HOW AI WILL TRANSFORM COMPUTERIZED SYSTEM VALIDATION

By Frank Henrichmann and Oliver Herrmann

Computerized system validation (CSV) remains a cornerstone of regulatory compliance, but it is still time-consuming, resource-intensive, and prone to human error. Risk assessments, test development, traceability, and documentation absorb enormous effort and often slow down innovation. Artificial intelligence (AI) has the potential to change this.

AI can interpret requirements, generate and execute test cases, capture evidence, and support more consistent risk assessments. Validation becomes faster, more efficient, and higher quality provided the right foundations are in place. Three pillars are critical: well-documented business processes, precise user requirements, and structured risk assessments. Equally important, validation deliverables must be stored as structured digital records. Only then can AI generate compliant, traceable, and inspection-ready outcomes. For validation teams, this means less document management and more responsibility as quality architects.

BACKGROUND

CSV, or software validation, focuses on verifying whether a company's computerized systems, including the software used, are performing as intended and are fit for purpose. CSV is a cornerstone of regulatory compliance in pharmaceuticals, biotechnology, and medical devices. It's also a time- and resource-intensive process. However, the rapid evolution of AI, combined with increasing regulatory expectations for data integrity, traceability, and quality by design, will fundamentally transform how validation can be approached.

Successful validation starts with well-documented business processes, precise user requirements, and structured risk assessments. These then drive the verification activities that establish the fitness for intended use. These validation activities are shaped by each company's structure, operating model, and product portfolio. Although activities such as quality control or regulatory submissions may look similar across organizations, the underlying processes are rarely identical and difficult to standardize. Requirements, therefore, need to be developed with a clear understanding of the business context, not by relying on generic templates or one-size-fits-all solutions.

CSV involves much more than just requirements gathering, risk assessments, testing, traceability, and documentation; however, these are the most resource-intensive aspects and often one of the biggest barriers to adopting new technologies in the pharmaceutical industry. In the coming years, AI has the potential to enhance the validation process, making it more effective and efficient when used appropriately. This article explores how high-quality input will underpin the AI-driven future of CSV, potentially replacing traditional manual validation with intelligent, automated systems capable of executing tests, verifying outcomes, and generating compliant evidence. Although other activities like process definition and training are also part of the broader validation landscape, they are outside the scope of this article; however, these areas may also benefit from AI in the future.

This article presents potential future developments based on current trends and expert insights. These are predictions, but the authors believe they are grounded in a reasonable interpretation of available evidence.

THE CURRENT STATE OF CSV

Validation is a regulatory requirement, but it is also often perceived as both a cost driver and an innovation barrier. Manual risk assessments, test development and execution, traceability, and evidence collection demand significant time and resources but remain prone to human error. Regulatory authorities, such as the

U.S. Food and Drug Administration and the European Medicines Agency, and orgnaizations, like the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), have emphasized a shift toward risk-based, critical-thinking approaches. This is to streamline validation and reduce the resource burden through a data integrity by design perspective. This is in line with the guidance published by the ISPE GAMP® Community of Practice (COP). Yet, an AI-supported digital transformation has the potential to go further, revolutionizing how CSV is performed and enabling the life sciences industry to adopt new technologies faster and at lower cost.

Clear, well-defined requirements that describe the system's intended use within the business process are best practice, and they are essential for progress. Despite years of GAMP guidance, ambiguous or incomplete requirements still lead to ineffective testing, missed scenarios, and compliance gaps. Moreover, there are challenges using automated tools that have been successfully adopted in the software development process, for other CSV-related testing (e.g., user acceptance or data migration testing). These challenges often stem from the significant manual setup efforts, which typically only yield value when a test is repeated multiple times.

