Your Practical Checklist for Transitioning to Computer Software Assurance (CSA)

Gain a Better Understanding of CSA Methodology Ahead of Anticipated FDA Guidance

Introduction

Computer software assurance (CSA) is a topic of keen interest in the life sciences industry. The U.S. Food and Drug Administration's upcoming CSA guidance (Computer Software Assurance for Manufacturing, Operations and Quality System Software), is expected mid-2022 as of this writing (March 2022). Understandably, companies awaiting updated guidance have numerous questions and concerns.

This e-book from ValGenesis offers educational insight to help industry stakeholders better prepare for, adapt to, and abide by upcoming CSA guidance. With the following key insights, ValGenesis helps you evolve and adapt to industry changes with greater ease.

What is CSA? How does it differ from computer software validation (CSV)?

The traditional CSV methodology has manufacturers spending most of their time documenting and a fraction of their time testing. More specifically, CSV focuses on producing accurate, approved documentation to present to auditors, then testing, then assurance needs, and finally, critical thinking.

The CSA methodology flips this paradigm by emphasizing critical thinking and applying the appropriate level of testing to higher-risk activities, then assurance needs, testing, and documentation — in that order. CSA supports product quality and patient safety by prioritizing critical thinking and digital technologies over burdensome testing and documentation. By streamlining the validation process, CSA can help companies achieve faster deployment and ROI.

CSA will not replace CSV; higher-risk applications will always require rigorous validation. However, CSA is the wave of the future and a more efficient way to perform CSV. The same guidance serves as the basis for both; CSA simply provides a fresh approach and methodology.

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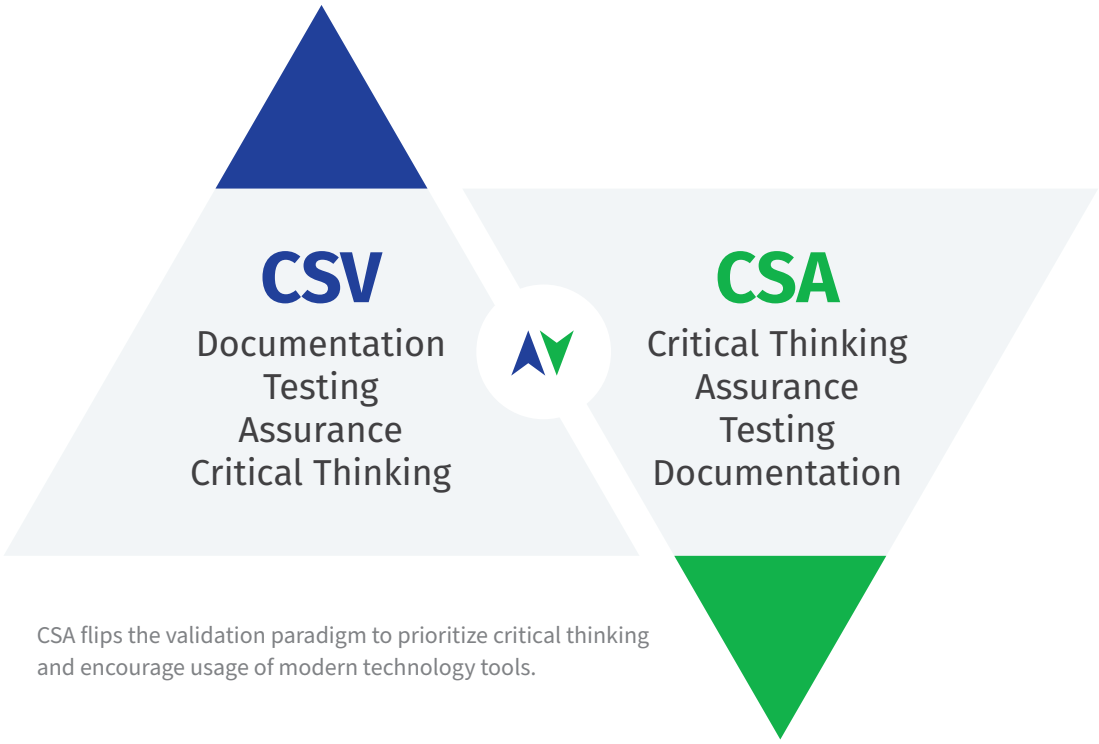
Why the shift in thinking?

In 1997, the FDA issued 21 CFR Part 11, which specifies how FDA-regulated companies must manage electronic records and signatures. The FDA's intentionally vague instructions led to excessive testing and documentation for fear of regulatory consequences, and this overwork costs the industry millions of dollars every year. In 2002, the FDA released additional guidance advising regulated companies to take a least-burdensome approach and integrate software management and risk management, laying the foundation for CSV.

The 2002 guidance has not solved the problem. Companies continue to generate huge amounts of documentation to appease auditors. This focus on documentation impedes critical thinking and the use of automation and modern technologies to enable more effective testing.

