KPMG

Shifting from compliance to quality

Taking steps toward adopting computer software assurance (CSA) in life sciences

KPMG life sciences computer system validation survey 2022

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Contents

Executive summary

From equipment automation and transactional systems to new technologies such as robotics, artificial intelligence, and advanced analytics, life sciences organizations have the need and desire to embrace a wide variety of technological innovations that drive efficiency and increase product quality. However, the industry has been slower to adopt advanced digitalization across the value chain, including in research, design, manufacturing, commercial, and distribution. Industry leaders say the lack of progress to embrace the innovations of Industry 4.0 is primarily due to reluctance to move away from the manual, risk-averse computer systems validation (CSV) processes to which they have been accustomed. With the cost of CSV typically at least 40 to 50 percent of the overall program cost, companies are accruing technology debt in fear of the upgrading to new versions and rendering them unable to adopt new technologies.

Over the past decade, the FDA has been advocating for a risk-based approach for verifying that the defined computerized system functions as intended versus a documentation exercise to demonstrate compliance to regulation. To drive these principles, U.S. Food and Drug Administration recently published a draft guidance outlining these strategies:

> “
>
> Computer Software Assurance for Production and Quality System Software.”

By transitioning CSV processes to the CSA approach, manufacturers will not only be able to raise product quality and ensure patient safety, but also reduce operating workloads and costs, deliver innovative solutions, and more rapidly adopt the latest technologies, all while complying with FDA regulations. The potential value of this transition is compelling the industry to take steps to pivot to CSA: According to a Gartner study, 40 percent of life science organizations will conform to CSA tenets by 2025.[1]

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> Life sciences companies are not moving away from CSV, but rather applying CSA within the framework of CSV. The FDA guidance document says that CSV will remain as it is a supplement to the current guidance, *General Principles of Software Validation*,” said Bhaskar Arya, Director of Global IT Quality Assurance at Bristol-Myers Squibb.

This report provides insights based on a survey of 163 life sciences professionals on CSA implementation and transition trends. Responses reveal the state of current validation systems, tools, processes, and budgets; future CSA adoption plans and progress; and barriers and pain points along the digital transformation journey. These findings, along with perspectives from KPMG life sciences industry leaders, are designed to help organizations align with CSA principles.

FDA Recommendations: “Computer Software Assurance for Production and Quality System Software”

On September 13, 2022, the U.S. FDA issued draft guidance providing recommendations on CSA for computers and automated data processing systems used as part of medical device production or quality systems. The guidance would allow for—and even encourage—the industry to adopt a simpler assurance approach that emphasizes critical thinking and assurance needs as opposed to testing and documentation.

Source: Computer Software Assurance for Production and Quality System Software – Draft Guidance for Industry and Food and Drug Administration Staff (U.S. Food and Drug Administration, draft guidance issued for comments on September 13, 2022)

KPMG Life Sciences Computer System Validation Survey 2022: Survey methodology

In September 2022, the KPMG Life Sciences Advisory practice and KENX, a life sciences conference and training network, surveyed more than 150 professionals in the life sciences sector who have knowledge of and/or responsibility for their organizations’ CSV activities. Respondent organizations are medical device, pharmaceutical, biotech, and biologics organizations, and 40 percent have total annual revenue of more than $500 million. Respondents are responsible for Computer System Validation (46 percent), Quality Assurance (23 percent), and Executive Management (10 percent).

[1] Gartner, “Life Science CIOs: Use Computer Software Assurance to Modernize Your GxP Validation Practice,” 25 January 2022

CSA: A paradigm shift

In place since the late 1990s, CSV is largely focused on documenting the validation process and testing results to avoid regulatory action versus applying control to support improving the quality of product and patient outcomes. Once these practices were recognized, the FDA has advocated for a risk-based approach, citing through FDA Guidance documents and Good Automated Manufacturing Practice, GAMP.

Nevertheless, the industry continues to apply risk-averse methodologies to ensure they pass FDA regulatory audits as inspectors have been conservative in their inspection approach. This has led to a burdensome level of documentation, testing, and other verification activities conducted at each stage of the software development lifecycle. As a result, organizations struggle with CSV in terms of resources, time, and cost, as well as the inability to implement modern technologies. Gartner research found that overall project costs are 30 percent higher using a traditional CSV approach.[2]

