WHITE PAPER:

THE FUTURE OF VALIDATION

9 Automation Trends Impacting Validation Processes

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Abstract

Traditionally, Computer Systems Validation (CSV) plays a critical role in ensuring the integrity, reliability, and compliance of computerized systems in various industries, including pharmaceuticals, biotechnology, healthcare, and finance. As technology continues to evolve, so do the challenges and opportunities in CSV. This white paper identifies and discusses nine key trends shaping the future of computer systems validation in 2023 and beyond. These trends encompass advancements in technology, regulatory changes, industry best practices, and the integration of artificial intelligence, all of which will drive the future of CSV.

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1 Adoption of Agile CSV Methodology

Typically based on the traditional “V-Model” waterfall methodology, traditional computer systems validation (CSV) processes are rigid and time-consuming and often struggle to keep pace with the rapid development of modern software applications. As cloud computing becomes more prevalent in life sciences and systems continue to grow more complex, simultaneously managing a full set of requirements and limiting testing cycles to one or two per year is nearly impossible.

Agile processes have essentially replaced waterfall in software development and system implementation, and in turn, many organizations are now expected to embrace Agile CSV methodologies. By applying iterative validation processes and continuous testing, Agile CSV enables faster validation cycles, reduces costs, and affords greater flexibility in adapting to changing requirements.

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Even the U.S. FDA recognizes the value of a more agile approach to validation. In September 2022, the agency released new guidance to the industry for validation. Titled Computer Software Assurance for Production and Quality System Software, the document – and its name change – reflect a new approach by the FDA. In this latest guidance, the FDA acknowledges that, “Given the rapidly changing nature of software, manufacturers have also expressed a desire for a more iterative, agile approach for validation of computer software used as a part of production or the quality system....”

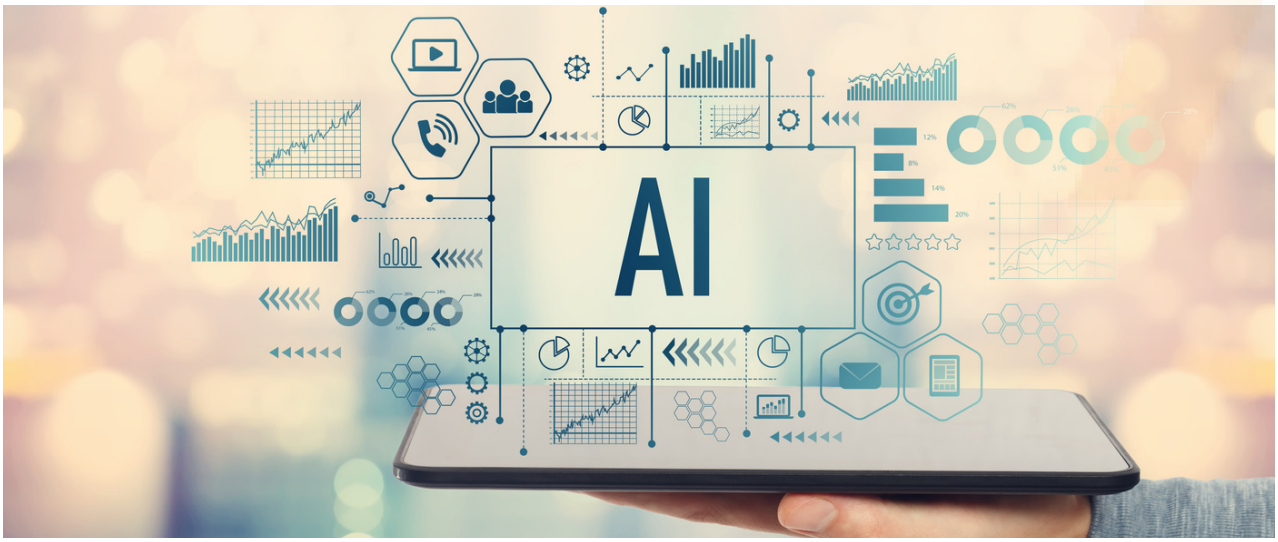
While the principles of validation still endure in the Software Assurance paradigm, it would serve organizations to adopt a more agile approach to validation initiatives. This approach demands automation to achieve its ultimate goals of establishing and maintaining the validated state and ensuring the software is fit for its intended use.