Broader implications of CSA

The goal for CSA is to encourage the industry to adopt digital technologies which will expedite the development and delivery of higher-quality therapeutics and medical technologies. CSA promotes a risk-based, least-burdensome approach consistent with the 2002 guidance that puts critical thinking at the forefront and leverages the technology and tools the industry has at its disposal.



CSA flips the validation paradigm to prioritize critical thinking and encourage usage of modern technology tools.

What are assurance needs?

In the traditional CSV approach, assurance needs follow documentation and testing in order of importance. With CSA, assurance needs come second after critical thinking. The flip in the paradigm prioritizes critical thinking and the push for implementing technology to speed the delivery and quality of new medical technologies and therapeutics. With the increased importance on assurance needs in the CSA model, it's critical to define what they are and understand how to address them.

Assurance needs are the activities you need to perform to ensure a computer system works as intended. According to the FDA's Case for Quality initiative, determining these activities involves three key actions:

1. **Identify the intended use of the system, which is explained in the user requirements.**
2. **Use a risk-based approach to identify the high-risk areas of the systems that can directly impact patient safety or quality.**
3. **Determine when a failure of these identified elements will cause a high-risk impact on safety and quality. These are the areas that will require the most rigorous assurance effort.**

To show you have a validated system that consistently performs as intended:

Validate that you've met the user requirements: This ensures the system is not going to cause harm, and that the system operates in a manner that doesn't jeopardize quality or safety.

Focus on quality instead of compliance: Focusing too much on compliance can cause organizations to lose sight of quality. True quality assurance ensures that compliance is delivered.

Conduct risk assessments upfront: Determining risk early on helps you identify where you need to focus your efforts to avoid wasting resources and time.

Leverage the tools you'll use to perform the validation: Current technology allows for automated, ad hoc, and exploratory testing to ensure the system is reliable and functions as intended.

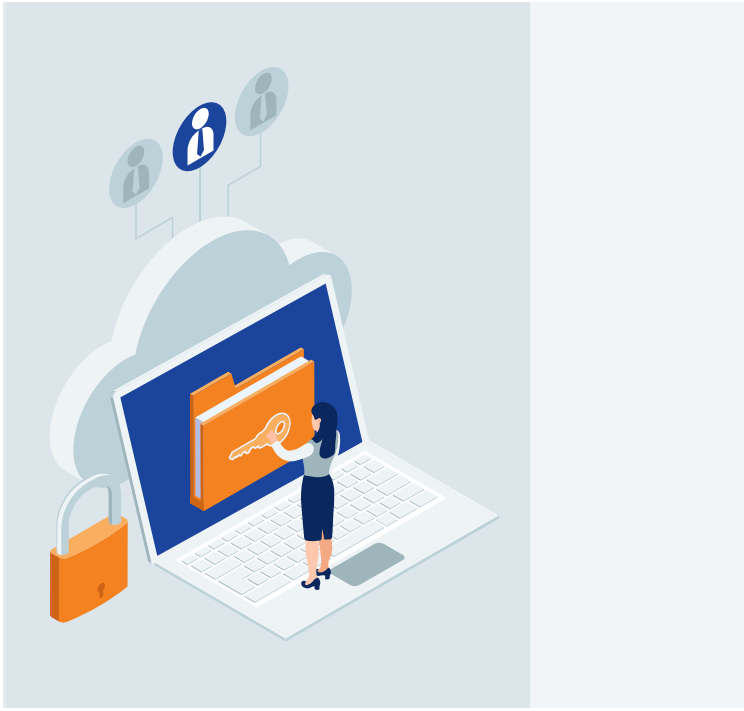
Employing these activities for assurance needs shows you have process control and are using the right technology techniques — both manual and automated — at the right time. It also illustrates that you have captured objective evidence supporting the fact that things were done in a controlled manner. All of these actions reassure regulatory bodies that validation meets or exceeds your quality standards.

