

AssurX

ENTERPRISE QUALITY & COMPLIANCE
MANAGEMENT SOFTWARE



You can rest assured.

Because Quality & Compliance Should Be a Given, Not a Goal

ASSURX'S FLEXIBLE, ALL-IN-ONE SYSTEM AUTOMATES QUALITY AND COMPLIANCE RELATED PROCESSES SO ISSUES CAN BE CENTRALLY MANAGED—FROM DETECTION TO CORRECTIVE ACTION TO TREND ANALYSIS. IT HELPS COLLECT, ORGANIZE, ANALYZE AND SHARE INFORMATION TO BETTER MANAGE RISK AND IMPROVE QUALITY AND COMPLIANCE PERFORMANCE EVERYWHERE IN YOUR ENTERPRISE.

Customers use AssurX solutions to manage manufacturing defects, customer complaints, safety issues, regulatory commitments, supplier quality, audits and findings, CAPAs, and much more. With its powerful analytical tools that help solve problems faster, AssurX has also proven to be instrumental in helping firms achieve and maintain ISO certification, comply with FDA, NERC and other regulatory requirements, and identify, assess and remediate their organization's risk exposure.

AssurX solutions follow best practices and are uniquely designed to service any industry—even the most highly regulated. They are working in a broad range of markets including: energy utilities • medical device • pharmaceutical • biotechnology • food • semiconductor • consumer goods • contract manufacturing • high technology • finance • insurance.

By providing clear views and shared information across functional areas, AssurX creates the power to easily detect, correct and analyze issues globally so companies can continuously improve operations, compliance and their bottom line.



Use AssurX For Automated:

CORRECTIVE & PREVENTIVE ACTION (CAPA)

Closed-loop corrective action tracking for companies following Good Manufacturing Practices (GMPs). Recurring issues are investigated, root causes identified, corrective/preventive actions implemented and evaluated for effectiveness—all in a best practices workflow.

AUDIT MANAGEMENT

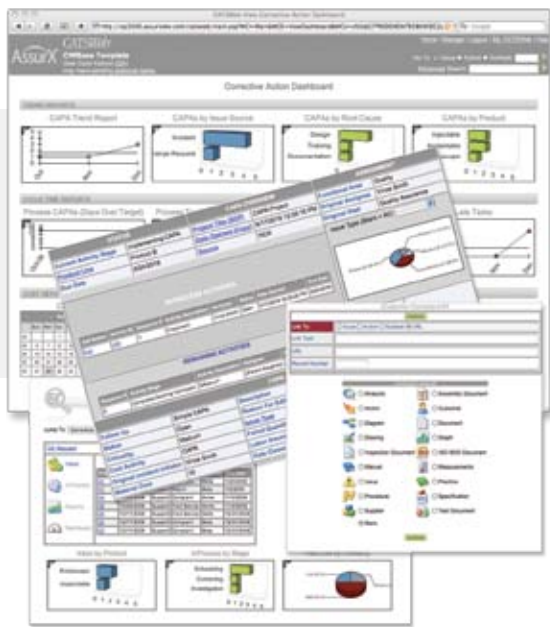
Comprehensive audit management process for closed-loop findings, closure, task assignments and escalation. Audits are conducted after being planned, findings are classified and follow-up is assigned to area managers. After follow-up actions are addressed, a final report is issued and routed for closure.

MANUFACTURING QUALITY

Comprehensive quality, nonconformance and defect tracking follows ISO and GMP standards for best practices. Get solid closed-loop issue and change request management, from initiation through disposition and corrective action. Track trends, cycle times and costs to facilitate root cause analysis and improve efficiency.

SUPPLIER QUALITY

Improve supplier quality management and performance by tracking purchased product issues from receiving through manufacturing and into the field. Manage supplier qualification and auditing. Assign findings, track follow-ups and issue reports. Consolidate supplier information and calculate supplier scores based on performance.



A simple, point-and-click interface and graphical reports make AssurX easy to use.

DOCUMENT MANAGEMENT

Closed-loop management of all documentation such as policies, procedures, training and work instructions. Implement revision control and change management with approval routings and email notifications. Disseminate notifications of document additions and changes based on affected roles.

CUSTOMER QUALITY

Automate all customer related events including complaints, returns, service calls and product improvement requests. Drive process workflows based on event type and severity. Improve responsiveness and customer satisfaction with escalation management.

PRODUCT DEVELOPMENT & CHANGE MANAGEMENT

Effectively manage continuous process improvement and new product development projects to reduce time to market. Easily assign and manage tasks required to implement changes across all functional areas including engineering, manufacturing, purchasing and service.

FINANCE PROCEDURES CONTROL

Transform static policy and procedure documentation into a real-time, closed-loop quality and risk control process to facilitate audits and help meet the stringent control requirements of COSO, Sarbanes-Oxley, the SEC and NASDAQ/NYSE. Manage problem reporting, escalation and resolution company wide.

MANAGEMENT DASHBOARDS, KPIS & METRICS

Globally monitor key performance indicators and drill down to the underlying data—in real-time, all the time—to improve compliance, customer satisfaction, risk exposure and the bottom line. Track trends by site, product, or any other parameter. Prevent recurring problems by finding root causes and implementing solutions.

Why AssurX:

Easy In, Easy Up-and-running

Known for its flexible, intuitive design, AssurX is quick and simple to configure and deploy. Turnkey processes such as corrective action management, complaint handling, regulatory reporting, issue tracking, audit management, customer support, and supplier quality are provided with full documentation, validation scripts, template forms, executive dashboards, and everything else needed for fast deployment.

