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Short communication

Evaluating the benefits and risks of transitioning from Computerized System Validation (CSV) to Computer Software Assurance (CSA)

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Introduction

In highly regulated fields, such as the pharmaceutical industry, demonstrating the suitability of a computerized system is vital. In the past, Computerized System Validation (CSV), which relied on guidelines provided in FDA 21 CFR Part 11 and EudraLex Volume 4, Annex 11, among others, was used to achieve this goal. As a result, CSV became more of a defensive approach focused on achieving compliance, involving elaborate, comprehensive test scripts and documentation.

Recognizing that the current "document everything" approach made it difficult for companies to adopt modern technologies that could increase their efficiency—such as cloud computing, artificial intelligence, and automated manufacturing—the FDA published guidance on Computer Software Assurance (CSA) in 2022. Computer Software Assurance is essentially a shift in philosophy from compliance with regulations to a quality-driven approach. In other words, CSA focuses on critical thinking, proper vendor vetting, and risk-based testing rather than mere documentation. While there are many advantages to making this change, it also presents some challenges.

Materials and methods

A comprehensive search was conducted across various databases to uncover relevant peer-reviewed literature. The search approach used selected keywords to identify articles written in English and published within the designated period. The articles underwent rigorous screening according to specific inclusion and exclusion criteria.

Results and discussion

The traditional CSV model is often described as an inverted pyramid, in which up to 80% of the project time is spent creating and evaluating documentation, whereas only around 20% is left for testing the software and analyzing the results. (Jungbauer, 2001) The objective of CSA, on the other hand, is to challenge this approach. By adopting ad hoc and exploratory testing methods for low- and medium-risk functions, CSA will shift its efforts so that 80% would be devoted to critical testing and 20% to documentation. (FDA, 2025)

Benefits of the transition to CSA

Innovation and Digital Transformation are accelerated: The reduction of documentation associated with non-critical functionalities enables faster deployment and lower costs for tools such as MES (Manufacturing Execution System) and LIMS

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(Laboratory Information Management System), as well as other data analysis solutions. Consequently, this would make it easier to implement Industry 4.0.

Resource Optimization: Using CSA allows QA and validation professionals to apply their skills more productively – to analyze elements that will influence patients' safety, product quality, and the integrity of the data obtained. Instead of preparing complex test scripts, experts could spend time on audit, exploration, and unscripted testing.

Enhanced Software Quality: It may seem contradictory, but proponents of CSA argue that less documentation leads to better software quality. Testing based on scripts often leads to happy-path validation – people tend to follow the steps described in the scripts without deviating from the established pattern. Therefore, they do not notice all possible defects. (Walia and Neri, 2024)

Using Supplier Activities: In CSA, the idea is to use the vendors' existing validation and testing results for the software. Thus, in the case of a high-quality QMS and suppliers' good reputation, a company would spend less time on its own testing.

Risks and challenges of the transition

Culture and audit-related considerations: The main obstacle to using CSA is cultural. Indeed, QA departments have, for many years, operated under the principle that "if it is not documented, it did not happen." Anything that deviates from a strict sequence of screenshots and fully detailed scripts raises concerns about how an audit will be conducted. (FDA, 2026) To change that requires management-driven change management and, first and foremost, educating quality employees to trust their own critical minds rather than just documents.

Risk assessment issues: The use of CSA depends largely on the company's ability to correctly evaluate risks. Since the guidance is much more flexible than CSV, the division between "high-risk" and "low-risk" functionality is subjective. This means that poor risk assessment may result in insufficient testing of the high-risk feature, potentially harming the product's overall quality. (FDA, 2026)

Regulatory issues related to global production: It is essential to recognize that, although the FDA strongly supports CSA, international manufacturers must also comply with other regulations. Thus, the EMA and other agencies operate under different frameworks, such as Annex 11. At the same time, while risk management principles are included in global guidelines (for instance, ISPE's GAMP 5 Second Edition), inspections in some countries may still require traditional paperwork. (ISPE, 2022)

Vendor-based problems: It should be acknowledged that when outsourcing testing to a vendor, one must be extremely careful, as the risks associated with vendor oversight can outweigh its advantages. Namely, if a manufacturer relies heavily on vendors' statements, even when the vendor's SDLC process has flaws, the responsibility lies squarely with the manufacturer.

Conclusion

CSA is more than an evolution from CSV; it marks a transformation that goes beyond mere process and approach changes. As a new regulatory philosophy that emphasizes critical thinking, risk analysis, and software quality over documentation, CSA provides the life sciences industry with a path to progress and flexibility. However, these benefits can only be achieved through changes in corporate culture, a complex risk analysis process, and vendor accountability. The extent of the success of any move towards CSA can best be determined by those who see validation as more than just an obstacle; it can be used as a tool.

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