

## DATASHEET

# AssurX Validation Management Solution

Accelerate compliance and reduce risk with a fully integrated validation management platform.



The AssurX Validation Management Solution (VMS) streamlines requirements management, test traceability, impact assessment, and regression testing to meet the stringent demands of GxP and other regulated environments. Our solution helps teams operate faster, reduce validation costs, and ensure high-quality outcomes—every time.

## Key Benefits

- **Standardized Validation Process:** Establish consistent, repeatable validation procedures aligned with GAMP 5 and your internal SOPs.
- **Time & Cost Savings:** Automate validation tasks and documentation to reduce manual effort and compliance risk.
- **Audit-Ready Documentation:** Generate real-time traceability reports, test evidence, and summary reports to demonstrate control across the lifecycle.

# Solution Highlights

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## **Project Oversight with Real-Time Dashboards**

Gain full visibility into current and upcoming validation efforts. The VMS dashboard provides live status updates, project tracking, and actionable insights via dynamic charts and reports.

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## **Automated Validation Documentation**

Streamline the generation of essential documents like:

- User Requirements Specifications (URS)
  - Functional Requirements Specifications (FRS)
  - Risk Assessments
  - Validation Protocols
  - Summary and Detailed Test Reports
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## **Robust Requirements & Risk Management**

Define and manage all requirement types (user, functional, design) with version control. Perform color-coded risk assessments to prioritize validation efforts and resource allocation. Import capabilities allow bulk entry from Excel™.

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## **Live Requirement Traceability Matrix (RTM)**

Automatically link requirements to test cases or individual test steps. The RTM updates in real-time and generates auditor-ready reports, providing clear traceability from requirement through to execution.

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## **Centralized Test Management**

Easily organize, prioritize, and execute test cases. Whether manual or automated, test cases are stored in a centralized repository and can be cloned, reused, or imported for regression testing. Built-in validation summary reports speed up documentation.

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## **Integrated AutoValidator™ for Test Execution**

AutoValidator works hand-in-hand with VMS to simplify test execution, enabling a paperless, streamlined quality process. From scheduling to results analysis, this integration supports both manual and automated testing strategies.

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## **End-to-End Issue Management**

Track and manage deviations, nonconformances, and validation issues from within the test script. Initiate and resolve issues rapidly with notifications and built-in workflows to maintain momentum across your validation cycle.

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The powerful combination of the AssurX Validation Management Solution and AutoValidator seamlessly aligns with any validation framework to support both manual and automated testing, ensure full requirement traceability, improve visibility into configuration issues, and generate comprehensive validation reports.