

# Audit Management Solution

AssurX Audit Management software streamlines audit-related tasks which include creating standardized audit and checklist templates, generating an audit plan, scheduling/assigning audits, conducting audits, identifying nonconformances and recommendations and track data and records through closure. Track and trend quality events to gain insight into your state of quality.



## VERSATILE, CONTROLLED AUDITING

An effective audit solution should not use a one-size-fits-all approach. AssurX makes it possible to select and define your audit processes based on the audits you need to conduct.

Manage any type of audit activities, data, and processes — from quality to EHS and compliance — while significantly reducing the time and effort involved to support being audit-ready.

Identify and manage issues and gain insights into the health of your quality and compliance and pinpoint areas that need improvement. Manages any type of audit including:

- Internal
- Suppliers
- Laboratory
- Operational
- Regulatory Compliance
- FDA
- ISO
- CGXP
- Risk
- Environmental Health and Safety
- Third Party

## INTUITIVE, CLOSED-LOOP REMOTE AUDITING

Collect and share information from multiple sources with closed-loop processes to recording findings, creating recommendations, and implementing action plans.

Easily configure/modify audit schedules, scope, processes, standards, expected evidence, and questions/lists. Intuitive checklists keep audit planning, routing, execution and resolution tasks controlled and consistent for tracking, trending, comparisons, and benchmarking.

Audit conclusions are automatically documented in a complete audit report once all findings are addressed. Attach unlimited files to any audit (support for attaching third-party registrar audit report).

## SEAMLESS INTEGRATION WITH THE ASSURX PLATFORM

Audit Management integrates with any other AssurX quality solution for an unbreakable trail of quality event management and data lineage.

Launch investigations, non-conformances, SCARs and corrective actions, initiate changes, and integrate with document management and training management to keep your processes, people and products compliant.

## ENTERPRISE SYSTEM INTEGRATION

Integrate with enterprise applications including ERP, MES, PLM, data repositories and others using AssurX's robust, flexible open interface solutions. Facilitate remote collaboration for input from other functional business areas, including external supply chain providers.

## REDUCE RISK THROUGH AUTOMATION

AssurX connects all stages of the audit process to ensure observations and issues are handled according to risk. Classify findings by multiple parameters including compliance risk, performance risk, safety risk, and other areas specific to your business. Assign risk scores that trigger an automated workflow of tasks, alerts and escalations based on the potential level of impact.

Real-time insight into metrics and trends help you ascertain and manage risk in accordance with corporate and regulatory compliance (FDA, ISO, GXP, NERC, EU, and more). View data from previous audits to identify past observations, CAPAs, adverse events, defects and changes.

## INCREASE AUDIT EFFICIENCY AND INTEGRITY

Create an electronic library of audit questions and workflows that automatically apply to new audits. The system serves as a single, secure repository to document and easily retrieve audit plan information including scope, applicable regulations and historical review.

Leverage your process knowledge to set resolution workflows (observation, mitigation, CAPA, etc.) based on pre-defined or updated procedures. Automated task assignments, email notifications and escalations further minimize cycle times.

## REDUCE THE COST OF COMPLIANCE

Reduce cost of compliance by standardizing audits to align with global regulations. Improve visibility through an audit trail of all plans, schedules, activities, findings, responses and final reports and enable leadership teams to easily examine audit scores for non-conformities.

All audit activities are digitally managed, scheduled and recorded to meet requirements for FDA and other regulations with full traceability including audit trail, electronic signature and data retention.

## AUDIT MANAGEMENT FUNCTIONALITY AT-A-GLANCE:

- Reduce process risks by automating routing for late tasks, escalations, reminders and electronic closure signatures.
- View and conduct all audit-related tasks from one dashboard.
- Generate print-ready audit reports with full audit details.
- Build electronic libraries of audit questions and responses to improve data quality and integrity.
- Documents, photos and videos can be attached at any stage to provide objective and supporting evidence.
- Download formatted spreadsheets to conduct off-line remote audits; import the data into AssurX without re-keying.
- Mobile ready for a real-time view of your audit records.
- Query and access audit conclusions and reports.
- Control access to audit information with users and groups with different permissions, including remote access for suppliers.
- Integrate with additional quality solutions to ensure closed-loop investigations and CAPAs.