- **NO CLIENT SIDE SOFTWARE/VALIDATION** with a fast, easy server installation.
- **RAPID DEPLOYMENT THROUGH EASY POINT-AND-CLICK CONFIGURATION** of workflows, fields, forms, rules, lists, signatures, etc. No programming required.
- **MINIMAL TRAINING NEEDED FOR USERS** due to a clean, intuitive interface with robust help file.
- **ONDEMAND (SOFTWARE-AS-A-SERVICE) OPTION** lets you Manage your business, Not your software.™ And, it gives the flexible option of bringing the system “in-house” at anytime.

Making It Simple To Get The Job Done Right

AssurX leads the industry in functionality and flexibility because we're committed to customer-driven continuous improvement. At every turn we're backing that commitment by delivering powerful functionality focused not only on performance, but designed with user friendliness in mind.

- **BUILT-IN DASHBOARDS**, dashboard templates and metrics. No additional third party tools needed.
- **EFFECTIVE, DETAILED ANALYSIS & DECISION MAKING** with the unique ability to query all fields as named and configured across all forms.
- **FULLY CONFIGURABLE POINT-AND-CLICK GRAPHICAL USER INTERFACE (GUI)**. Use your own images, logos, styles and corporate colors.
- **POINT-AND-CLICK ADMINISTRATION** for form design, signature workflows, escalation rules, and more. Eliminates the need for revalidation as the system is enhanced.
- **FULL TEXT SEARCH** (basic to advanced). The most sophisticated on the market today.
- **INCLUDES OUT-OF-THE-BOX, READY TO USE FORMS & BEST PRACTICE WORKFLOWS** you can easily modify. Or, build your own using simple configuration tools that require NO programming.

**ASSURX QUALITY
& COMPLIANCE
SYSTEMS MANAGE:**

CAPAS

NONCONFORMANCES

AUDITS & FINDINGS

EXCEPTION REPORTS

RISK MANAGEMENT

CUSTOMER COMPLAINTS

MANUFACTURING QUALITY

SUPPLIER QUALITY

RMAS

ISSUE TRACKING

COMMITMENT TRACKING

SAFETY ISSUES

DOCUMENT MANAGEMENT

CALIBRATION TRACKING

CHANGE CONTROL

eMDR

PRODUCTION QUALITY CONTROL

TRAINING MANAGEMENT

SAFETY INCIDENT REPORTING

REGULATION & STANDARDS
COMPLIANCE

**Secure And Compliant,
You Can Rest Assured**

SECURITY CONTROLS

With tight, built-in security controls—from suspicious activity alerts to field/record access restrictions—AssurX enables the administrator to define a wide number of parameters to ensure “strong” passwords and a secure system.

- **SOPHISTICATED ACCESS RESTRICTIONS** including both record and field level can be based on groups, departments, personalities and/or employees.

REGULATIONS & STANDARDS COMPLIANCE

No matter how heavily regulated the business—from FDA monitored industries to energy, food and finance—AssurX keeps you compliant with up to the minute regulations and standards.

- **FDA COMPLIANT: 21 CFR Part 11, 21 CFR Part 820, GMP, ISO, and more.**

ELECTRONIC SIGNATURES

Once added to a specific record, signatures cannot be modified, copied, transferred, or deleted. Signatures can be of various types (approval, acknowledgement, etc.) and comments may be included with each.

RECORD ARCHIVING (AUDIT TRAIL)

AssurX automatically maintains a secure, time-stamped compliant audit trail of all changes made to any electronic record. Records and changes are displayed together in their entirety.

- **NERC & FERC COMPLIANT: All Electric Reliability Standards including NERC CIP.**
- **HIPAA COMPLIANT: DHHS Health Data Protection regulations.**
- **FINANCIAL REGULATIONS COMPLIANT: SOX, Patriot Act, and more.**

AssurX Plays Well With Others

Information systems are rarely afforded the luxury of operating in isolation. AssurX provides an open integration interface that delivers robust, flexible interaction with any of your existing information systems and databases.

- **WORKS WITH ANY REPORTING TOOLS:** Business Objects (Crystal Reports/Enterprise), Cognos/IBM, etc.
- **INTEGRATES WITH ANY EXTERNAL SYSTEM:** ERP, MES, SCM, internally developed applications, databases, etc.

**With AssurX Technology,
One Simple System Fits All**

Its true zero client architecture means AssurX runs on all browsers and operating systems with no requirement to install, upgrade or manage client computers. Built-in, configurable processes are designed to integrate seamlessly with each other providing a single, all-in-one solution for managing quality and compliance enterprise-wide.

- **HIGHLY RELIABLE** using advanced, field-proven technology. True Zero Client, 100% Web-based solution including both user and administrative controls.
- **PROVEN SCALABLE** to hundreds or thousands of users, independent of client browser version or client operating system. Flexible and all-inclusive handling of unlimited number of quality processes without additional modules.
- **FASTEST RESPONSE TIMES** and smallest bandwidth consumption, since only pure HTML is delivered to client computers.
- **COST-EFFECTIVE EXTENSIBILITY** with open architecture lets you make advanced custom configurations (event hooks, connectivity to other databases) that don't change core code—so upgrades are seamless.

Take advantage of AssurX's flexible solutions and address the quality and compliance challenges facing you today. To find out how AssurX can help meet those challenges, call us at 1-888-9-ASSURX.



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