QUALITY MANAGEMENT AND REGULATORY COMPLIANCE SOFTWARE
AssurX’s powerfully flexible enterprise quality management software (QMS) unites and coordinates information, activities and documentation in one reliable system, effectively managing any quality or compliance-related operations. The easiest on the market to deploy, configure, use and adapt, AssurX is ideal for every business—of any size—including the most highly regulated.

AssurX replaces paper-based and siloed processes with a single platform. AssurX eQMS transforms the way you visualize, manage, track, and communicate information. AssurX’s configuration capabilities are highly flexible and designed for organizations in highly regulated industries including:

- Pharmaceutical, medical device, and manufacturers that must comply with regulations including FDA CGMP, FDA 21 CFR, EU GMP, electronic medical device reporting (eMDR/EU MDR), and others
- Manufacturing organizations that must comply with ISO 9001 Quality Management Systems Requirements
- Distribution, transportation and other service industries that depend on quality operations to improve supply chain efficiencies
- Energy and Utility Entities regulated by North American Electric Reliability Corporation (NERC) compliance requirements for Critical Infrastructure Protection (CIP), Control Systems (PRC) and Reliability Standards Management

ASSURX BUSINESS BENEFITS

Ease of Implementation
AssurX pre-configured processes are provided with full documentation, validation scripts, template forms, management dashboards—everything needed for fast deployment.

Control
A forms-based architecture makes it possible to automate any quality or business process for your specific needs. Dashboards, status reports, alerts, notifications, and escalations keep you in control of quality and compliance health.

Compliance Readiness
AssurX is built with features and functionality designed for highly regulated industries required to maintain compliance. Electronic signatures, records management and access restrictions protect the integrity of quality data.

Robust Integration
AssurX provides an open integration interface that delivers robust, flexible interaction with existing information systems and databases to facilitate quality production. Integrate with any other AssurX solutions, reporting tools including SAP® Crystal Reports, SAP® Business Objects, IBM Cognos® and Qlik®, enterprise business system including ERP, PLM, LIMS, CRM, CMMS, and internally developed applications and databases.

Adaptability
The AssurX platform is designed to easily adapt to meet your evolving business needs with powerful functionality focused on performance and flexibility. AssurX software has virtually unlimited scalability.

WHY AUTOMATE YOUR QUALITY MANAGEMENT SYSTEM WITH ASSURX?

- Use AssurX’s out-of-the-box, pre-configured processes or configure your own for unique or complex applications.
- Access relevant information across the entire product or service quality supply chain.
- Reduce risk with greater control of priorities, deadlines, documentation and certification with rules-driven workflows.
- Make informed decisions based on measurable risks and evidence.
- Maintain audit-ready data for more efficient internal and external audits.
- Integrate all clinical, manufacturing and quality processes into a connected ecosystem for full traceability.
- Simplify complex processes and close gaps to minimize future compliance risk.
- Quantify and measure the effectiveness of process revisions.
The AssurX platform is uniquely designed with a high level of configurability and an unmatched ease of deployment. Build integrated, precision quality systems that rapidly adapt to change.

- Automate notifications, escalations, routing and approvals for any process.
- Launch corrective and preventive actions (CAPAs) from any point in any process.
- Accelerate response to issues caused by unexpected failures, defects, and other nonconformances.
- Electronically submit vigilance and adverse event reports based on regional submission requirements.
- Track and monitor performance of processes and products throughout their lifecycle. Plan and facilitate GxP audits and inspection.
- Build out and integrate processes as required; expand your quality ecosystem to meet your needs.
- Deploy AssurX as an onsite solution, in the AssurX Cloud QMS™, or as a hybrid solution.
ASSURX SERVICES

Validation Management Services
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.

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
- 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, online 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.

COMMITTED TO YOUR SUCCESS.

A FLEXIBLE SYSTEM OF SEAMLESSLY INTEGRATED SOLUTIONS.

BUILT FOR REGULATED INDUSTRIES.

BUILT FOR COMPLIANCE.

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