

AUDIT MANAGEMENT SOLUTION

AUTOMATED, COMPLIANT EFFICIENCY FROM PLAN TO TREND

The AssurX Audit Management solution automates and streamlines your entire audit process. This versatile software allows you to easily plan, schedule, conduct and document audits of any kind; process and track the resolution of findings; and identify and track trends across your organization.

Versatile, Controlled Auditing

The software supports any type of audit (across any part of your business) including internal, supplier, laboratory, operational, regulatory, GxP, risk assessment, third party and EH&S.

By creating an electronic workflow of tasks, assignments, alerts and escalations that can be automated to the level you prefer, AssurX keeps all stages of the audit process efficient and ensures important activities and issues are being handled properly and on-time.

It consistently maintains an electronic archive and time-stamped audit trail for all audit

plans, schedules, activities, findings, responses and final reports for easy search and retrieval.

The software tracks and delivers live, detailed visibility into audit activities, metrics and trends to help you manage risks across the business—all while meeting regulatory requirements and maintaining compliance (FDA, ISO, GxP, NERC, SOX, EMEA and more).

AssurX Audit Management is available as traditional OnPremise (licensed), or OnDemand (cloud-based SaaS) software.

WHY ASSURX AUDIT MANAGEMENT IS THE ANSWER:

AUTOMATICALLY LOGS AUDIT FINDINGS, MANAGES THE RESPONSE AND RESOLUTION PROCESS, AND LAUNCHES CORRECTIVE ACTIONS WHEN REQUIRED