2 Emphasis on a Risk-Based Approach

Risk-based computing in life sciences has been in use for over 25 years. With the ever-growing complexity of computer systems, a risk-based approach to CSV is critical. The latest FDA guidance calls for manufacturers to establish a risk-based framework for computer software assurance throughout the software's lifecycle, because in the context of validation, risk analysis is used to determine the level of validation due diligence required.

In 2023 and beyond, we anticipate a greater shift toward prioritizing validation efforts (or "assurance activities") based on risk assessments. This approach enables organizations to focus on critical components and reduce the burden on less impactful elements. The result is a streamlined validation process and enhanced overall system performance.

Many companies now leverage automated tools to track and manage risk assessments over time. Automation is particularly helpful in allowing users to identify, analyze, and prioritize risks associated with CSV activities. Tools such as ValidationMaster™ Enterprise Validation Management System use online risk matrices, risk scoring algorithms, and other methods to assess risks comprehensively.



3 Integration of AI/ML in CSV

Artificial Intelligence (AI) and Machine Learning (ML) technologies are progressively infiltrating various industries, including life sciences. AI/ML test automation is here, and it's revolutionalizing quality and stability testing, troubleshooting, and validation of the computer systems that help develop, manufacture, and deliver new life sciences products to market.

The impact of AI/ML in computer systems validation cannot be overstated. AI/ML systems continuously learn from new data, adapt validation methods, and improve their own performance over time, continually providing a more efficient and effective validation process. AI/ML also can be integrated into live data streams to validate/confirm data in real-time, identifying issues as they occur rather than waiting for batch processing. AI/ML's biggest impact on validation lies in its ability to automatically generate test cases for software applications, validating different functionalities and scenarios with reduced manual effort. This is the real game-changer for CSV.

Starting now, AI/ML will increasingly be used to automate validation tasks, optimize testing procedures, and analyze large datasets for improved decision-making. AI-driven validation tools enhance efficiency, accuracy, and compliance, providing a competitive advantage to forward-thinking organizations.

4 Blockchain for Enhanced Data Integrity

The implementation of blockchain technology is set to revolutionize data integrity in CSV. By providing an immutable and transparent record of system changes and transactions, blockchain ensures the traceability and authenticity of validation data. Life sciences organizations can integrate blockchain technology into computer systems validation to significantly improve the overall efficiency, security, and reliability of their validation processes, fostering trust among stakeholders and ensuring the integrity of critical systems and data. In industries where computer systems are part of a broader supply chain (e.g., pharmaceuticals, food, automotive), blockchain can be used to track and validate the components and systems used, ensuring compliance with regulatory requirements. Blockchain's nature makes it easier to audit and demonstrate compliance with validation standards and regulations. This can reduce the time and effort required for regulatory audits.

In 2023 and beyond, more organizations are likely to explore blockchain-based solutions to bolster data integrity and meet stringent regulatory requirements.

5 Increased Focus on Cybersecurity in Validation

CSV is intended to ensure computer systems perform according to their intended use. However, the rise in cyber threats poses a significant challenge to validated computer systems. OnShore Technology Group recognized the importance of protecting validated computer systems from cyberthreats and conceived its own proprietary Cybersecurity Qualification (CyQ). As shown in Figure 1 below, as validation engineers conduct installation, operational, and performance qualification (IQ/OQ/PQ) testing, the OnShore Technology Group CyQ Readiness Assessment℠ provides an additional layer of security qualification. The CyQ assessment evaluates a company's cybersecurity readiness to ensure it can identify, detect, defend against, respond to, and recover from a cyber event in accordance with the NIST Cybersecurity Framework.