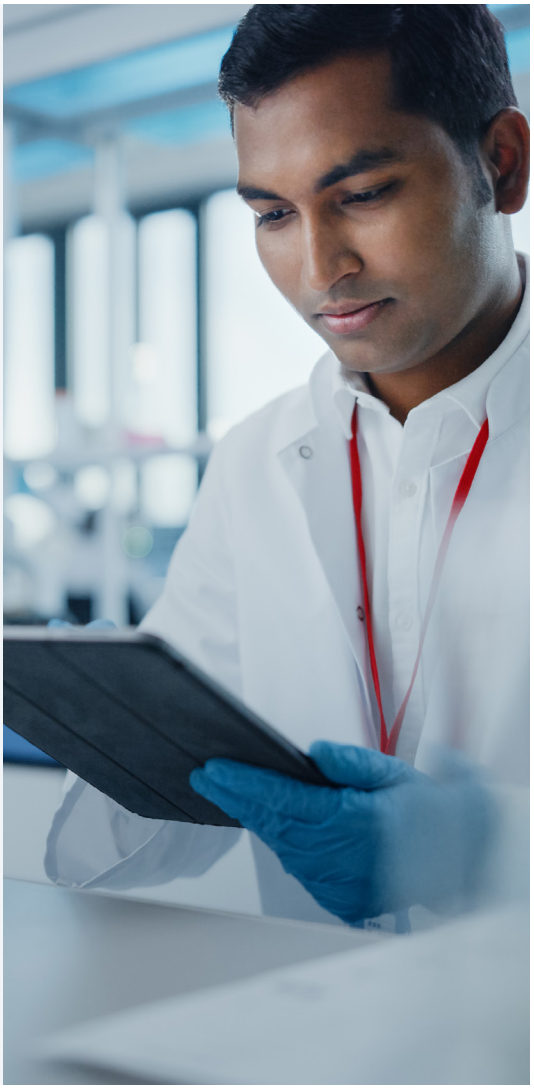
CSA and testing

When it comes to testing, the associated problems may not be the test scripts or steps themselves, but inferior or incorrect requirements. Software builds upon the foundation of good requirements. The same is true of testing: good tests are based upon good requirements.

Common characteristics of good software requirements:

- Clear/unambiguous
- Testable
- Correct
- Understandable
- Feasible
- Independent
- Self-contained/stand-alone





The importance of risk-based validation and a least-burdensome approach

As encouraged in the 2002 FDA guidance, risk-based validation is the approach the industry should be using, and CSA guidance reminds us of that. It's important to know the level of risk and base your testing upon the appropriate level of rigor that is, in turn, associated with a requirement. We need to avoid over testing and spending too much time and resources on low- and medium-risk activities. A least-burdensome approach must be implemented to the degree of risk associated with these requirements and test steps, which will result in high quality and compliance.

Types of testing

Once you are ready for testing, here are some approaches you can use:

Ad hoc, automated, and exploratory (unscripted) testing: These types of tests require no preparation, documentation, or test scripts; they're more relevant for low- to medium-risk features or systems that will not have a direct impact on patient or product safety.

Traditional CSV (scripted) testing: This type is associated with CSV methodology. It's based on pre-approved protocols, requires substantial preparation, and follows a prescribed step-by-step method with expected results and pass/fail outcomes.

An important note to consider is that you can leverage existing testing if your software supplier has already performed testing, even factory user acceptance testing

Traceability

One tool you should use throughout the entire software development lifecycle as well as the entire validation lifecycle is a traceability matrix. This is the mortar that holds the validation together. A traceability matrix ensures that the requirements have been adequately tested and reveals any uncovered test steps.

More testing doesn't equal better validation

CSA reminds us to use critical thinking, risk-based validation, and a least-burdensome approach to direct our testing efforts where they are most needed, especially in system features that are critical to patient and product safety. CSA preserves time and resources and is a more efficient approach moving forward.

Focus on digitizing your validation

Remember, your validation isn't better or more thorough because you have a taller stack of paper documentation. A document-centric mindset reduces the use of risk-based critical thinking — the leading tenet of CSA — and leans away from digital technologies and automated systems that can streamline validation efforts.

The push for automated processes

Technology is readily available to digitize validation and produce records that are stored in a database management system instead of as paper documents. As the industry moves forward into digitizing validation, records should be the primary focus, not documents. With records, organizations can sort information, query information, generate PDFs if needed, and so much more. CSA encourages automated testing so the features can be tested in minutes compared to the days testing takes in a traditional paper-based CSV process.

An added bonus of digitizing is that records can be related to one another, automatically generating a traceability matrix in minutes.

Making technology work for you

Automation and digital technologies can reduce the burdens associated with validation and help you attain high product quality. Although documentation is still part of the process, digitizing validation shifts the emphasis to generating records instead of paper documents. From the IQ, OQ, and PQ to the protocols installation to operational performance, all of those can be records, which gives your organization more options, power, and benefits.

CSA preserves time and resources and is a more efficient approach moving forward.

Transitioning to CSA

Having the right steps in place will position your organization for CSA success:

- [ ] Perform a thorough internal assessment of your current validation processes to review where your priorities and areas of focus lie.
- [ ] Have a flexible CSV solution in place with a software partner who ensures thorough implementation and regular updates.
- [ ] Update your internal validation best practices to align with CSA methodology.
- [ ] Train your team to ensure your validation processes are aligned with your updated best practices and CSA methodology.

Improve your process with ValGenesis VLMS

With ValGenesis Validation Lifecycle Management System (VLMS) — a cloud-based suite of solutions designed to address and simplify all areas of a regulated company's complex validation needs — you'll enjoy a host of robust features, including:

- Assessments powered by decision-tree logic
- Applied critical thinking with procedural risk assessments at a system and function level
- Change management summary with immediate change impact notification
- Automatic task notification, schedules, and nudging features with email
- Automatic validation inventory with validation statuses
- Integrated close-looped CSV lifecycle management with change control
- Dynamic electronic traceability matrix generation with forward and backward capabilities
- Electronic protocol execution
- Tightly coupled automated testing and robotic process automation integration
- 21 CFR Part 11-compliant features like time-stamped audit trails, reporting, and electronic signature capabilities

Partner with CSA industry experts and thought leaders from ValGenesis to meet or exceed CSA guidance. Visit ValGenesis.com or call 1-888-825-4363 to learn more about our solutions.

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