

# RISK BASED VALIDATION SOLUTIONS

The FDA draft guidance on Computer Software Assurance (CSA) is a shift from document-focused Computer System Validation (CSV) to critical thinking assurance practices. AssurX validation methodology aligns with the new guidance to utilize a risk-based approach to streamline the validation of systems using non-product software.



The FDA draft guidance is intended to enhance the verification and validation process to demonstrate system fitness for use as opposed to depending on the process of generating a mandatory set of deliverables. The new guidance encourages use of automated testing as well as the acceptable use of vendor documentation and formal testing of the installed software. The new approach reduces the amount of redundant documentation and validation activities, and increases the focus on ensuring the software works as intended in the installed environment.

CSA encourages the use of critical thinking early in the process to plan the activities and define the minimum documentation required to ensure that the software performs as specified.

## FOUR-STEP PROCESS

The **four-step process** is designed to identify and apply the least burdensome approach that will ensure that the software is fit for its intended use.

### Step 1: Identify the intended software use.

Does the software impact product quality or patient safety? If not, you do not need the same level of assurance as with software that impacts the product or patient safety. For example, software such as document management, change management, and audit management does not require the same level of testing as software within a device.

### Step 2: Determine areas or functions that can impact product quality, patient safety, or system integrity.

CSV focuses on calculating the severity of impact and probability of failure, leading to a prioritization of risk. CSA, however, recommends calculating the impact on patient safety and product quality, as well as the implementation method of the software functionality.

### Step 3: Leverage vendor documentation where possible.

Companies should not waste time reproducing audited vendor documentation and validation. If the vendor has quality documentation and validation in place, it is highly recommended to use it.

### Step 4: Conduct scripted and unscripted testing activities as needed based on risk.

Using a risk-based approach requires experts to understand business processes and evaluate a system's functionality to get more value from the software (Figure 2).

**Unscripted testing** is used on lower risk systems that do not directly impact the product or patient safety. Detailed test scripts are not needed, but companies should document a test objective and pass/fail results.

**Scripted testing** is for higher risk systems that directly impact the product or patient safety. The traditional step-by-step procedure with expected results and pass/fail should be documented.

Figure 1: Implementation methods will determine precise functional requirements that are tailored to your unique operating environment.

Implementation Method Definitions	
Out of the Box	Feature works by installing the software and adding necessary master data
Configured	Feature is enabled through the settings of parameters without changing the code of the software
Custom	Feature requires programming or changes to the software code

Figure 2: Risk rating should determine the use of scripted vs. unscripted testing.

Risk Rating	Assurance Activities
5	Requirement validated through robust scripted testing
4	Requirement validated through limited script testing
3	Requirement validated through unscripted testing
2	Requirement validated through ad-hoc testing
1	Relies on vendor audit and baseline assurance

# RISK BASED VALIDATION SOLUTIONS

## ASSURX CSA GAMP 5 DOUBLE V MODEL

With the FDA's shift to CSA, AssurX has developed a model that provides customized validation services based on a critical thinking approach that supports the GAMP 5 Model.

Our validation services team can evaluate business and system requirements, environment, and system architecture to provide a comprehensive validation package. Integrate CAPA, effectiveness reviews and process audits to drive continual improvement within your quality ecosystem.

## VALIDATION DELIVERABLES

### User Requirement Specification (URS)

Documents how and what the customers need the system to do to meet their intended purpose.

### Functional Requirement Specification (FRS)

Describes how the system will functionally meet the User Requirements.

### Risk Assessment (RA)

Helps determine if the system is GMP, GLP, GxP (or other regulations) applicable, and the level of risk to the applicable regulations. Documents the outcome of evaluation and the risks and impacts related to the processes and functions supported by the software or solution. RA helps determine the level of testing for the functional requirements.

### Validation Plan (VP)

Outlines and defines which processes and solutions will need to be validated, the priority and order in which this will be done, as well as who is responsible for the validation process, and the most important part, the Acceptance Criteria.

### Design Specification (DS)

Documents the elements of the system and captures detailed descriptions of system components to present a clear understanding of what the system is required to do, and details access and security configurations for CFR Part 11 compliance.

### Configuration Specification (CS)

Describes the configurations, required functions and settings that are being applied outside of the OOB software.

### Requirement Traceability Matrix (RTM)

Documents the relationship between requirement and testing scripts by cross-referencing the validations performed to the user requirements and functional requirements.

### Installation Qualification (IQ)

Provides documented evidence that the system has been installed and configured correctly per the Design Specification document.

### Operational Qualification (OQ)

Provides documented evidence that the system operates according to the functional requirements.