AI'S ROLE IN THE FUTURE OF CSV

AI technologies offer significant potential to revolutionize CSV. Specifically, these technologies include machine learning (ML), natural language processing, and generative AI models, including large language models (LLMs). At each step of the process, an expert in the CSV loop will remain essential to oversee outputs, ensure appropriate interpretation, and confirm that results are accurate, compliant, and fit for intended use. But, when used with large datasets of system behavior, regulatory expectations, and past validation results, well-configured AI systems will increasingly be capable of the following:

- Interpreting and validating requirements throughout the life cycle
- Mapping requirements to specifications and verification activities
- Generating comprehensive test scenarios
- Executing tests (e.g., black-box, white-box, and migration, authorization, and integration)
- Capturing and storing test evidence
- Analyzing discrepancies and proposing corrective actions
- Supporting the creation and maintainance of data flow diagrams

However, these new capabilities hinge entirely on the availability of clear, complete, and well-structured input, including processes, requirements, and risk assessments. Defining these inputs requires the expertise and practical knowledge of the people who perform the process daily, as well as strong business analysis skills and critical thinking to recognize and manage subjectivity. This includes the influence of personal assumptions, biases, and judgments that inevitably shape human decision-making.

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As emphasized in ICH Q9(R1), awareness and control of such subjectivity are essential to achieve effective and reliable risk management outcomes [1]. Even the most sophisticated AI may fail to make accurate assumptions or produce valid, traceable outputs without reliable, high-quality, and unbiased input.

FROM RISK ASSESSMENT TO COMPREHENSIVE TEST COVERAGE

Process analysis, requirements gathering, and risk assessment are some of the most critical elements of current CSV, yet they remain highly manual in nature. Although essential as input for prioritizing and scaling testing and identifying controls and verification activities, traditional risk assessment is inherently constrained by human bias and limited knowledge. Likewise, the manual development and execution of test scripts is resource-intensive and often drives extended timelines and increased costs. Automated testing can provide efficiencies when tests must be executed repeatedly. However, as stated previously, such tools generally require significant upfront configuration and maintenance before benefits can be realized.

In an AI-enabled validation framework, risk assessments could be supported by models considering prior assessments and controls. This would help to identify additional considerations and promote consistency with evaluations and controls performed on comparable systems. Such support does not replace expert judgment. But it provides a broader, data-driven basis for decision-making.

AI systems also have the potential to generate test scripts, for both manual and automated execution, directly from approved and accepted requirements and specifications, and in alignment with the risk assessment. Although AI-driven test execution may not achieve full coverage of all possible scenarios, it can address a far greater number of test cases than is feasible with manual methods alone. Importantly, an expert in the loop must remain responsible for reviewing and approving the test strategy and outcomes. AI-supported automated test environments can simulate thousands of potential user interactions and system states, applying both behavior-focused and structure-focused testing approaches. This increases overall test coverage and allows validation teams to examine edge cases and failure modes that might otherwise be overlooked.

Automated testing is already established in software development for repetitive and/or regression tests. However, the same principles can be extended to less frequently executed user acceptance tests. This is because the setup efforts would be much smaller. In such cases, users may not perform the tests directly but would retain accountability by reviewing the test approach, automated execution, and accepting the test evidence. Over time, this evolution could potentially enable continuous, AI-powered testing routines. These routines could deliver significantly enhanced coverage, improved assurance, and greater confidence in system performance while maintaining regulatory compliance and alignment with GAMP principles. Yet, this would require continuous oversight, monitoring, and change control of the relevant AI tools themselves.

THE CENTRALITY OF EXCELLENT INPUT

AI-driven validation is only as strong as its inputs. Three elements are indispensable: 1) well-documented business processes, 2) precise user requirements, and 3) structured risk assessments. Together, these form the foundation for automation, traceability, and regulatory compliance. These inputs have always been essential to validation, but in an AI-enabled future, they become even more important. The following explains why.

Clarity Enables Automation

AI models depend on data. Machines can't interpret requirements or assessments written with ambiguity or inconsistency reliably. Structured, precise, and testable requirements and consistent risk assessments are necessary for generating accurate test cases and scripts.

Traceability Requires Structure

In regulated environments, traceability from user requirements to the verification activity and evidence is critical. With high-quality requirements, AI can automatically generate traceability matrices and maintain bidirectional links between all elements.

Change Management Becomes Easier

When requirements are process oriented, well-defined and risk assessed, AI systems can easily trace and test any change based on risk. This minimizes the risk of unintended consequences and ensures continuous validation during system updates.

