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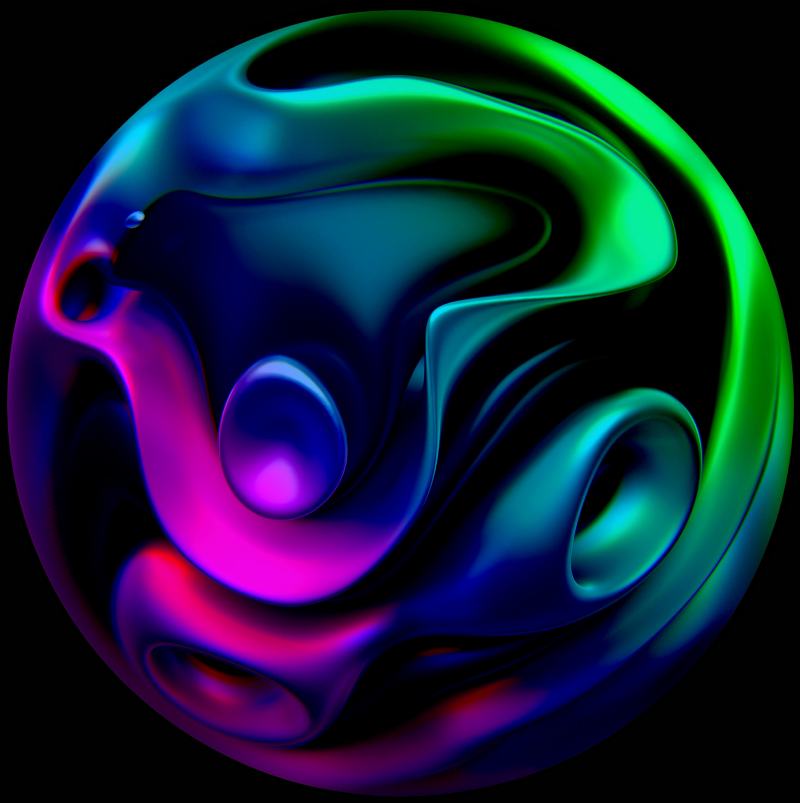


Accelerating Computer Software Assurance (CSA) readiness

Moving at the speed of business

The journey toward "Assurance"

The life sciences industry is moving at a swift pace toward digital transformation as a result of industry 4.0. This has led to the need for an optimized regulatory and compliance approach to systems development and maintenance. The current state of system validation is perceived as an impediment to faster deployments, wherein the focus is on good documentation practices rather than building systems that are fit for their intended use.

A risk-based approach to validation has been around for some time; however, companies have been challenged with identifying software risks and the desired level of validation effort. This is where an enhanced focus on critical thinking is required.

Industry and regulators are working toward various initiatives, such as "Case for Quality," to align on an optimized approach and, in that regard, the Food and Drug Administration (FDA) is moving to update its guidance on the validation of Good practice (GxP) systems. The new FDA guidance being drafted, CSA for Nonproducts Manufacturing, Operations, and Quality Systems Software, focuses on high-risk GxP elements, simplified documentation, and automation to help achieve compliance with regulatory requirements.

In this point of view, we:

- Share current challenges, thoughts on CSA leading practices, and how critical thinking can be leveraged to drive overall efforts to help achieve quality and compliance
- Outline an approach to shift from "Validation" to "Assurance"

Shift from "Validation" to "Assurance"

Computerized system validation (CSV) today has resulted in:

- Risk-agnostic validation approach for GxP systems and, thus, failing to optimize efforts
- Heavy focus on "audit readiness," as opposed to achieving confidence that leads to unnecessary documentation
- Retesting versus leveraging supplier documentation postaudits
- Exhaustive manual testing and evidence-gathering, making testing time-consuming without a strategy around high-risk elements
- Complicated risk assessment process lacking focus on priority risk areas

Some changes that we envision as part of Quality 4.0 and CSA:

Quality by design: Developing regulated systems and conducting validation (in this case, "assurance") efforts to build quality into the system, as opposed to a more "compliance checklist" effort.

