AssurX

QUALITY AND COMPLIANCE SYSTEMS **FOR EVERY ENTERPRISE**

QUALITY MANAGEMENT AND REGULATORY COMPLIANCE SOFTWARE

AUTOMATE. ADAPT. IMPROVE.

AssurX is a powerfully flexible enterprise quality management software (EQMS) that coordinates and harmonizes information, activities and documentation in one reliable platform. Effectively manage any quality or compliance-related issue within a closed-loop system.

Available in the AssurX Cloud or on-premise, AssurX is ideal for any regulated business—regardless of size or complexity.

AssurX EQMS customers encompass a wide range of industries, including:

- Pharmaceutical & Biotechnology
- Medical Device & Diagnostics
- Nutritional Supplements
- Food & Beverage
- High Tech Manufacturing
- Aerospace & Defense
- Contract Manufacturing
- Commercial & Retail

DYNAMIC AND CONFIGURABLE

AssurX replaces manual and legacy quality systems by automating and integrating quality processes into a scalable, rules-driven electronic ecosystem. Use AssurX's out-of-the-box, pre-configured processes, or configure your own for unique or complex applications.

The AssurX platform easily adapts over time to meet your evolving business needs with powerful functionality focused on configurability, scalability, performance and flexibility.

Point-and-click administration (forms design, signatures, escalation rules, etc.) eliminates the need for re-validation as the system is enhanced.

A TRUE EQMS PLATFORM

AssurX provides all core quality and compliance processes within the software system, eliminating the need to budget for and install quality "modules."

Pre-configured workflows are available to you from day one. Start with the solutions you need to deploy first, and seamlessly integrate new processes when you're ready.

COLLABORATE ACROSS THE VALUE CHAIN

Create a quality ecosystem of connected processes that enables users, managers, regulatory bodies and suppliers to collaborate on quality issue management, compliance requirements, reporting, training, and audits.

FULL VISIBILITY AND CONTROL

Dashboards, status reports, alerts, notifications, and escalations keep teams and management aware of late tasks and review requests. If an issue is detected, a corrective action can be assigned and followed to closure, with linkages to the task that the issue was initiated from.

Visibility into trends and data helps you make informed decisions to continually improve quality operations.

RISK-BASED COMPLIANCE

Automatically coordinate, track, and assess activities to minimize risk ensure compliance with global regulations and ISO standards.

Findings, evidence, applicable policies and procedures, training, and electronic approvals can be linked to any task. Get instant, detailed insight into compliance risk and status with graphical management dashboards.

AssurX has over 25 years of experience helping our customers achieve compliance with regulations including FDA CGMP, FDA 21 CFR, EU GMP, electronic medical device reporting (eMDR/EU MDR), ISO quality standards, and other industry-specific standards.

ROBUST INTEGRATION

AssurX provides an open integration interface that delivers robust, flexible interaction with existing information systems and databases to facilitate quality production.

AssurX integrates with any reporting tools including Microsoft® BI, SAP® Crystal Reports, SAP® Business Objects, IBM Cognos® and Qlik®, enterprise business systems including ERP, PLM, LIMS, CRM, CMMS, and internally developed applications and databases.

AssurX is uniquely designed with a high level of configurability and an unmatched ease of deployment. Create an integrated, precision quality management system that rapidly adapts to change and scales seamlessly.

ONE **ENTERPRISE PLATFORM** TO MANAGE QUALITY AND REGULATORY COMPLIANCE.

AUDIT MANAGEMENT
Manage any type of audit activities, data, and processes while significantly reducing the effort involved to support being audit-ready. Identify and manage issues and gain insights into the health of your quality and compliance.

CALIBRATION MANAGEMENT
Quantify, control, and demonstrate acceptable device measurements. Capture all the required data used for calibration measurements. Retain all information in one centralized location.

CHANGE MANAGEMENT
Facilitate and control any type of change. Enable cross-functional engagement and provide the visibility required to achieve desired outcomes for product or process improvement. Engage all areas within the scope of change impact analysis.

COMPLAINT MANAGEMENT
Ensure that all complaints and adverse event reporting requirements are processed in a timely manner and in alignment with industry regulations. Document, review, and electronically submit reportable events to the FDA, EMA and other international bodies.

CORRECTIVE AND PREVENTIVE ACTION (CAPA)
Automate all steps required to evaluate and investigate quality issues and implement the appropriate actions and controls to minimize future incidents. Integrate CAPA with additional processes, data, and documents to create continual improvements in the quality chain.

