Computer System Validation (CSV) to Computer Software Assurance (CSA)

Taking a More Risk-Based Approach

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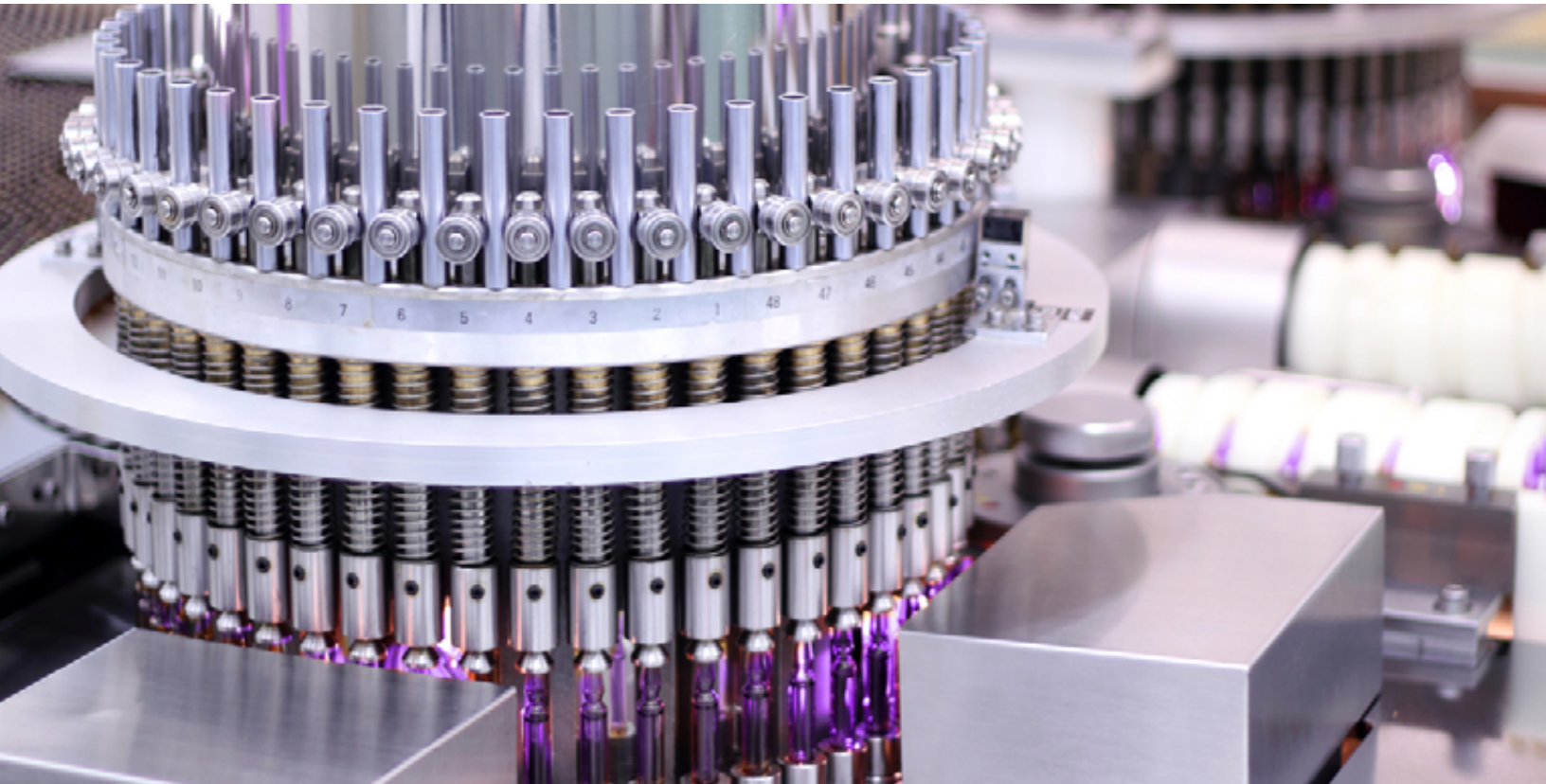
Contents

The Shift to CSA:
What Does It Mean for You?