KEEPS AUDITS EFFICIENT WITH AUTOMATIC TASK ASSIGNMENT, EMAIL NOTIFICATIONS AND ESCALATIONS, REDUCING AUDIT CYCLE TIMES

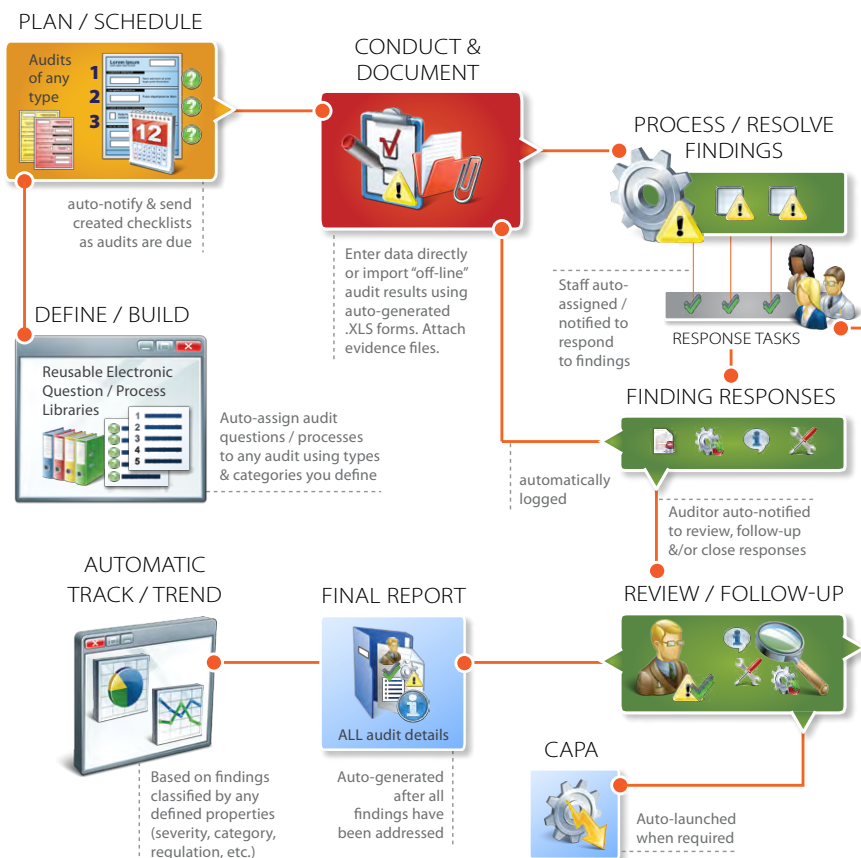
INCREASES AUDIT CONSISTENCY WHILE REDUCING ERRORS AND MISSING RECORDS

CREATES AN ELECTRONIC LIBRARY OF REUSABLE AUDIT QUESTIONS AND PROCESSES THAT CAN BE AUTOMATICALLY APPLIED TO NEW AUDITS

AUTOMATED TRACKING, TRENDING AND RISK ASSESSMENT BASED ON FINDINGS CLASSIFIED BY PROPERTIES YOU DEFINE

MEET REGULATORY REQUIREMENTS AND MAINTAIN COMPLIANCE (FDA, ISO, SOX, EMEA, GxP, NERC & MORE)

ASSURX'S AUTOMATED SYSTEM KEEPS ANY AUDIT PROCESS CONTROLLED AND EFFICIENT



AssurX Audit Management handles any type of auditing, keeps your process controlled and efficient, and provides one easy to search/retrieve repository for all audit related information.



ABOUT ASSURX

With decades of expertise built into our quality management and regulatory compliance software, AssurX helps any company exceed quality expectations, ensure compliance, manage risks and better govern their enterprise. AssurX is a highly versatile set of software solutions that unites and coordinates information, activities and documentation in one reliable enterprise system, letting you easily orchestrate operations; detect, correct and prevent problems; and improve the bottom line.



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Key Built-in Features

PLAN, CONDUCT & MANAGE WITH EASE

The software includes best-practice workflows, ready to use or modify, for a variety of audits.

- Easily define and set audit schedules, scope, processes, standards, expected evidence, and auditing questions
- Build electronic libraries of reusable audit questions, standards and processes; and automatically apply them to new audits using types and categories you define
- Creates a single place to document, and easily retrieve all:
 - Audit plan information including scope, applicable regulations, historical review
 - Audit inputs, notes, meeting minutes, findings, observations and other data
- File-attach relevant documents of any format, such as .doc, .xls, .pdf, to any AssurX audit record(s)
- Auditors can enter results directly into the system, or instantly generate a formatted Microsoft Excel® spreadsheet to conduct audits offline. Offline responses can be imported into the system without rekeying
- Automated notices and reminders for upcoming and late audits, tasks and electronic signatures. Supervisors can receive alerts about late items, and very late tasks can be reassigned according to your rules
- Automatically log findings & observations
- The system sets each Finding Resolution workflow, such as Observation, Mitigation or CAPA, based on rules you define
 - Documents progress and results
 - Automatically initiate corrective actions, when required

INSTANT AUDIT CONCLUSIONS & REPORTS

Audit conclusions are automatically documented in a complete audit report once all findings are addressed.

- Automated routing for electronic closure signatures
- Generates a print-ready comprehensive internal or external audit report with all audit details, including findings, resolutions and approvals

ACTIVITY MONITORING, METRICS & TRENDING

From one simple dashboard users can:

- Search and access all audit records and view pending audits and findings
- Report and query across one or all connected processes by any parameter such as product or problem type
- Measure and trend audit findings classified by parameters you define such as severity, category or reference regulation
- Audit managers can also initiate new audits, manage tasks and schedules, access controls, and view the status of any audit related activities instantly

ENTERPRISE INTEGRATION

Like all AssurX products Audit Management integrates with any of our other quality and compliance solutions such as CAPA, Complaints, and Document Management, so no matter where a finding originates, or how many departments an issue touches, the system can effectively manage audits and responses.

- Easily integrate with any external system or database such as ERP, MES, HR, internally developed applications, etc., using AssurX's robust, flexible open interface

BUILT FOR COMPLIANCE

All audit activities are systematically managed and recorded in closed-loop routines to meet requirements for FDA and other regulations with: validation, audit trail, electronic signatures, retention and traceability. Once added to a specific record, signatures cannot be modified, copied, transferred, or deleted. AssurX automatically maintains a secure, time-stamped record archive (audit trail) of all changes made to any electronic record.