CUSTOMER QUALITY MANAGEMENT
Streamline the processing of customer-reported complaints and events, RMAs, field service, and product improvement requests. Qualify, prioritize, route, track and trend quality issues for efficiency and insights into products and performance.

DESIGN CONTROL
A product lifecycle management that provides full traceability of medical device requirements and deliverables, addressing key areas to be documented within the Design History File (DHF), including Design & Development Planning, Design Inputs, Outputs, Review, Verification & Validation, Design Transfer, and Design Changes.

DEVIATION MANAGEMENT
Capture, investigate, and disposition deviations and nonconformances. Best practice workflows expedite the identification of the deviation source anywhere in the quality value chain. Track and manage deviations from initiation, through investigation and root cause analysis, to CAPAs and change controls.

DOCUMENT MANAGEMENT
Automate routing, review, revision, approval and distribution of documents. Improve control and visibility throughout the document life cycle. Maintain a centralized, secure repository for easy search and controlled document access.

EHS ISSUE MANAGEMENT
Automate EHS incident management to streamline investigations for rapid response, investigations, and closure with appropriate corrective and preventive actions. The solution creates a consistently classified and secure system that contains all incident details.

SUPPLIER QUALITY MANAGEMENT
AssurX Supplier Quality Management (SQM) helps manage suppliers, vendors, contract manufacturers, and service providers with one solution. Quickly detect, inspect, contain and resolve quality issues to assure your customers the highest quality products and service.

MANUFACTURING QUALITY
Automate the tracking, documenting, and resolution of manufacturing-related quality incidents such as non-conformances, deviations, defects, failures, and exceptions. Manage quality issues from detection through investigation, disposition, CAPA, and change control in a single system.

RISK MANAGEMENT
Manage risks associated with failure of any process or product. Risks initiated from any source are automatically associated with related product records across the system, forming an enterprise approach for rapid response and mitigation.

TRAINING MANAGEMENT
Facilitate management of any type of training by routing training tasks with reminder, notifications, escalations, and verification of results. AssurX provides a centralized location for all training activities, materials, records, certifications, and other related documents.

QUALITY MANAGEMENT REVIEW
Schedule and conduct QMRs as required by compliance guidance and industry standards. Review and evaluate the effectiveness of the QMS, determine effectiveness, and automate tasks related to outputs for changes to policy and quality objectives and other elements to further improve quality.

VALIDATION MANAGEMENT
The AssurX Validation Management Solution establishes repeatable processes for managing requirements, performing risk assessments, testing, and reporting. The results are increased speed, improved quality, and reduced costs.

COMMITTED TO YOUR SUCCESS.

WHY AUTOMATE YOUR QMS WITH ASSURX?

+ Eliminate gaps and errors inherent in paper-based and segregated business silos.
+ Reduce risk with greater control of priorities, deadlines, documentation and certification with rules-driven workflows.
+ Utilize data analytics to identify issues, risks and trends and make informed decisions.
+ Maintain audit-ready data for more efficient internal and external audits.
+ Automate regulatory report submissions.
+ Track and monitor performance of processes and products throughout their life cycle. Plan and facilitate GxP audits and inspections.
+ Simplify complex processes and close gaps to minimize future compliance risk.
+ Build a future-proof system that adapts to changing business needs and regulatory requirements.
+ Integrate all clinical, manufacturing and quality processes into a connected ecosystem for full traceability.
+ Access relevant information across the entire product or service quality supply chain.

ASSURX PROFESSIONAL SERVICES

VALIDATION MANAGEMENT SERVICES

The AssurX Validation Management Services team has extensive experience qualifying electronic quality software systems. Using a proven methodology, AssurX will collaborate with your team to validate the AssurX platform and each configured solution.

Validation of the AssurX system— regardless of configuration, risk, or complexity—is performed in a way that not only reduces time and effort but also becomes a valuable business tool. The AssurX validation services experts can evaluate business and system requirements, environment, and system architecture and create a validation package to execute a successful implementation and demonstrate sufficient validation.

PROFESSIONAL SERVICES

AssurX provides expert technical and program management oversight for customer deployments around the globe. Our primary goal is to maximize business value for our customers by creating smooth technology transfers and accelerated implementations. Services include:

- Configuration and process development services
- Project management services
- Integration services (ERP, PLM, MES, LIMS, CRM, CMMS)
- Data migration services using AssurX import technology

TRAINING

AssurX offers a full range of training programs from regularly scheduled classroom courses to on-site, on-line, and custom training programs, AssurX training is flexible and designed to make customers self-sufficient in managing, using, and expanding the use of AssurX software.

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