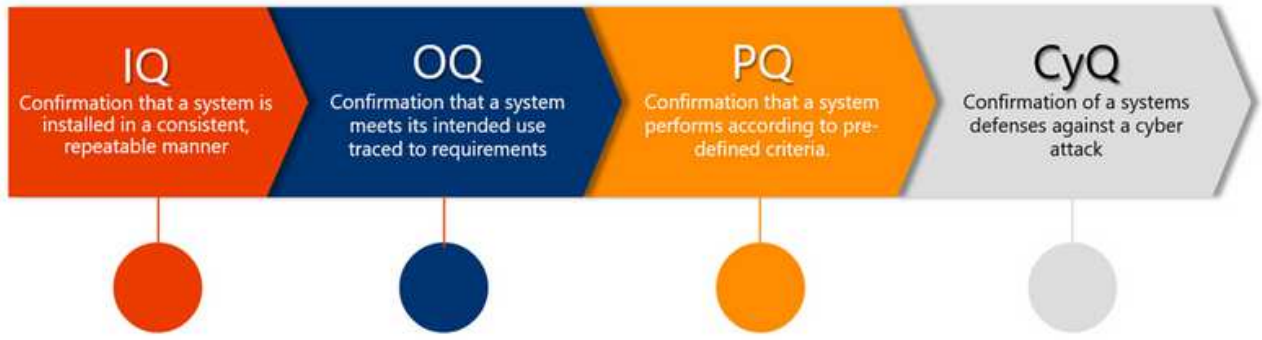


Figure 1 - CyQ Readiness

In light of the current threat landscape, cybersecurity will be at the forefront of validation practices in 2023 and beyond. Organizations will invest in robust security measures, conduct thorough risk assessments, and implement advanced encryption techniques to safeguard sensitive data and protect computer systems from potential breaches. For validated computer systems environments, life sciences companies will need to conduct CyQ Readiness Assessments.

6 Adoption of Cloud-Based Validation Solutions

Cloud computing continues to gain momentum across industries, and life sciences is no exception, with a surge in the adoption of enterprise software for Enterprise Resource Planning, Manufacturing Resource Planning, Enterprise Content Management, Enterprise Quality Management, Laboratory Information Management Systems, Electronic Laboratory Notebooks, barcode scanning, and other technologies. As applications move to cloud environments, a shift in CSV strategy is in order. Cloud vendors are responsible for the IT infrastructure, so vendors must be carefully considered prior to selection. In addition, the validated state must be maintained for cloud-hosted systems, which means continuous testing must be conducted to keep pace with cloud cadence releases.

Even with these considerations, many organizations still have yet to develop effective strategies for automated testing.

In 2023 and beyond, automating the testing process is no longer a luxury, it is a necessity, especially as cloud-based solutions continue to gain traction among life sciences companies. Cloud platforms offer scalability, accessibility, and cost-effectiveness, facilitating collaborative validation efforts across geographically dispersed teams. Forward-thinking life sciences companies are also adopting enterprise validation management systems such as ValidationMaster™ to support automated testing with AI/ML for validating cloud-based computer systems.

7 Integration of IoT Devices and Edge Computing

Internet of Things (IoT) devices and edge computing are becoming integral components of modern computer systems. As their prominence grows, the validation process must evolve to encompass these technologies.

CSV will soon encompass comprehensive testing and validation of IoT devices, sensors, and edge computing platforms, ensuring their reliability and interoperability with core systems.

