

Computer Software Assurance: Your Key To CSV Modernization



Companies desire validated systems but typically do not sustain a Quality Management program that effectively coordinates use definitions, roles and responsibilities, and risk-based validation approaches. They have bloated document reviews and approvals by individuals with little knowledge of the Computer Software Validation process. Many organizations have unnecessary evidentiary processes to support fear-based testing, and a lack of confidence and understanding in the Quality Management System resulting in “forced,” repetitive, and redundant processes. **The FDA has recommended that life science organizations start the transition from Computer System Validation (CSV) to Computer Software Assurance (CSA) to mitigate these risks and allow for worry-free audits.**

Benefits of CSV Modernization

Cost savings from transitioning from CSV to CSA:

- Adopting Standardized Practices: 15%-20%
- Focusing on Risk Management (GAMP): 15%-20%
- Centralized Resources & Approach: 15%
- Technology Adoption: 10%

Total transformational cost savings: 55%-65%*

**From International Society for Pharmaceutical Engineering - GAMP*

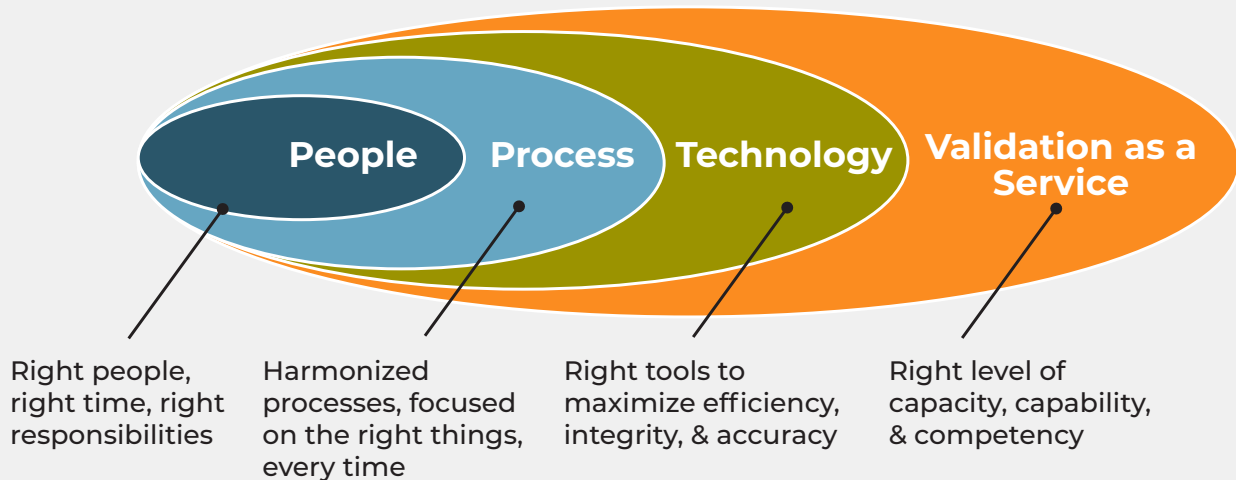
Additional benefits:

- Increased speed to market
- Consistent communication & awareness
- Clarity of roles & responsibilities
- Business controls around spend, risk tolerance, and velocity
- Increased business confidence & engagement
- Enterprise-wide reporting & transparency
- Centralized & harmonized
- Employee satisfaction

