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Reimagining pharma validation: How CSA, AI and gen AI are transforming the industry

Pharmaceutical companies are under immense pressure to accelerate innovation, reduce costs and maintain uncompromising compliance.

Yet, traditional validation approaches, which often rely on manual, documentation-heavy processes, are slow and no longer viable for organizations aiming to scale and compete globally.

To meet those demands, forward-thinking pharma leaders are turning to a powerful combination of computer software assurance (CSA), AI and generative AI (gen AI). Together these technologies are redefining validation and quality engineering, shifting the paradigm from exhaustive documentation to intelligent, risk-based assurance. Cognizant is at the forefront of this transformation, helping enterprises modernize at scale and unlock measurable value across the validation lifecycle.

Why CSA, AI and gen AI are strategic enablers

CSA represents a fundamental shift from exhaustive documentation to risk-based testing, enabling pharmaceutical organizations to align validation efforts with business-critical outcomes. When integrated with AI and generative AI, CSA evolves into a scalable, intelligent framework that accelerates compliance, enhances quality and reduces operational overhead.

> "CSA advocates more testing with less documentation. It's more important to remove defects than to collect documentation for inspection purposes."
>
> — Ken Shitamoto, GAMP CSA SIG and FDA-Industry CSA Team

Cognizant's approach blends deep domain expertise with advanced technologies to help pharma organizations unlock measurable value—delivering faster time to market, reduced cycle times and improved regulatory alignment.

From paper-based operational qualification (OQ) to fully automated, paperless validation, Cognizant has helped clients streamline operations, minimize documentation burden and accelerate release velocity.

Gen AI agents are now being deployed across the validation lifecycle to automate and optimize key activities such as validation plan coauthoring, risk assessments, deviation analysis and synthetic test data creation. These agents have demonstrated up to 35% reduction in cycle time, improved traceability and enhanced test design quality—all while maintaining essential human oversight to ensure ethical governance and strategic alignment.

Gen AI in action: Intelligent validation at scale

Cognizant is now deploying gen AI agents across the validation lifecycle to automate and optimize key activities such as:

- Validation plan co-authoring
- Risk assessments
- Change control co-authoring
- Deviation analysis and CAPA generation
- RTM generation
- User story to test cases to automation code to execute test
- Synthetic test data creation
- Hot spot locator
- Defect triage and failure analysis

These agents have demonstrated up to 35% reduction in cycle time, improved traceability and enhanced test design quality—all while maintaining essential human oversight to ensure ethical governance and strategic alignment with business goals.

Business impact: Real results from CSA transformation

The shift to CSA, AI and gen AI is not just a technological upgrade; it's a strategic transformation delivering measurable business outcomes. By replacing manual, documentation-heavy validation with intelligent, risk-based assurance, pharmaceutical organizations are achieving faster, leaner and more compliant operations.

Cognizant's CSA implementations have delivered:

30%–40%
reduction in validation costs

20%–25%
faster validation cycles

$1.34M
in approved cost benefits over three years for a leading biotech firm

These results underscore the value of modernizing validation with CSA and intelligent automation—not only in terms of efficiency and cost savings, but also in enabling pharma companies to scale innovation while maintaining regulatory rigor.

Enterprise adoption: What leaders need to know

While CSA, AI and gen AI offer powerful tools for modernizing validation, successful transformation requires more than technology. It demands a deliberate shift in mindset, governance and organizational culture. Pharma leaders must champion this change to realize its full potential across the enterprise.

Our hybrid testing model, combining scripted, unscripted and exploratory testing with vendor results and AI agents, delivers agility and precision across diverse environments. This approach enables pharma organizations to move beyond reactive validation toward intelligent, proactive quality assurance at scale.

Cognizant recommends the following pillars for effective adoption:

- Executive sponsorship and governance to drive enterprise-wide alignment and accountability
- Change management and training to prepare teams for new ways of working
- Outcome-based metrics such as cycle time, defect rates and cost savings to measure impact
- Automation and AI integration across the validation lifecycle to scale efficiency
- Risk-based validation tailored to system complexity and business impact to ensure relevance and compliance

Key resources

Cognizant's innovation stack for pharma leaders

To support enterprise-wide transformation, Cognizant offers a robust platform and toolkit designed to modernize validation and quality assurance, including:

FlowsSource™

An AI-powered full-stack engineering platform that accelerates development and validation workflows

Smart V&V

Automated validation and compliance controls that reduce manual effort and improve traceability

CSA methodology and toolkit

A modern framework that streamlines validation through risk-based, scalable practices

These solutions empower pharma organizations to shift from manual, reactive validation to intelligent, proactive quality assurance—delivered at speed and scale.

A call to action for pharma leaders

With over 60% of the top 20 pharma companies adopting CSA in some form, the shift toward intelligent validation is underway. Yet few have implemented CSA enterprise-wide and are prepared to unlock the transformative potential of digital validation.

Cognizant's leadership in CSA, AI and gen AI is helping pharma executives reimagine validation—not as a compliance obligation, but as a strategic lever for innovation, operational excellence and competitive advantage.

Are you ready to lead the transformation?

Let Cognizant help you architect the future of pharma validation.

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