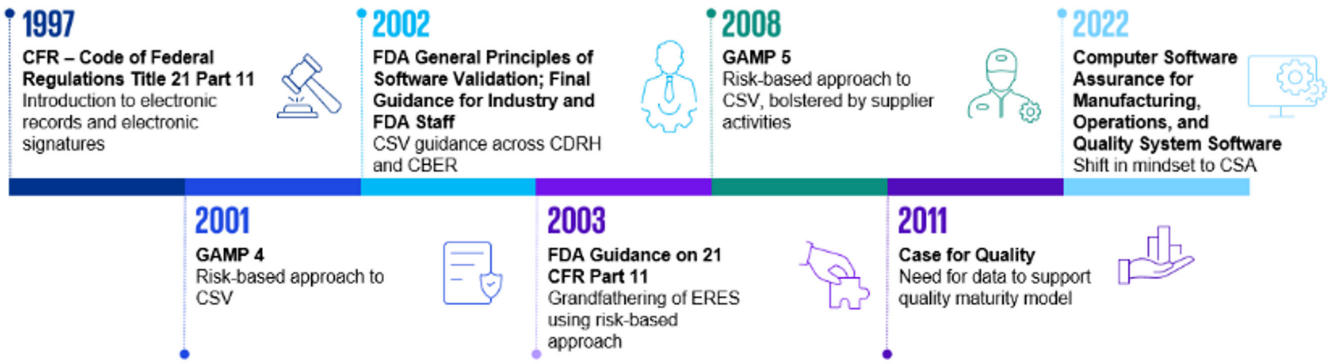
> Reluctance to keep up with technology trends and update technical systems increases cost of ownership and adds risk of software going out of service," said Roy Devine, Global Process Owner, Computer Systems Validation, at Becton-Dickinson.

> It's better to manage the environment to keep with technology and continually upgrade than maintain a static platform that hasn't changed in years."

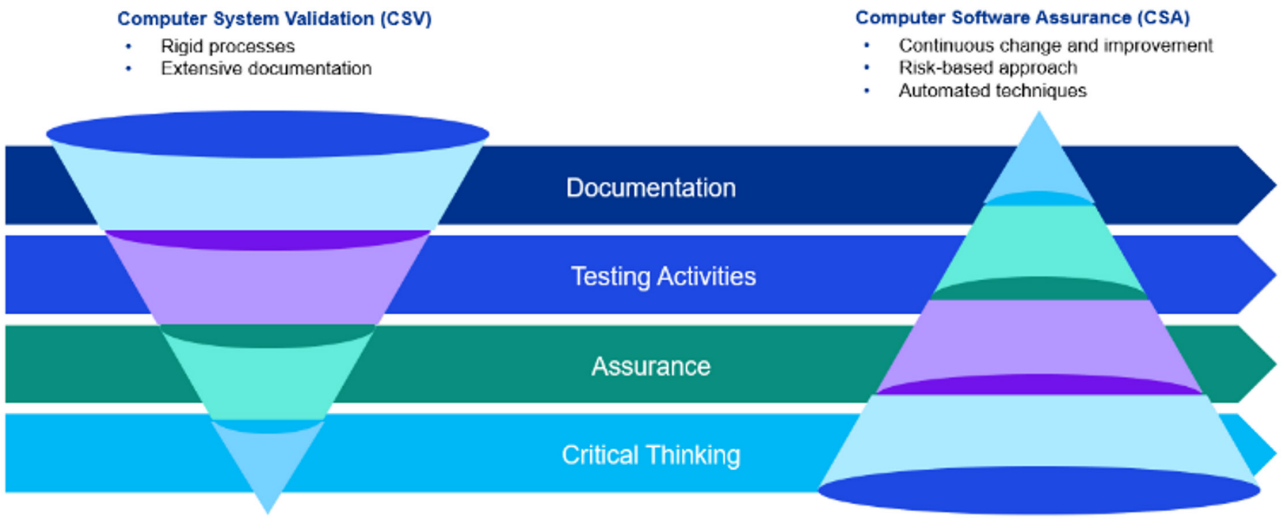
Organizations are starting to understand that CSA changes the game by helping prevent higher-risk defects in the software development process, while also offering higher confidence in the computer system than traditional validation approaches. CSA's risk-based approach helps ensure that the appropriate level of documentation and testing is applied to demonstrate that the computer system has met its intended use.

Defining CSV and CSA: What's the difference?

- CSV: Establishing documented evidence that provides a high degree of assurance that a computerized system will consistently achieve its predetermined specifications and intended use.
- CSA: A set of activities or actions to be performed to give confidence that software functions as intended and meets the organization's needs.