AI-POWERED VALIDATION WORKFLOW OF THE FUTURE

Let's envision a typical future validation process supported by AI-enabled tools:

- Business processes definition: Subject matter experts (SMEs) and business analysts define the business processes supported by AI-enabled tools to ensure clarity and consistency.
- Requirement definition: AI-enabled tools extract high-quality, structured functional and nonfunctional requirements using corporate templates and terminology.
- Risk assessment: AI-enabled tools support the risk assessment of processes, requirements, and features based on previous projects and help maintain consistency across projects and functions.
- Automated mapping: AI-enabled tools map requirements to functional and technical specifications, verifying coverage and identifying inconsistencies and gaps.
- Generate data flow diagrams: AI-enabled tools analyze the technical and process documentation and maps out the data flow, including interfaces to other processes and systems.
- Test generation: Based on the mapped requirements, AI-enabled tools generate a comprehensive suite of test cases potentially covering unit, integration, system, and user acceptance tests.
- Test execution: Automated testing tools execute the test cases across various environments. AI-enabled tools monitor execution, capture system behavior, and log detailed evidence.
- Result analysis: AI-enabled tools analyze results in real time, flag discrepancies, and suggest corrections. After adjustments, failed tests can be re-executed automatically.
- Evidence generation: Executed tests, validation reports, and traceability matrices are autogenerated, formatted to expectations, and ready for review.
- Human oversight: Validation teams review AI-generated outputs as each output is generated, focusing on verifying appropriate coverage, investigating anomalies, and ensuring compliance, rather than manual execution and document management.
- All outputs: Processes, requirements, risk assessments, test cases, traceability, and evidence must be structured digital records. Only then can AI-enabled tools operate effectively and ensure regulatory acceptance.

VALIDATION TEAM CHANGES

The transition to AI-powered validation processes will dramatically alter the skill sets validation teams require. In particular, this will impact the following.

Business Analysis

Business analysis will become critical, requiring validation teams to develop even stronger business analysis capabilities. The ability to define and document clear processes, identify the intended use, and elicit complete requirements will potentially become the most valuable asset in the validation process.

Manual CSV Activities

The need for manual CSV activities, such as manual test script writing, execution, and spreadsheet-based traceability, will decline as activities are increasingly taken over by AI tools. The creation of documentation or records and execution of tests will be automated, but the responsible parties will focus on providing suitable input and reviewing and accepting the outputs. For small and mid-sized companies, a more traditional, document-based approach may remain appropriate and fully acceptable, especially when their organizational structures and resources justify a more pragmatic, less digitalized approach.

Consequently, the validation team roles might change. This is because validation experts will ensure that automation tools have the correct inputs to function effectively and review the quality and structure of requirements, and other outputs, rather than execute validation tasks like manual testing and tracking of activities. Validation teams will remain essential. However, their responsibilities will shift toward enabling automation through high-quality inputs and reviewing AI outputs for compliance and correctness.

BENEFITS OF AI-DRIVEN CSV

Using AI in CSV offers a wide range of compelling advantages, transforming how validation is approached in regulated environments. One of the most immediate benefits is speed. By automating testing activities, companies may significantly reduce validation timelines, allowing faster system deployment without compromising compliance. Scalability may be another key strength. As pharmaceutical systems become increasingly complex, with numerous integrations across platforms, AI-enabled validation can potentially significantly help manage this complexity. Whether a standalone application or a global enterprise system, the model can scale to meet the demands of large-scale environments.

AI-enabled automated testing has the potential to generate and later execute test cases directly from approved requirements and specifications. For complex systems, this capability may extend to exercising a significant proportion of branches and execution paths within the software. Complete path coverage may not always be achievable with current technologies. However, such approaches are expected to deliver substantially greater test coverage and traceability than is typically achievable with manual methods.

In addition, consistency is likely to be significantly improved. For example, risk assessments could be supported by models considering prior evaluations, helping to identify additional considerations and promoting alignment with assessments performed on comparable systems. This not only broadens the perspective applied to risk evaluation but also enhances overall consistency. And unlike manual testing, which is prone to human error and variability, automated approaches ensure that test results are repeatable and reliable every time. This leads to higher confidence in validation outcomes and minimizes the risk of overlooked issues. The model also enhances audit readiness by potentially enabling continuous validation. Rather than treating validation as a one-time event, this approach maintains a constant state of compliance, supported by automated documentation and real-time monitoring.

