrence and others as determined by your organization.

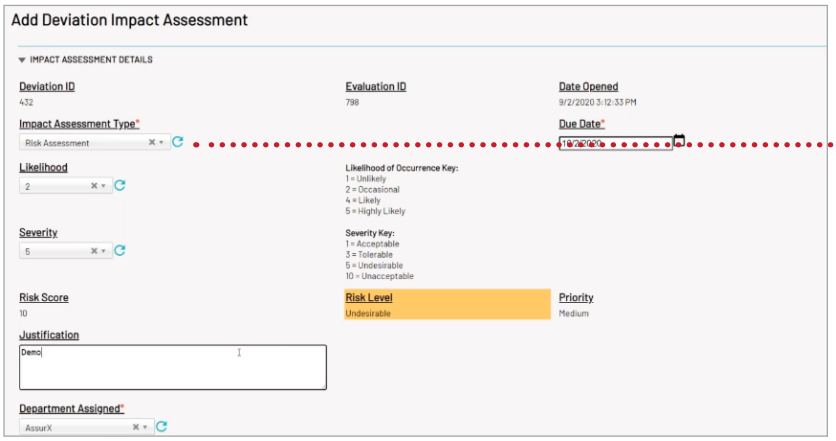
Demonstrate a structured, repeatable method to identify product defects or changes in product quality and all activities performed to eliminate the issue. Integrate CAPA, effectiveness reviews and process audits to drive continual improvement within your quality ecosystem.



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 stores all assessments in the master deviation record.

BENEFITS AT A GLANCE:

- Gain insights to help continually improve processes and produce higher quality products.
- Demonstrate consistency in the deviation management process.
- Manage risk by routing tasks in terms of impact.
- View 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, ingredients, or any other criteria.

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

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