

ASSURX VALIDATION

MAKING EQMS CHANGES & VALIDATION EASIER

Having served regulated industries for more than two decades, AssurX understands the needs and issues of those that must validate their products and services for quality and regulatory purposes. The validation (and ongoing control and management) of electronic systems used to support quality initiatives continues to be a major issue. AssurX has architected their software solutions, tools and documentation to ensure our customers can properly and effectively implement and manage ongoing changes to their enterprise quality management system (EQMS).

AssurX tools and techniques are built into the architecture of its software and services to minimize validation and re-validation efforts, and make the EQMS more effective. AssurX solutions offer the broadest range of system configurability while meeting all quality expectations and regulations, and help our customers more effectively validate and manage changes to their EQMS with:

Controlled Internal Processes

The development and modifications to our products are managed via internal controlled processes and procedures, which have been successfully audited multiple times.

Thorough Documentation

- IQ/OQ test report of the core system
- IQ/OQ test scripts for customer execution
- PQ of individual solutions/processes (i.e. CAPA, Complaints, Doc Mgmt, etc.)
- Online help documentation including video administration and user guides
- Documentation is editable should additional configuration be required

Software Architected For Unparalleled Configuration

- No need for custom functionality
- No client code to validate
- Same software used by all customers (versions/patch levels may vary)
- Can be implemented as complete ready-to-use software, or be used as an excellent starting point to configure your company's specific requirements

Built-in Tools to Maintain & Meet Compliance Regulations

- **Built-in 21 CFR Part 11 compliance:**
 - Electronic signatures
 - Onscreen color coded change history for easy tracking of historical changes
 - Ability to quickly query historical changes to records
- **Form Manager™** tool provides:
 - version control of processes
 - controlled migration of processes from development to validation to production with *minimum to no regression testing*
- **Records Manager™** helps meet records retention policies
- **Workflow Builder™** for graphical workflow design and versioning

Experienced Professional Services

If required, AssurX's experienced staff helps to document requirements, execute configuration changes, write and/or execute test scripts, and manage your validation process.

About AssurX

AssurX, Inc. provides fully automated enterprise quality management and regulatory compliance software solutions. This powerfully versatile software unites and coordinates information, activities and documentation in one reliable system to effectively improve quality, ensure compliance, manage risks and better govern your enterprise. The easiest on the market to deploy, configure, use and adapt, AssurX is ideal for every business—of every size—even the most highly regulated.

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