

CSA/CSV

 solabs™

Automating Quality Operations



What is CSA

Computer **S**oftware **A**ssurance: a **risk-based** approach for establishing and maintaining confidence that software is fit for its intended use.

What is CSV

Computer **S**ystems **V**alidation: process of establishing documented evidence that provides a high degree of assurance that a computer system consistently operates in accordance with its predetermined specifications and quality attributes.

CSA Origin and Guidance

FDA

- 09JUN97 – Draft guidance of “General Principles of Software Validation” issued
 - Addressed software failure concerns
- 11JAN02 – Final guidance of “General Principles of Software Validation” issued
- 2011 Launched the "Case for Quality".
 - Focus on quality – facilities & controls for device design/manufacture
 - Integration of Critical to Quality practices
 - Stakeholder Engagement - , collaborative approach to med device compliance
- 13SEP22 - Draft guidance of Computer Software Assurance for Production and Quality System Software
 - Risk-based approach: Focus on “critical” and “high-risk”

CSA Origin and Guidance

FDA

- 24SEP25 - Final guidance of Computer Software Assurance for Production and Quality System Software
 - Critical thinking & assurance vs. testing & documentation
- 03FEB26 – Updated final guidance
 - Harmonization of 21 CFR 820 with ISO 13485 2016

What To Use CSA or CSV???

Traditional CSV...


- Stage Gate (waterfall) methodology = not flexible
 - Requirements → Design → Build → Validate → Deploy → Maintenance
- Primary focus on compliance (21 CFR 11 & 820), not fitness for use
- Does not weight testing approach
- Documentation intensive = High cost
- Screenshots, Screenshots, Screenshots...
- Over-Validating – Qualify “All” without regard to risk

2008-2022 CSV...

- GAMP 5 roll-out
 - Attempt to bridge gap/transition to Agile methodology

What To Use CSA or CSV???

... or CSA

- Agile methodology = Iterative, flexible approach
 - Analyze → Plan → Design → Build → Validate → Deploy → Maintenance
- Risk-based: Aligns testing requirements according to risk
- Relies on critical thinking
- Documentation light = Lower cost
- Iterative process – Forward looking
- Right size validation – Qualify only what makes sense
- Aligns with/expands upon GAMP 5
- Does not eliminate CSV
 - Sets new expectation for approach

How to Implement CSA

CSA - Lifecycle

- Identify high-risk functionality impacting safety, product quality, and/or data integrity to determine the level of testing required
- Define requirements incrementally and integrate user feedback. Keep the focus on the intended use.
- Design/build functionality in small, usable increments, allowing for changes to be quickly made.
- **Only test what needs to be tested** - Use Risk-Based scripted and unscripted testing
 - Scripted testing uses detailed method(s) and acceptance criteria to challenge High-Risk functional attributes.
 - Unscripted testing uses ad hoc and exploratory testing for Low-Risk functional attributes.
- Take small bites – Evaluate and Document throughout the project
 - Don't wait until the end of the project. Test and document during “sprint” cycles to ensure continuous compliance.
- Perform a final review of the validation, post deployment

Audience Poll- Raise Your Hand!

1. Which approach emphasizes risk-based testing?

A. CSV B. CSA C. Both D. Not sure

2. How comfortable are you adopting CSA?

A. Very B. Somewhat C. Neutral D. Not comfortable

3. Biggest barrier to CSA adoption?

A. Regulatory B. Training C. Resistance D. Tools

QUESTIONS?

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Thank You!