

Quality System Software Validation Services

AssurX Validation Management Services is designed to support software development and validation efforts. A partnership designed to manage technology changes, improve quality and implementation efficiencies, and provide documentary evidence to demonstrate compliance.

AssurX Validation Management Services increase the efficiencies of custom validations to satisfy your organizational and regulatory requirements that cover FDA 21 CFR Part 11, EU Annex 11, ISO 13485 and others.

AssurX helps our customers minimize validation activities associated with future enhancements and configuration changes by re-validating your system with minimal disruption. Using our services will increase your company's quality levels, reduce costs, and maximize your team's productivity.

The AssurX Validation Management Services team has extensive experience developing protocols to validate electronic quality systems—giving your team more time to focus on quality management and product innovation. With our proven methodology, AssurX collaborates with your team to validate the AssurX platform and each configured solution. Validation services are customizable according to your organization's needs.

PROJECT DELIVERABLES + VALIDATION PLANNING

Project deliverable documentation or technical documentation tends to be the most overworked and underestimated delivery in the software development processes. Our team can create and maintain your deliverables to ensure they are on schedule and budget. AssurX works with your team to develop a structured approach to confirm the validation plan clearly defines the scope and goals of the validation project. Services include:

- + Gathering User Requirements and Functional Requirements
- + Creating a Validation Plan
- + Creating User Requirement Specification (URS) & Functional Requirement Specification documents (FRS)
- + Performing Risk Assessment and creating a Functional Risk Profile (FRP)
- + Building a Requirement Traceability Matrix (RTM)
- + Documenting Design Specifications
- + Updating existing deliverables to add new configurations, functionality or include traceability

INSTALLATION QUALIFICATION & OPERATIONAL QUALIFICATION

AssurX provides a comprehensive IQ/OQ Test Script that includes rigorous testing and documentation of the AssurX Platform. Validation Management Services will execute the test script as well as perform any necessary configuration changes that are required to meet your organization's regulatory requirements. Services include:

- + Provide the Customer IQ/OQ Test and Report
- + Customizing the Customer IQ/OQ Test and Report
- + Executing the Customer IQ/OQ Test and Report
- + Providing the Execution Report
- + Executing Operational Qualification (OQ) test scripts for installed solutions
- + Automating IQ/OQ
- + Executing Operational Qualification (OQ) test scripts for installed solutions



BENEFITS OF VALIDATION MANAGEMENT SERVICES

- + Reduce cost and time-to-completion with custom validations that satisfy requirements and regulatory guidelines.
- + Assure efficient, accurate evaluation of regulatory and quality compliance tailored to your specific business needs.
- + Reduce your time to go-live and cost of third-parties by leveraging the expertise of professionals with extensive practical experience.
- + Utilize Validation Management Services as needed to minimize validation of future enhancements and configuration changes.
- + Validation standards executed are in compliance with global regulations.
- + Scale to an unlimited number of users, processes and facilities.
- + Avoid gaps that can lead to observations and warning letters.
- + A validation services team that operates independently from Implementation Services to eliminate any perceived bias in the process.

PROCESS QUALIFICATION CREATION & EXECUTION

AssurX Validation Management Services provides an extensive library of Process Qualification (PQ) documentation for our pre-configured solutions. Our services can execute pre-built PQs and provide an Execution Report.

If your solutions have been configured, AssurX will tailor the Process Qualification document to ensure that the critical aspects and functions of the configured process have been thoroughly tested.

Each PQ has Requirements Traceability Matrix (RTM) built into the document that links requirements to the validation process. Our team ensures that all requirements defined for a system are tested in the PQ.

After your approval of the PQ, we are able to conduct the formal validation by executing the steps within the PQ on your configured solution and providing you the Execution Report.

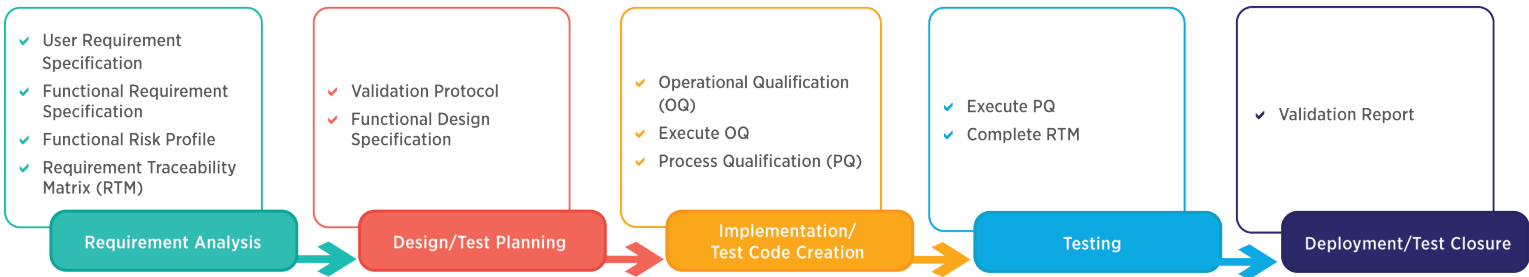
CUSTOMIZABLE HELP FOR EACH SOLUTION

Validation Management Services offers customizable user guides to provide contextual information and help reduce the amount of time it takes to train users on the new platform.

AssurX understands that there is no one-size-fits-all approach to software validation. Our Validation Management Services team will tailor our processes to work optimally with your internal software validation procedures.

AssurX validation experts have experience across proven reference models including V-Model/Waterfall and Agile frameworks.

ASSURX VALIDATION MANAGEMENT SERVICES DELIVERABLES



INTEGRATED APPROACH TO POST-RELEASE STLC AND SDLC

In the post-release update/maintenance Software Design Lifecycle (SDLC), AssurX will run Software Testing Lifecycle (STLC) in tandem phases to identify and eliminate gaps in new functionality and ensure quality objectives are being met.

AssurX Validation Management Services provides traceability through every stage of the software development and software testing lifecycle to ensure complete testing and validation coverage. Our process ties together the SDLC and the STLC stages to include requirement gathering and analysis, design, planning, development, testing, validation and deployment of the software life cycle to create an integrated approach for SDLC and validation.

➤ ABOUT ASSURX

With decades of expertise built into our quality management and regulatory compliance software platform, AssurX helps companies maintain quality and compliance, streamline workflow, control risks and better manage any enterprise.

Our incredibly configurable software and deep understanding of users' needs produce a unique system that easily adapts as your business evolves. AssurX is an ideal partner for regulated companies looking for better operational control and efficiency while staying compliant.

To learn more about how AssurX can help with your quality and regulatory compliance management needs, please call 1-888-9-ASSURX.