[2] Gartner, "Life Science CIOs: Use Computer Software Assurance to Modernize Your GxP Validation Practice," January 25, 2022



The methodology encourages organizations to apply critical thinking to the assessment of risk and corresponding assurance activities, rather than taking an almost one-size-fits-all approach. Automation and continuous improvement—two more CSA key tenets—further serve to reduce the manual work of validation, enabling organizations to lower total project spend and reallocate dollars to higher-value activities.

Lastly, CSA supports and promotes industry innovation. By removing antiquated validation practices and taking advantage of automation technologies such as validation management tools, life sciences organizations can improve overall quality and process control, while focusing on manufacturing higher-quality products that ensure patient safety and clinical efficacy.

> A risk-based approach does not mean skipping critical steps, but paying more attention to more critical items," said Devine of Becton-Dickinson.

> The biggest gain of transition to CSA is going from check-the-box compliance to improving quality, increasing critical thinking, and spending less on whether the design will work and more on the problem that is trying to be solved."

Key findings: Where are we and what's next?

With the publication of the FDA draft guidance, life sciences will need to understand their current state of compliance and what the next steps are for implementation. Common questions they are asking are:

- How can life sciences organizations benefit from CSA adoption?
- How ready is the industry to enact a risk-based approach and shift from CSV to CSA?
- As organizations go through the transition process, will their digital capabilities help them or hold them back?

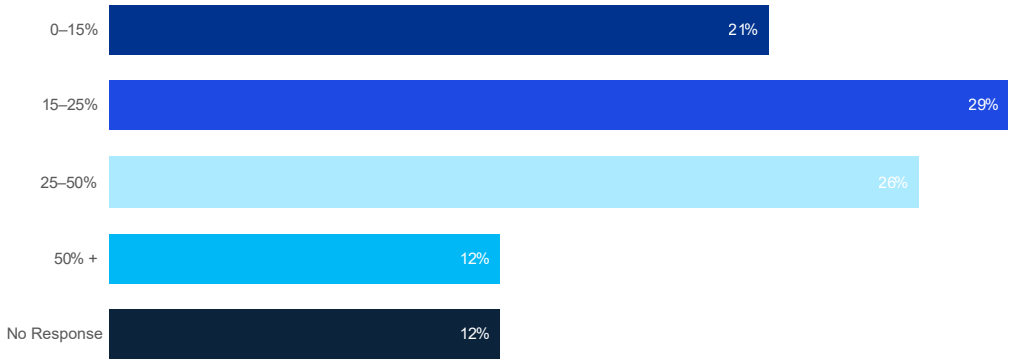
Key takeaways from the KPMG Life Sciences CSV Survey 2022 help answer some of the biggest questions about the future of CSA in life sciences.

Theme #1: Adoption drivers

Key finding: Current CSV budgets and resource constraints—as well as the prevalence of GxP-relevant systems—confirm the benefits of transitioning away from CSV and toward CSA.

Project spend: As industry regulators, analysts, and practitioners know well, there is a strong business case for CSA adoption among life sciences organizations. For decades, CSV activities have eaten up a sizable portion of organization's total product development budgets: 38 percent of respondents say their organization spends at least one-quarter (25 percent) of project spend on CSV tasks. In other words, CSV validation activities are taking dollars away from other key product development activities, such as selection and licensing of software, working with the business to define requirements, and actually manufacturing products.

How much of your project spend is used to execute CSV activities?

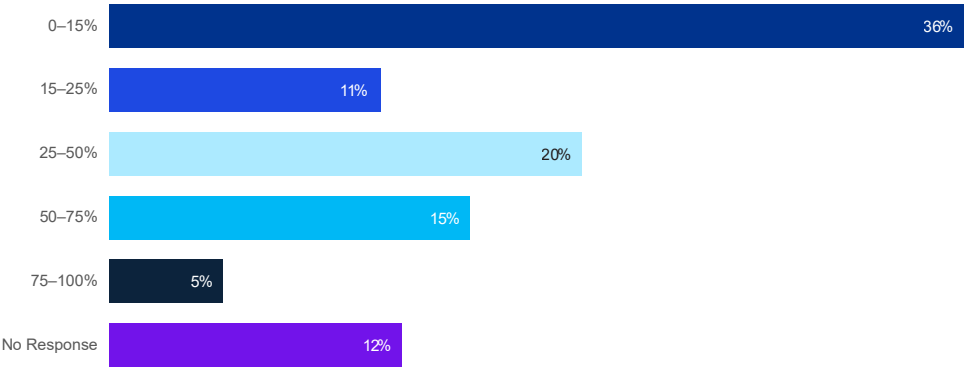


About Three-quarters of respondents spent less than 50 percent of the project spend to execute CSV activities.
About One-tenth of respondents believe that they spent more than 50 percent of the project spend to execute CSV activities.