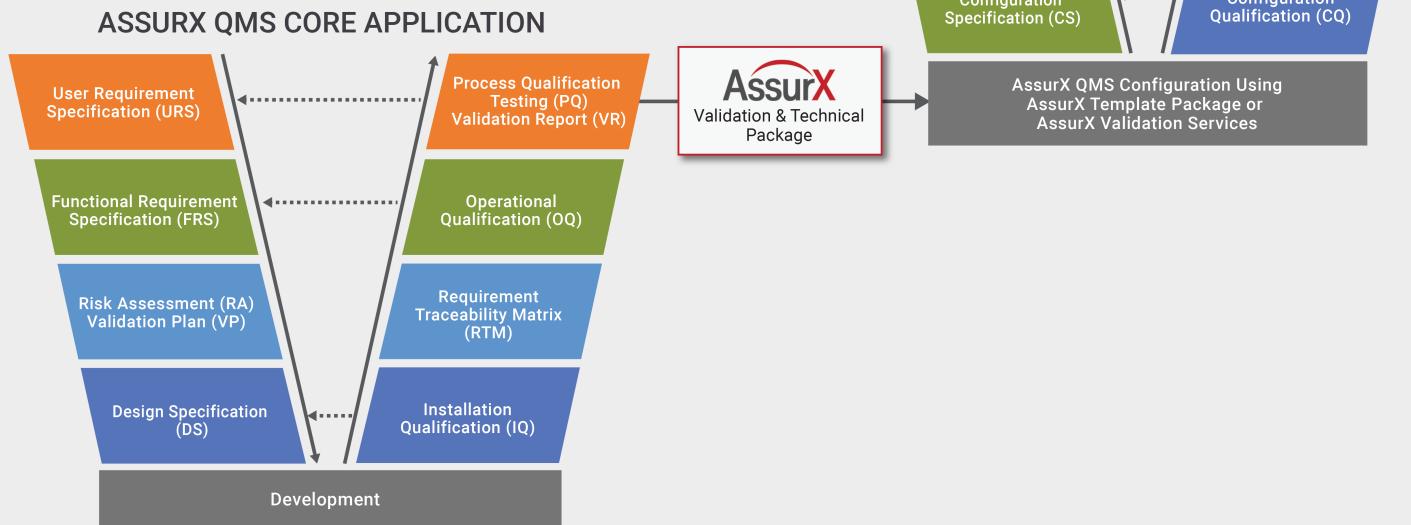
### Process Qualification (PQ)

Provides documented evidence that the system performs according to the user/functional requirements.

### Validation Summary Report

Summarizes and provides an overall conclusion related to the testing activities on the installation, operational, and performance qualifications.

## ASSURX GAMP 5 DOUBLE V MODEL



## ASSURX VALIDATION PACKAGES

AssurX Technical and Validation Packages provide efficiency, compliance, and flexibility to allow our customers to decide how they want to utilize our services.

### 1. AssurX Technical and Validation Documentation Package

AssurX follows SDLC process to ensure we have quality documentation and validation in place to eliminate the need to reproduce documentation and validation on our OOB processes.

AssurX validation packages reduce the overall computer system validation project time by leveraging our extensive experience and complete packages, helping to decrease production time without compromising compliance or quality. Packages include the execution of the PQ in the customers environment to ensure your solution is validated for intended use.

## 1

### AssurX Technical Package

- User Requirement Specification (URS)
- Functional Requirement Specification (FRS)
- Validation Plan (VP)
- Risk Assessment (RA)
- Design Specification (DS)
- Requirement Traceability Matrix (RTM)

### AssurX Validation Package

- Reusable Installation Qualification (IQ)
- Executed IQ with screenshots
- Reusable Operational Qualification (OQ)
- Executed OQ with screenshots
- Reusable Process Qualification (PQ)
- Executed PQ with screenshots
- Execute PQ in customer environment
- Validation Summary Report

## 2. Self-Validation using AssurX Technical and Validation Template Package

AssurX can provide all the necessary templates that follow SDLC and meet CSV/CSA standards. Our templates help customers to detail the necessary objectives that are required for each document type.

### 2 AssurX Template Package

- Validation Plan Template
- User/Functional Requirement Template
- Risk Assessment Template
- Design Specification Template
- Configuration Specification Template
- Installation Qualification (IQ) Template
- Operational Qualification (OQ) Template
- Process Qualification (PQ) Template
- Validation Summary Report Template

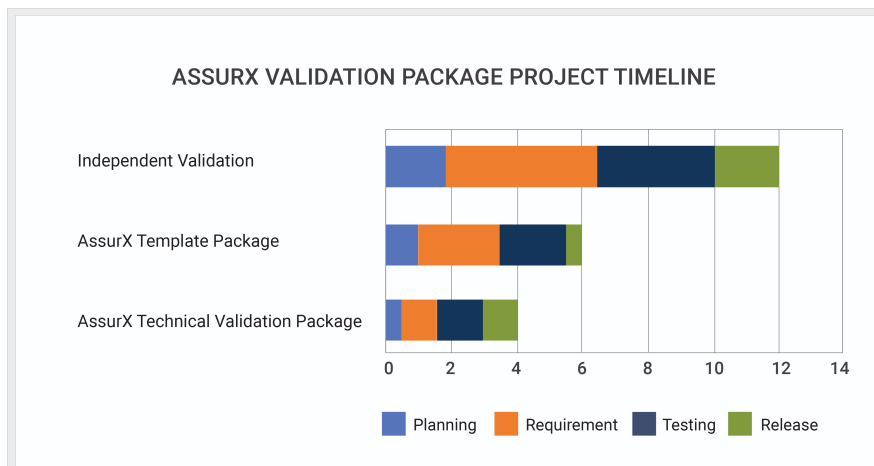
## 3. Leveraging AssurX Validation Services for Configuration Changes

AssurX has simplified the development and validation process for configurations performed on AssurX solutions. Using AssurX Packages and Templates is an ideal starting point for your own configurations and validations of the AssurX Solutions. Our team creates a partnership between your company, professional services and validation to create a seamless software release process.

Our team will assist in documenting customer specific requirements (URS), create the Configuration Specification (CS) to capture the configuration changes and process and then validate the changes within a Configuration Test Script.

## BENEFITS OF VALIDATION MANAGEMENT SERVICES

- » Reduce cost and time-to-completion with custom validations that satisfy requirements and regulatory guidelines (Figure 3).
- » Ensure 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.
- » Utilizes a validation services team that operates independently from Implementation Services to eliminate any perceived bias in the process.



Figures 3: AssurX Validation services help significantly minimize the time and cost it takes to complete the validation process.

Want to learn more?  
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