8 Global Harmonization of CSV Regulations

CSV regulations historically vary across regions, creating challenges for multinational companies. More than 25 years ago, ISPE GAMP 5® sought to establish a harmonized CSV approach that would be acceptable in all major geographies. Through its global consortium of life sciences companies, GAMP 5® established an essential framework for validation. ISPE recently published its *GAMP 5®, Second Edition*, which recognizes mobility, cloud computing, agile methodologies, and a host of other advancements that must be considered for validation. Global harmonization can bring significant changes to the validation process.

In 2023 and beyond, we will see an increasing push for global harmonization of CSV regulations to streamline and optimize validation efforts, reduce duplication, and facilitate international compliance. OnShore Technology Group has established its own unique methodology called Lean Validation℠, which leverages 21st Century best practices coupled with automation (Figure 2).

What is Lean Validation?

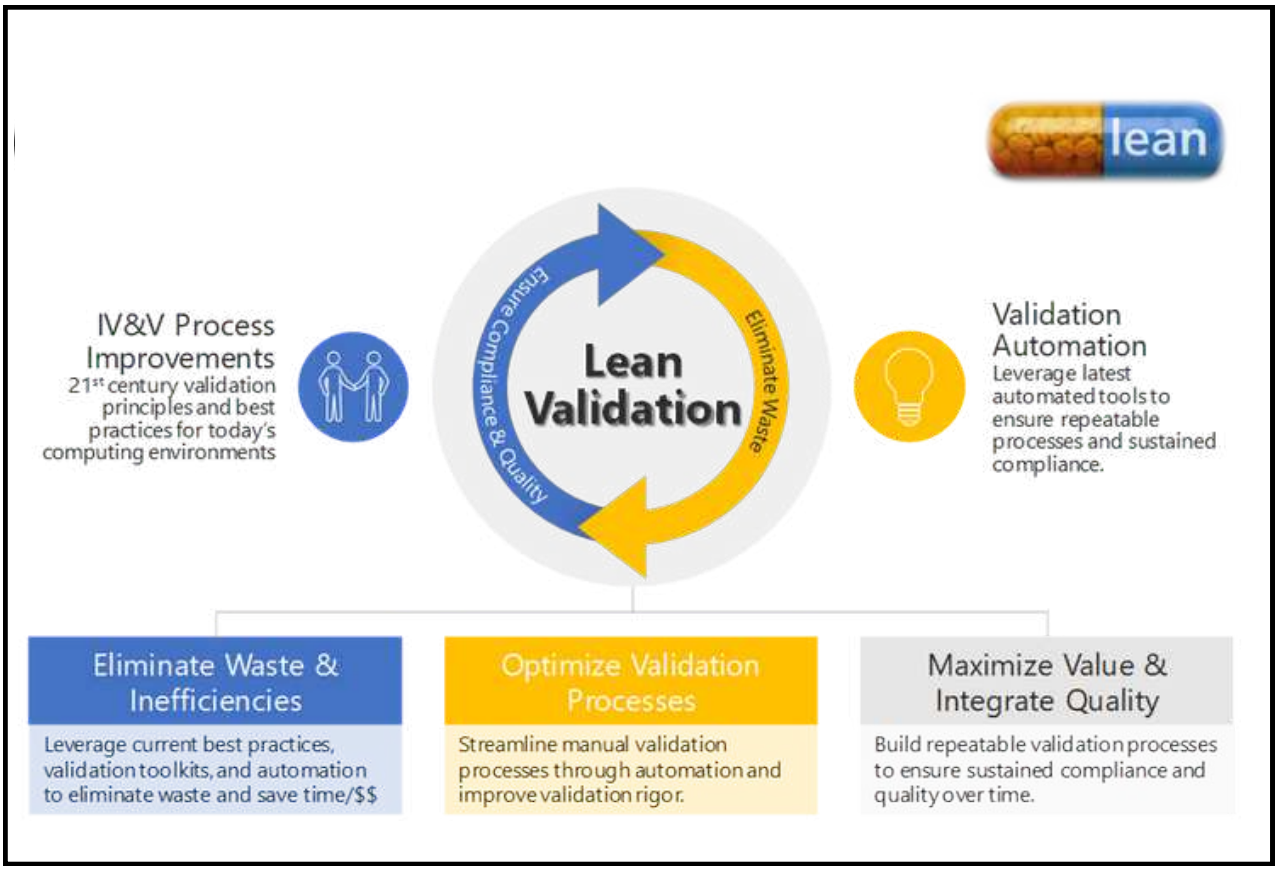


Figure 2 – OnShore Technology Group's Lean Validation℠ Methodology

9 Focus on Data Integrity and Data Governance

Data integrity is a fundamental requirement in regulated industries. Life sciences companies must comply with strict regulations and guidelines from health authorities such as the Food and Drug Administration (FDA) in the United States or the European Medicines Agency (EMA) in Europe. These regulations mandate maintaining data integrity to ensure data generated during research, clinical trials, manufacturing, and distribution are accurate, reliable, and complete. Failure to comply with these regulations can have serious consequences, including product recalls, fines, and legal actions. In life sciences, data integrity directly impacts patient safety. Accurate and reliable data is essential for assessing the safety and efficacy of drugs, medical devices, and other healthcare products. Errors or discrepancies in data can lead to misinterpretation of results and potentially harmful consequences for patients. Data integrity is also closely linked to quality control in life sciences companies. It ensures manufacturing processes are consistent and products meet required standards. Without data integrity, product quality may be compromised, leading to potential safety issues for patients and consumers.

Life sciences companies invest significant resources in research and development activities, and data integrity helps ensure results obtained from experiments, clinical trials, and studies are valid and can be used to make informed decisions about the development and approval of new treatments and therapies.