Lastly, there may be a significant gain in cost efficiency. By reducing the need for manual scripting, execution, and review, companies can substantially lower validation costs. This needs to be balanced against the cost of introducing the AI solution. This depends, for example, on the pattern of use, the size of the model, the quality of the prompting, and the required SMEs. Resources could be reallocated to strategic activities like innovation, system optimization, and quality improvement, driving even greater long-term value.

CHALLENGES AND CONSIDERATIONS

Even though the tools are already partially available, the industry is in the early stages of adoption, as regulatory uncertainty is a primary concern. Although regulators are showing growing interest in modern validation approaches, clear guidance on AI use in validation is still limited. For example, the draft of EU Annex 22 states, "Generative AI and Large Language Models (LLM), and such models should not be used in critical GMP applications. If used in noncritical GMP applications, which do not have direct impact on patient safety, product quality or data integrity, personnel with adequate qualification and training should always be responsible for ensuring that the outputs from such models are suitable for the intended use, i.e. a human-in-the-loop and the principles described in this document may be considered where applicable" [2].

Whether applications supporting the validation of GMP-relevant computerized systems are considered critical or noncritical should be evaluated in a documented risk assessment and justified. Furthermore, an early engagement with regulatory authorities is encouraged for companies planning to use AI/ML in the validation of GxP systems. Without explicit expectations, companies may hesitate to rely on AI-generated test results or automated documentation, fearing these may not be accepted during inspections. Additionally, before AI tools can support validation, they must be qualified themselves. Organizations must prove that the AI performs reliably, within defined limits, and produces consistent results. This qualification effort can be complex and time-consuming, especially when the underlying AI logic evolves or depends on dynamic data inputs.

AI tools are only as effective as the data on which they are trained and the quality of the instructions and the data input. To generate reliable and compliant outputs, organizations must provide AI models with their own processes, business rules, and validation documentation. By providing company-specific knowledge to the model, the resulting outputs will be more accurate, relevant, and aligned with expectations. Without this specific knowledge, even the most advanced AI cannot deliver high-quality output that meets the needs and expectations of the organization.

The shift toward AI also exposes a skills gap in many organizations. Traditional validation teams may lack expertise in AI. Implementing these tools effectively requires a mix of domain knowledge and technical capability. This often necessitates the support of specialized personnel or external partners.

Beyond technical and regulatory challenges, organizational resistance to change often exists. The pharmaceutical industry is inherently conservative, prioritizing safety and compliance. Familiar processes such as manual testing, scripted protocols, and spreadsheet-based traceability are deeply embedded in quality culture. Replacing these familiar processes with AI-supported workflows requires new tools, plus a shift in mindset and governance.

Overreliance on automation presents another risk. Though AI can increase efficiency, human oversight remains essential. Poorly configured tools or flawed input data can lead to incorrect validation outcomes, which may go undetected if teams place too much trust in automation. Striking the right balance between AI capabilities and expert review is crucial.

Therefore, despite the potential, several challenges must be addressed to realize this future fully:

- Regulatory acceptance: Regulated companies must be assured that such approaches with embedded human control and oversight are acceptable and compliant.
- Process and requirement maturity: Organizations must invest in training and tools to improve how they define processes and extract and engineer requirements.
- Data quality: AI relies on clean and comprehensive data sets to learn and operate effectively.
- Qualification of AI Itself: Regulators will require that AI-based validation systems be qualified and their outputs auditable.
- Change management: Shifting from manual to AI-assisted validation will require cultural and procedural change.
- Human oversight: Although automation will handle most activities, final responsibility will still lie with qualified personnel.

AI ON VALIDATION

To illustrate the shift, we asked AI to reflect on the future of validation. Here's what it said:

"From the vantage point of AI, the future you describe is not only plausible - it is already beginning. Human oversight remains essential. AI can generate, execute, and monitor, but accountability, judgment, and compliance decisions stay with qualified professionals. The role of validation teams will evolve. Instead of writing test scripts or managing documents, experts will focus on ensuring input quality and verifying outputs. This shift moves teams from *document managers to quality architects*. Requirements are the foundation. In AI-driven validation, requirements are not just inputs; they are the DNA of compliance. With clear, consistent, and complete requirements, AI can create test coverage, traceability, and inspection-ready evidence at scale. AI is not replacing validation - it is redefining it" [3].