Following the launch of their 'Case for Quality' initiative in 2011, the FDA did not understand why so few companies were investing in automated solutions and why so many continued to run long-outdated versions of software. The initiative found that the burden of Computer Systems Validation (CSV) deterred technology investments and as a result, inhibited quality best-practice.

As a result, the FDA partnered with industry to strike a balance between promoting automation and value-add CSV activities. They aimed to improve quality, remove non-value add activities, and focus testing on high risk areas, therefore reducing validation cost and time by focusing on the software's impact to patient safety, impact to product quality, and impact to quality system integrity (direct or indirect system). Too often, testers spend time ensuring their protocol is error free, as opposed to spending time on automated solutions that verify the software meets its intended use.

Let's start by reviewing what the shift from Computer System Validation to Computer Software Assurance (CSA) is, as both business and quality teams are often confused about the what and the why. Fundamentally, the intent of transitioning from CSV to CSA is to change the focus of validation efforts from documenting extensive test suites to executing more extensive system testing to ensure proper functionality. This shift in approach to validation aims to realign effort to planning and preparation first, then defining the testing to be performed, and finally test execution and documentation.



1 CAN IT BE THAT EASY?

The FDA guideline states, “Manufacturers must establish and follow quality systems to help ensure their products consistently meet applicable requirements and specifications.”

This wording has not changed, and therefore the actual desired intent and outcome of the validation process have not changed, only the guidance on approach. This “new” process affects how we ensure consistency and meet requirement specifications. It will shift the focus from primarily documentation oriented to a more thoughtful paradigm. The shift will emphasize a more Risk-Based Approach (RBA).

CSA does not mean less testing, but rather the appropriate amount of testing. In order to achieve this, critical thinking is required to determine the best approach. You must start by defining what needs to be tested in the beginning and perform targeted testing that is pre-defined in the lifecycle validation process.

2 WHAT DOES A CSA APPROACH MEAN FOR TESTING?

As stated earlier, CSA does not imply no testing or less testing. It does require critical thinking up front to determine the areas of the business process and/or system functionality have a direct impact on patient safety, product quality, or system integrity which will be directly correlated to what needs to be tested. It is about performing the appropriate amount of targeted testing to challenge the intended use of the system rather than testing system functionality.

There are several fundamentals that CSA ascribes to:

Documentation should add value and not be created just to create it.

CSA starts with the correct level of requirements defined ahead of time. The appropriate level of lifecycle documentation will be determined by the risk and complexity of the system.

The appropriate level of testing will be based upon ensuring the application functions properly in areas that affect patient safety, product quality and system integrity.

These fundamentals can be achieved by including subject matter experts (SMEs) from the business, IT, and quality organizations to assist in identifying and evaluating areas of risk. A common challenge within the industry is that the resources involved in the validation of the system are not familiar with the business process and/or intended use of the system. If the foundational knowledge is not present within the implementation/project team, the team will be unable to identify the functionality which is truly high risk (from a patient safety, product quality, and system integrity perspective) and will most likely classify too many specifications as high risk. This "critical thinking" also sets the stage for the scope and extent of testing activities, whether it is scripted or unscripted testing.

3 PREPARE, PLAN AND TEST (CRITICAL THINKING)

Business input in the form of clear, accurate business requirements is key to the success of the CSA validation process. It is critical to ensure the quality and business teams work together to demonstrate control of the system or application. There are three basic steps in this collaboration:

Prepare and understand the business requirements

Plan discussions on the classification of the risk levels

Decide what form of testing will take place in correlation to the risk

With CSA, the shift in validation is intended to focus more on the high-risk classified items, not on absolutely every element of system functionality. The testing classification, when done properly, will take into consideration the impact to patient safety, product quality and system integrity.