**Audit Management**

68  
Late Audits

69  
Open Audits

0  
Late Findings

0  
Open Findings

0  
Findings Requiring Approval

[Add Audit](#)
[Add Audit Schedule](#)
[Add Audit Question Library](#)

**Audits**

STATUS  
Open X

ACTIONID	TYPE	AUDIT TITLE	START DATE	DEPARTMENT/FACILITY	AUDITOR
21	Internal Audit	Demo AssurX Audit	4/6/2020	AssurX	Jan-Michael Stone
25	Internal Audit	April ISO 9001 Audit	4/6/2020	AssurX	Jan-Michael Stone
45	Internal Audit	Deviation #42	4/15/2020		Jan-Michael Stone
420	Internal Audit	Deviation #418	8/1/2020		Jan-Michael Stone
50	Internal Audit	Deviation #48	4/15/2020		Jan-Michael Stone
368	Internal Audit	Demo Audit	8/13/2020	AssurX	Jan-Michael Stone
67	Internal Audit	Deviation #65	5/1/2020		Jan-Michael Stone

View the status of audit records from the AssurX audit dashboard. Personalize the dashboard views to present the right information to the right people.

**INSTRUCTIONS:**  
 1. Enter information regarding the audit. Mandatory fields are designated in red.  
 2. Selecting the Audit Type will automatically change the form fields.  
 3. Required Audit Information is provided when the audit is ready to be closed. Upon final signature the audit will automatically be closed.  
 NOTE: Audit questions will be added for a new Audit report based on the Type and Scope selected. There are no Audit Library filters for this selection.

**Schedule Title**  
 Demo Schedule

**Audit Title**  
 Demo Personnel Audit

**Audit Type**  
 Internal Audit

**Schedule Line Number**  
 688

**Start Date**  
 7/10/2020

**Scope**  
 Personnel

**Audit Schedule**  
 215

**Duration (days)**  
 1

**Distribution**

**Data Created**  
 7/1/2020

**Due Date**  
 7/22/2020

**Status**  
 Closed

**INTERNAL AUDIT INFORMATION**

**Dept. Audited**  
 AssurX

**Department Contact**  
 Jan-Michael Stone

**Department Manager**  
 Jan-Michael Stone

**Documents Reviewed**  
 SOP

**AUDIT SCOPE / OBJECTIVES**

**Audit Scope**  
 Demo

**Audit Objectives**  
 Demo

**AUDIT CHECKLIST**

**Appendix Sheet**  
 Yes

**Preparation Completed**  
 Yes

**Auditee Contacted**  
 Yes

**Pre-Audit Meeting**  
 Yes

**MANAGE AUDIT QUESTIONS/RESULTS**  
 1. This Audit Question is manually added to a question.  
 2. To add a question to an existing audit, click on the question.  
 NOTE: If the question is not added, the question will not be added.

EDIT LINE	SCOPE	QUESTION	CRITERIA	EVIDENCE	MEETS CRITERIA	RESULT	CRITERIA NOT MET (ADD FINDING)	FINDING ID
Personnel	How do you determine competence on the basis of appropriate education, training or experience?				Yes	Meets Criteria		
Personnel	Show me documented information where appropriate of competence/training.			Documented information as evidence of competence/training where appropriate.	Yes	Meets Criteria		

Create audits based on type and build electronic libraries of audit questions. Access scope objectives, audit checklist, findings, activities, documents and reports from the audit record.

## ABOUT ASSURX

With decades of expertise built into our quality management and regulatory compliance software platform, AssurX helps companies maintain quality and compliance, streamline workflow, control risk and better manage any enterprise.

Our incredibly configurable software and deep understanding of users' needs produces a unique system that easily adapts as your business evolves. AssurX is an ideal partner for regulated companies looking for better operational control and efficiency while staying compliant.

To learn more about how AssurX can help with your quality and regulatory compliance management needs, please [connect with us online](#).