AI's Benefits

AI support will reshape the validation of computerized systems, making the process more innovative and efficient. Key benefits could include the following:

- Cost and resource reduction: Automates repetitive tasks, reduces manual effort, and frees up teams for higher-value work.
- Better quality, consistency, and compliance: Improves accuracy, detects validation gaps, and enhances data integrity.
- Faster system adoption: Speeds up validation timelines, enabling quicker rollout of new technologies.
- Supports innovation: Reduces bottlenecks and empowers companies to adopt digital tools and modern systems with confidence.

CONCLUSION

As AI transforms the validation landscape, industry guidance must evolve accordingly. ISPE plays a central role in aligning best practices with regulatory expectations. ISPE's foundational framework, *ISPE GAMP® 5 Guide: A Risk-Based Approach to Compliant GxP Computerized Systems*, has long emphasized a risk-based, scalable approach to CSV. Recent updates to *ISPE GAMP® 5 2nd Edition* and the publication of the *ISPE GAMP® Artificial Intelligence Guide* and the *ISPE Good Practice Guide: Digital Validation* mark critical steps toward enabling intelligent, automated validation. By staying ahead of innovation, ISPE can ensure that the pharmaceutical industry remains compliant while leading the way to intelligent validation.

This next era of validation rests on three pillars: well-defined business processes, precise user requirements, and structured risk assessments. These are anchored by one decisive enabler: validation deliverables stored as structured digital records. Only with these pillars in place can AI generate valuable and compliant traceability, reliable test evidence, and audit-ready outcomes. That is, AI can revolutionize validation, but its success depends entirely on the clarity, consistency, and completeness of its inputs. By investing in the three pillars, organizations prepare themselves for a faster, smarter, and more reliable future of validation. In this future, AI will not replace humans. However, it will redefine the role of validation teams, transforming them from document managers to quality experts focused on compliance and continuous improvement. In AI-driven validation, requirements are not just inputs. They are the foundation for achieving and demonstrating compliance which are necessary for AI to revolutionize validation.

References

1. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. "ICH Harmonised Guideline Q9(R1): Quality Risk Management." Adopted January 2023. https://database.ich.org/sites/default/files/ICH_Q9%28R1%29_Guideline_Step4_2022_1219.pdf
2. European Commission. Annex 22 Consultation Guideline, 2. health.ec.europa.eu/document/download/5f38a92d-bb8e-4264-8898-ea076e926db6_en?filename=mp_vol4_chap4_annex22_consultation_guideline_en.pdf&utm_source=chatgpt.com. 29 September 2025.
3. Text generated by Lumo (Proton), response to the prompt: "Write a concise statement on how the validation of GXP-relevant computerized systems will be transformed in the future through the usage of AI. What are the activities that can be supported or covered by AI? How will Validation teams change or benefit, considering the documentation and testing activities?" 29 September 2025.

About the authors

Frank Henrichmann is Sr. ExecutiveConsultant at Q-FINITY. With 25 years of experience in quality functions, he has expertise in computerized systems within GxP-regulated environments. He co-authored both editions of the *ISPE GAMP® Good Practice Guide: Validation and Compliance of Computerized GCP Systems and Data* and contributed to *ISPE GAMP® 5 Second Edition* as a chapter lead. He has been an ISPE member since 2001, is an ISPE-certified GAMP trainer, and is the current Chair of the global GAMP® Steering Committee.

Oliver Herrmann is Managing Director of QFINITY, which he founded in 2004. With 20 years in GxP-regulated environments, he combines process management with CSV. Oliver works as CSV Lead in ERP implementation projects and supports the introduction of MES and LIMS systems. He contributes to several leadership roles in the global GAMP community. He studied applied computer science and holds certifications as ISACA Data Privacy Solutions Engineer, Scaled Agile Framework Practitioner, and Microsoft Systems Engineer. He joined ISPE in 2002, is an ISPE-certified GAMP trainer, and is the current Chair of the EU GAMP Steering Committee. He co-authored both editions of the *ISPE GAMP® Good Practice Guide: Validation and Compliance of Computerized GCP Systems and Data* and contributed to *ISPE GAMP® 5 Second Edition.*