A good starting place for the planning effort is to have the business define how the software/ application will be implemented. This is the overarching use case, or implementation model. The key question to answer is how “out-of-the-box” will the deployment be? This use case is key in the prepare phase to ensure the correct level of validation activities are planned for. There are three basic deployment levels:

Out-of-the-Box

Configured

Customized

A risk-based approach dictates that areas of high risk will command a higher level of documentation and related testing. Low and medium risk functionality that is met by out-of-the-box software may leverage upstream vendor qualification activities so long as a vendor evaluation has been conducted with a favorable outcome. Low and medium risk features that are configured to meet intended use require testing, albeit could be in the form of unscripted testing. High risk features, regardless of the implementation methodology, should be fully tested by the regulated company to ensure the as-built system meets its intended use.

The depiction below summarizes the key strategies and elements when implementing a CSA model.

PREPARATION

- Determine the deployment model: out-of-the-box, configured, customized.
- Determine features and impact: Features, operation, functionality and impact on device/product safety, quality or integrity.

PLANNING

- Focus on high-risk factors that impact safety and quality.
- Leverage the upstream qualification/validation activities of trusted, qualified suppliers.
- Medium/low-risk features do not require rigorous efforts. Identify the features/functions that can be tested using unscripted testing.
- Leverage automation where possible.
- Plan of action if something arises.

TESTING

- **High risk** functionality requires scripted testing, which is used for higher risk (direct) systems or features. Scripted tests usually contain—at a minimum—a test objective for the test script, a step-by-step test procedure, expected results, and a pass/fail.
- **Medium risk** functionality may be tested using an unscripted testing approach, which is less formal than scripted testing. Unscripted testing is carried out without the use of detailed test scripts. There should be a test objective and a pass/fail, but no step-by-step test procedure.
- **Low risk** functionality can leverage vendor provided test cases with little to no scripting.

The CSA Documentation Shift: Where to Begin?

Transitioning to a CSA approach requires a multi-phased approach. Included below are some of the highlights:

1 ASSESS

Assess your company's current validation landscape. Perform an assessment to understand where your organization is spending time, effort and cost. For example, determine how much time the company spends on planning, designing, testing, documenting, etc. Once you understand the current landscape, you can develop a transition plan that will help you implement and adopt CSA.

2 PLAN

Create a Transition Plan that outlines the process and timelines for the transition to CSA. The transition plan should:

Specify how to handle in-flight implementations/projects

Specify the policies, procedures, and work instructions that need to be revised to reflect the new CSA framework/methodology

Identify changes in stakeholder roles/ responsibilities

Specify how awareness will be created within the organization

Identify which business units and/ or resources need to be trained on the new CSA framework

3 TRAIN

Provide training for the business units and resources. This should focus on helping your team understand and recognize the importance of the CSA framework/methodology and give them the tools to execute in real-world scenarios.

4 IMPLEMENT

Once the organization has completed the aforementioned, it is time to implement the CSA framework/methodology, policies, procedures, work instructions, and templates allowing project teams to leverage the new methodology. Throughout the implementation period, the organization should collect metrics to measure performance against key criteria and business outcomes—and adjust accordingly.

The Fundamental Message: Do Not Document Just to Document

The FDA guidelines and industry recognize that existing standards (i.e., GAMP5) provide the baseline for testing. The shift to CSA provides the industry the encouragement to move towards critical thinking. Included in the shift of thinking are core concepts focused on the right level of documentation and testing.

Upfront preparation will take longer than traditional processes; however, in the end, it will save time, resources, re-work and focus testing on higher risk functionality.

Testing will ensure the system should perform “reliably and consistently.” Validation does not start at testing but rather starts with the scope of the system, the business requirements, and the design specification of system operation. Considering this new emphasis and aligning the resources ahead of your next project will go a long way to ensuring the proper perception of the value of the CSA approach as improving results and saving.

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