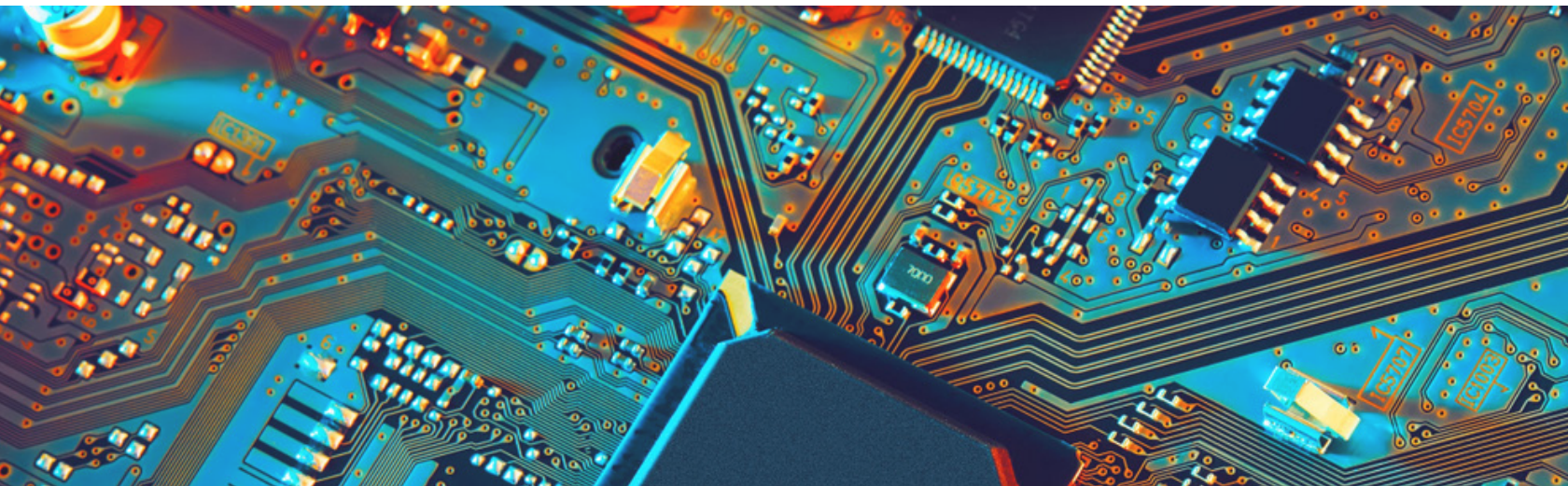
The Journey



Trissential's Computer Software Assurance (CSA) Vision



Validation as a Service is an acceleration approach to help projects identify the right strategy, understand project responsibilities, and create an accurate estimate for cost and resources to secure the right people, process, and technologies for the successful completion of a validation project.



Defining Computer Software Assurance (CSA)

Computer System Validation (CSV)

Overall process for ensuring assurance that a computerized system does exactly what it is designed to do (meets requirements) in a controlled and reproducible manner through documented (created, reviewed, approved, & signed) evidence.

Approach: Risk-based approach applying different traditional validation methodologies

Risk: Lack of documented evidence and extensive system testing (leading to more fear-based validation methodologies)

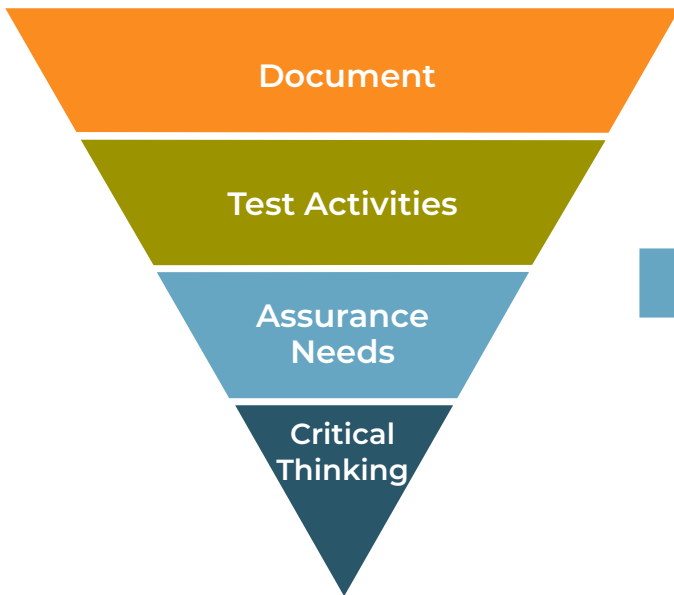
Computer Software Assurance (CSA)

Overall process of applying critical thinking to a risk-based approach to define a new framework for assuring quality, patient/consumer safety, and data integrity.

Approach: Risk-based approach centered on critical thinking, applying automated/unscripted testing, and the integration of digital technologies

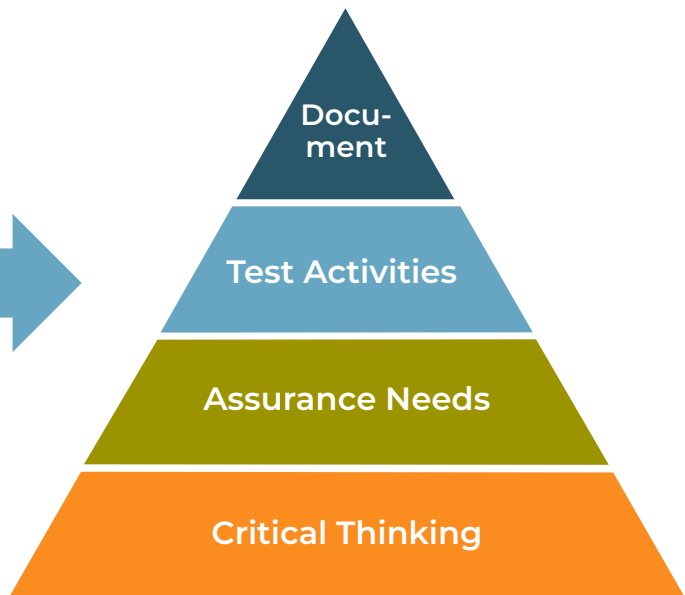
Risk: Implementing automated/unscripted testing and new technologies that are unproven in the validation space

CSV Practical View



Too extensive, too expensive and too much interpretation of what is required

CSA Practical View



Shift-left, practical, risk-based and automated



Next Steps

- 1 Understand your organization's current state in your CSV modernization journey by scheduling a 30-minute intro call with our Quality team - Visit: <https://calendly.com/events-175/csa-intro-call>
- 2 Trissential's **Competency Center** takes a deep dive into your project scope and deliverables, which includes:
 - Prioritize Program Goals and Scope
 - Assess Applications, Processes, Tools
 - Facilitate Value Stream Expectations and Establish Metrics
 - Establish Competency Framework
 - Identify Dependencies
 - Define Implementation Pilot's and Associated Activities

Email info@trissential.com for more information on the Competency Center

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