DATASHEET

Risk-Based Validation Solutions with CSA & GAMP 5 Alignment

Why Risk-Based Validation Matters

The FDA's Computer Software Assurance (CSA) guidance marks a pivotal shift in how regulated organizations approach validation. Traditional Computer System Validation (CSV) emphasized exhaustive documentation, often resulting in delays, increased costs, and a compliance-over-quality mindset.

CSA introduces a smarter path—one that emphasizes critical thinking, risk-based decision-making, and ensuring software performs as intended in its real-world use. It encourages organizations to:

- Reduce redundant documentation
- Leverage qualified vendor deliverables
- Focus on value-added testing aligned to risk
- Prioritize patient safety and product quality

AssurX's validation approach aligns seamlessly with these principles, helping companies streamline validation while maintaining global regulatory compliance.

TRADITIONAL CSV	MODERN CSV
Heavy Documentation	Lean Documentation
Manual Only Testing	AI-Driven Automation (Or Risk-Based Testing)
Focus on Evidence	Focus on Intended Use
Leverage Vendor Docs	Accept and Integrate Vendor Docs

CSA Four-Step Risk-Based Approach

1. Identify Intended Use

Assess whether the software impacts product quality, patient safety, or data integrity. Systems used for auditing or recordkeeping may require less rigorous validation than those that directly affect product release or compliance decisions.

2. Evaluate Risk Severity

Determine the potential impact of failure for each function. Consider both risk level and implementation method—whether out-of-the-box, configured, or customized. Then align the resulting risk score with the appropriate testing effort: scripted, exploratory, or ad-hoc.

3. Leverage Vendor Documentation

Avoid duplicating validation efforts by incorporating qualified vendor documentation, such as test results, installation records, or audit evidence, when appropriate. This allows internal teams to focus validation efforts where risk is highest.

4. Align Testing Type with Risk

- High-risk: Scripted testing with detailed pass/fail steps
- Moderate-risk: Exploratory or limited-script testing
- Low-risk: Unscripted or ad-hoc testing with documented objectives and results

This approach promotes faster validation cycles, more efficient resource use, and alignment with CSA expectations and GAMP 5 guidance.

RISK RATING	VALIDATION APPROACH	TESTING METHOD	USE OF VENDOR DOCUMENTATION
5 VERY HIGH	Requirement validated through robust scripted testing	Fully scripted & documented tests	May reference vendor docs, but internal testing required
4 HIGH	Requirement validated through limited scripted testing	Structured functional tests	Supplement with vendor docs where applicable
3 MEDIUM	Requirement validated through unscripted testing	Exploratory tests with logs	Can use vendor docs for background and traceability
2 LOW	Requirement validated through ad-hoc testing	Informal testing with notes	Rely heavily on vendor-supplied test evidence
1 VERY LOW	Leverage vendor documentation and baseline assurance	No additional internal testing	Vendor documentation and audit evidence sufficient

AssurX Risk-Based Validation Services

AssurX's risk-based validation framework aligns with both FDA's CSA guidance and the GAMP 5 Double-V Model. Validation rigor and documentation scale according to the type of implementation:

- **Out-of-the-Box (OOTB):** Minimal testing required; leverages vendor validation assets
- **Configured:** Requires configuration-specific risk assessments and functional validation
- **Custom**: Demands full lifecycle validation with traceability across all deliverables

Validation Deliverables:

- User Requirements Specification (URS)
- Functional Requirements Specification (FRS)
- Risk Assessment (RA)
- Validation Plan (VP)
- Design and Configuration Specifications (DS/CS)
- Installation, Operational, and Performance Qualifications (IQ/OQ/PQ)
- Requirement Traceability Matrix (RTM)
- Validation Summary Report (VSR)

Flexible Validation Service Packages

AssurX offers three adaptable service models to meet validation needs across industries and project scopes:

1. Full Technical & Validation Package

Complete documentation and protocol execution Includes:

- Executed IQ/OQ/PQ with screenshots
- PQ executed in the customer validation environment

2. Self-Validation Template Package

Compliant templates for all deliverables which enable internal teams to execute validation while adhering to best practices.

3. Configuration Change Validation Services

Ideal for validated systems undergoing updates. Includes updated URS, Configuration Specification (CS), and change-specific testing scripts

Strategic Value of Risk-Based Validation

- Accelerate validation timelines by up to 40%
- Reduce costs and dependency on third-party resources
- Allocate internal resources more effectively through risk-based prioritization
- Ensure audit readiness and reduce the risk of regulatory observations
- Minimize revalidation effort through reusable documentation and testing assets
- Scale validation efficiently across sites, systems, and business units
- Preserve independence between validation and implementation to avoid bias
- Maintain alignment with evolving global regulations (e.g., FDA, EMA, GxP)

A Smarter Path to Compliance and Efficiency

Risk-based validation and CSA are no longer optional, they are regulatory expectations and the foundation of modern quality systems. With the right framework, organizations can streamline validation, reduce overhead, and improve compliance outcomes. AssurX enables companies to confidently meet global regulatory demands by executing efficient, risk-prioritized validations that support quality, speed, and scalability.