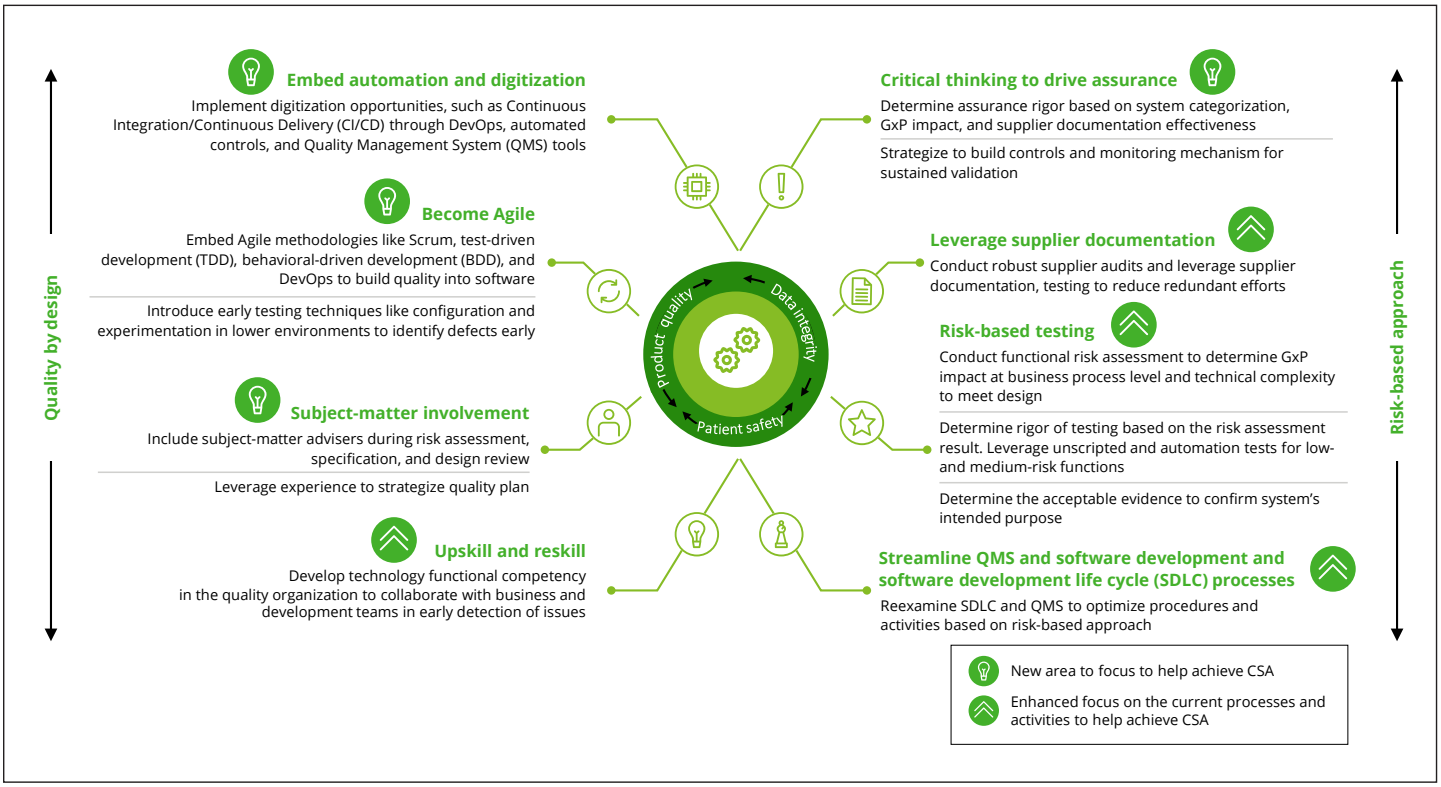
Risk-based approach: Tailored risk management and testing approach to help achieve confidence in system operation and performance. This includes automation, exploratory, unscripted, and limited scripted testing; increased use of tools; and leverage of supplier documentation to help avoid duplication efforts.

Critical thinking

The focus of the FDA's CSA will likely shift toward a less burdensome validation approach and also may confirm a high degree of confidence that the system is fit for its intended use.

Additionally, the new approach will likely also help to uncover risks (direct and indirect) around patient safety, product quality, and data integrity.

Recommended focus areas to help achieve CSA



Future of testing

The testing space will continue to evolve into one of the specific focus areas to move quality at the speed of business. A few techniques that should be considered when strategizing an assurance approach are as follows:

1. Configuration and experimentation

What is it?

Technique used by developers to build and test continuously before deploying into quality environment

How can it be used?

This type of testing helps boosts confidence by instilling quality right from the start; however, it cannot be used as official objective evidence.

2. Exploratory testing

What is it?

Technique used by developers and testers to explore system behavior. System knowledge is essential to engage in this type of testing.

How can it be used?

- Can be used for low-risk functionalities in development and quality environments
- Limited instructions required and evidences (should be self-explanatory) are required to provide for use as objective evidence in quality environment

3. Automated testing

What is it?

Utilize automated tools to test system

How can it be used?

- Use of repetitive testing, such as regression, in quality environments
- Detailed instructions and evidences are required for use as objective evidence in quality environment

4. Unscripted testing

What is it?

Testing without formal instructions, but with a clear objective and pass/fail criteria

How can it be used?

- Can be used for low-to-medium-risk functionalities in quality environment
- Limited evidences (should be self-explanatory) are required for use as objective evidence when used for testing low-to-medium-risk functionalities in quality environment

5. Scripted testing

What is it?

Testing with formal instructions

How can it be used?

- Required testing of high-risk functionalities and intended use of system
- Detailed instructions and evidences are required to provide objective evidence

As we await FDA guidance, organizations in the life sciences space should start proactively thinking and charting out their road map to make the transition from CSV to CSA.

Experiment with a new approach using pilots as opposed to big-bang:

As part of the shift toward CSA, create a transition plan which includes identifying the projects and systems that have both direct and indirect impact on patient safety, product quality and data integrity and start applying CSA principles. Implement metrics to measure specific indicators: efficiency and quality (CSV versus CSA).

Embrace the change and get your organization ready:

It is critical that quality leadership understands and drives CSA from the top through the organization. Focus on the need for new skills and CSA training for the organization. Emphasize in clear messaging across the organization that CSA is about improving quality and does not mean undocumented testing.

Embark on digitization and automation:

Conduct gap assessment against current manual processes in SDLC to identify potential opportunities for digitization and automation. Automating testing efforts in lower-risk environments to identify early defects and improve quality can be a quick win.

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Conclusion

Traditional CSV practices need a competent assessment in areas involving manual processes, heterogeneous system landscapes, and fragmented automation. Such activities are less effective and more cost-sensitive. The focus should be on value-adding tasks that reduce errors and do not slow down go-to-market time.

A futuristic view for embracing industry 4.0 needs CSA. It is exciting to see how regulatory bodies across the globe are coming together to help the life sciences industry move from "reactive" to "proactive."

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