Organizations will place greater emphasis on robust data governance practices, including data validation, data mapping, and data lineage tracking. This approach ensures that data used in CSV processes is accurate, consistent, and reliable. Throughout the validation process, data integrity must be assessed and documented.

Conclusion

The future of Computer Systems Validation in 2023 and beyond promises to be dynamic and transformative. By embracing agile methodologies, incorporating AI and blockchain technologies, and prioritizing cybersecurity and data integrity, organizations can navigate the evolving landscape of CSV successfully. The trends highlighted in this white paper will shape the future of CSV, enabling organizations to build compliant, reliable, and future-proof computerized systems. Embracing these trends will empower organizations to adapt to changing regulations and technological advancements, ultimately leading to improved efficiency, reduced costs, and enhanced user experiences.

The **ValidationMaster™ Enterprise Validation Management System** supports the full validation lifecycle, streamlining and optimizing validation exercises through automation, collaboration, and optional AI. Available in multiple languages with more than 40 third-party integrations, the time-saving, resource-maximizing platform comprises:

- **ValidationMaster™ Studio**, a mobile- and desktop-accessible web client with point-and-click-access to a series of modules to support validation activities and reporting: **Dashboards**, **Requirements**, **Testing**, **TestMaster AI** (optional), **Incidents**, **Risk**, **Reporting**, **Administration**, and **Validation Kanban Boards**
- **ValidationMaster™ QMS Portal**, which integrates the functionality of DocuSign, Nintex, and Muhimbi
- **ValidationMaster™ IQ LMS** Portal for training and self-service access to help topics

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About the Author

Valarie King-Bailey, M.B.A., is an internationally experienced engineering, marketing, and technology executive with over 30 years of experience. Recipient of the 2021 Kenneth G. Chapman Award for Significant Contributions and Validation Excellence, Ms. King-Bailey specializes in software validation and compliance management systems. She is the founder and CEO of OnShore Technology Group, Inc., a U.S.-based global firm specializing in software validation and verification of technology solutions. Under her leadership, OnShore developed the "Lean Validation" term and methodology for streamlined, optimized, and efficient validation processes. Her firm also created and exclusively distributes the ValidationMaster™ Enterprise Validation Management System.