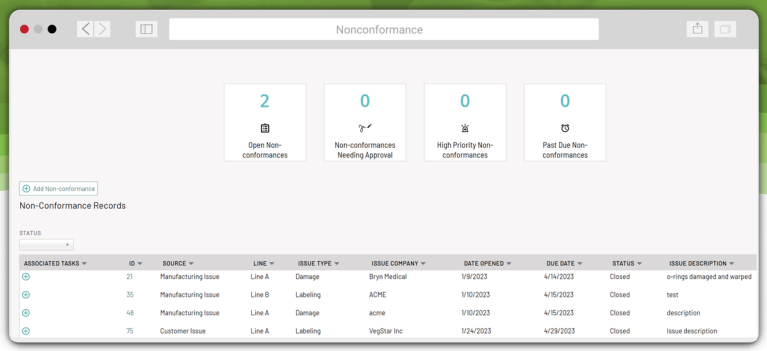
DATASHEET

Nonconformance Management

AssurX Nonconformance Management software helps manufacturers expedite the identification and remediation of the deviation source anywhere in the quality value chain. Streamline and automate the tracking, documenting, and resolution of quality incidents, such as nonconformances, deviations, defects, failures, and exceptions.



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 other systems with a robust, open interface. Exchange information bi-directionally with other functional areas where nonconformances require input from suppliers, development, and other departments.

Reduce Investigation Cycle Time	• Track issue management through dashboards, notifications and escalations. • Collaborate with R&D, suppliers, and other business areas in a central platform. • 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).
In-depth Root Cause Analysis	• Conduct a process-driven, step-by-step impact assessment to identify all potential nonconformance causes. • Prioritize nonconformances according to risk level and follow the appropriate steps to resolve the highest risk nonconformances first. • Conduct data-driven analysis to identify and respond to potential related quality events. • Track nonconformance and incident information by lot, part, ingredients, or any other criteria relevant to your operations.
Centralize Records	• Powerful query tool can track and manage all stages of a nonconformance from discovery through investigation, remediation, disposition, and process changes.
Secure Deviation Records	• Role-based security and a full audit trail. • Automate nonconformance process and create, edit and view permissions for designated users. • Compliance with industry requirements for 21 CFR Part 11 electronic signatures.
Apply Quality Risk Principles	• Data entered into the AssurX record generates a risk level based on assigned risk factors. Factors can include severity, likelihood, and others as determined by your organization. • Demonstrate a structured, repeatable method to identify product defects or changes in product quality, as well as all activities performed to eliminate the issue. • Integrate CAPA to drive continual improvement within your quality ecosystem.
Conformance with ISO Requirements	• In accordance with ISO 9001, AssurX helps enterprises establish procedures for determining responsibility and authority for dealing with various aspects of an actual or potential nonconformance.