Advancing from CSV to CSA in an AI-driven world

A modern assurance framework for life sciences

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Executive summary

The life sciences industry is undergoing a critical transformation from traditional Computer System Validation (CSV) to Computer Software Assurance (CSA). With the publication of FDA's CSA guidance, the agency is encouraging companies to move from traditional CSV approaches, which are documentation-heavy and low-value, to a risk-based approach that allows them to implement the least burdensome approach while achieving an acceptable level of systems quality.

The adoption of AI across the life science value chain, driven by evolving regulatory expectations and modern technology architectures (SaaS, cloud, DevOps), only increases the need for a new, more streamlined approach to ensuring system qualification.

CSA is not simply a streamlined version of CSV — It is a modern assurance model centered on risk-based thinking, intended-use testing, supplier leverage, and critical SME judgment. This model enhances patient safety, product quality, and data integrity while significantly improving speed and efficiency.

Why CSV needs to evolve

Traditional CSV approaches have led to documentation-heavy processes with limited assurance value, overemphasis on scripted testing, slow validation cycles, limited scalability, and poor alignment with Agile and DevOps.

CSA as the modern assurance model

CSA differentiates from CSV in the following ways:

- Risk-based prioritization with the primary focus on patient safety. The impact on product quality and data integrity is determined by its impact on patient safety.
- Critical thinking by internal SMEs over the documentation volume.
- Focus on testing the intended use and GxP requirements with an emphasis on unscripted testing vs formal testing across both GxP and non-GxP.
- Increased reliance on supplier testing documentation.

Impact of AI on CSA and GxP validation

Regardless of whether a client uses CSA or CSV, they will need to adapt their approach as they adopt AI applications. A CSA approach will allow flexibility to address AI's unique challenges, specifically by developing a validation plan that focuses on real risks and ensures that enhanced risk assessment, monitoring, transparency, and governance are effective.

Additionally, clients can use AI accelerators to develop validation deliverables, further reducing timelines, effort and quality assurance.

UST differentiators

UST has over 250 functional QA/RA, manufacturing and clinical development experts who support global deployments. Our centers of excellence for both CSA and AI allow UST to leverage best practices, train internal resources, and develop cutting-edge strategies and capabilities. Our Change Management consultants help clients with the adoption of CSA process.

UST also provides AI agents to accelerate validation documentation, review processes, and traceability.

Strategic benefits

For our clients, we improved the CSA adoption rate. This allows our clients to achieve the benefits of CSA, including faster system implementations, reduced validation effort and cost, improved compliance and inspection readiness, and establishment of scalable AI governance.

Implementation roadmap

ASSESS

CSA maturity and gaps, and evaluate readiness for CSA

DESIGN

Draft SOPs, forms and templates, train clients on critical thinking

TRANSFORM

Apply CSA to an initial project and deploy AI accelerators

SCALE

Rollout and continuous improvement

Conclusion

UST combines life sciences domain expertise, QA/RA depth, global delivery scale, and AI-enabled validation accelerators to help organizations move from documentation-heavy CSV to intelligent, risk-based CSA while strengthening compliance, reducing validation burden, and enabling faster digital transformation.

Since 1999, UST has worked side by side with the world's best companies to make a powerful impact through transformation. Powered by technology, driven by AI, inspired by people, and led by our purpose, we partner with our clients from design to operation. Our AI-driven digital solutions, proprietary platforms, engineering, R&D, products, and innovation ecosystem turn core challenges into impactful, disruptive business outcomes. With deep industry knowledge and a future-ready mindset, we infuse expertise, innovation, and agility into our clients' organizations—delivering measurable value and positive lasting change for them, their customers, and communities around the world. Together, with 30,000+ employees in 35+ countries, we build for boundless impact—touching billions of lives in the process.

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