Percentage figures are rounded off to whole number

Insourcing versus outsourcing: The heaviest burden of cumbersome CSV processes falls on internal teams. Most of the dollars spent on CSV execution stays in-house, often stretching internal resources. According to our survey, 36 percent of organizations outsource no more than 15 percent of their project spend, and 67 percent outsource less than 50 percent of their project spend.

How much of that spend is outsourced?



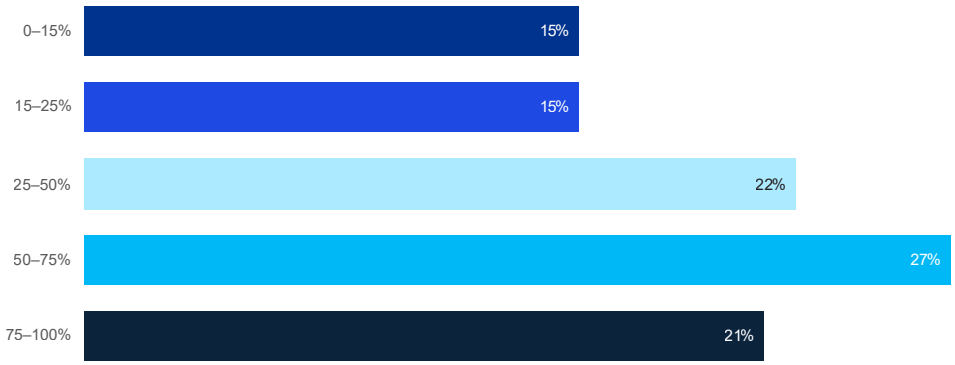
Sixty-seven percent of respondents consider that less than 50 percent of their project spend is outsourced.

Percentage figures are rounded off to whole number

GxP-relevant systems: The transition to CSA has the potential to improve cost and operating efficiency across the majority of enterprise systems. According to our survey findings, about half of respondents say their organizations' IT systems are more than 50 percent GxP relevant. This means that, in order to comply with rigorous regulatory requirements and guidelines, a significant number of systems need to apply CSV controls to system development lifecycles. Therefore, the transition to CSA methods could have a major impact on cost and operating efficiency.

Companies should take a data-centric view versus a system view. Data can be moved through systems; it doesn't matter where it sits. Providing people with the data they need across systems leads to better intended use," said Becton-Dickinson's Devine.

What percentage of your organization's IT systems are GxP relevant?

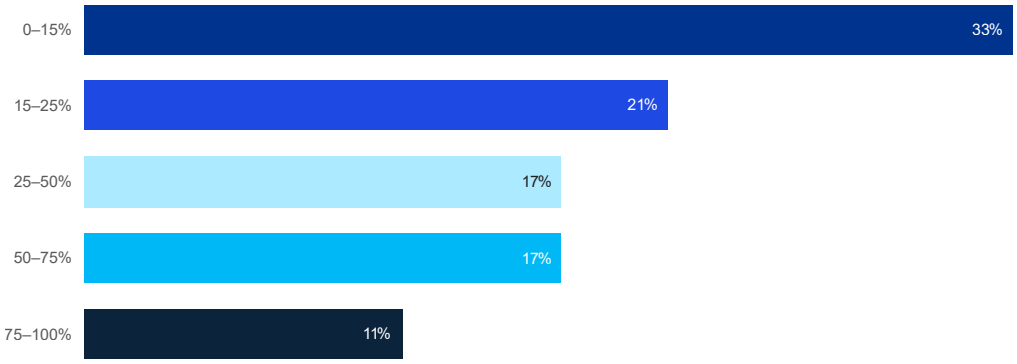


About half of the respondents believe that their organizations IT systems are more than 50 percent GxP relevant.

Percentage figures are rounded off to whole number

Out-of-the-box solutions speed adoption: With technology recognizing the requirements of Global Health Authorities and building solutions specific to the industries, life sciences organizations have been implementing out-of-the-box GxP solutions more and more over the past decade. One-third (33 percent) of respondents say no more than 15 percent of their organizations' GxP solutions are customized, while only about one-quarter of respondents (28 percent) customize 50 percent or more of their GxP solutions. In contrast, out-of-the-box solutions can help speed CSA adoption, as automated testing can be more easily and rapidly applied. And companies can leverage from vendor-assessment documentation to allow a greater focus on critical high-risk functions.

How many of your GxP solutions are customized versus out-of-the box?



About one-quarter of respondents identifies that more than 50 percent of their organizations GxP solutions are customized versus out-of-the-box.

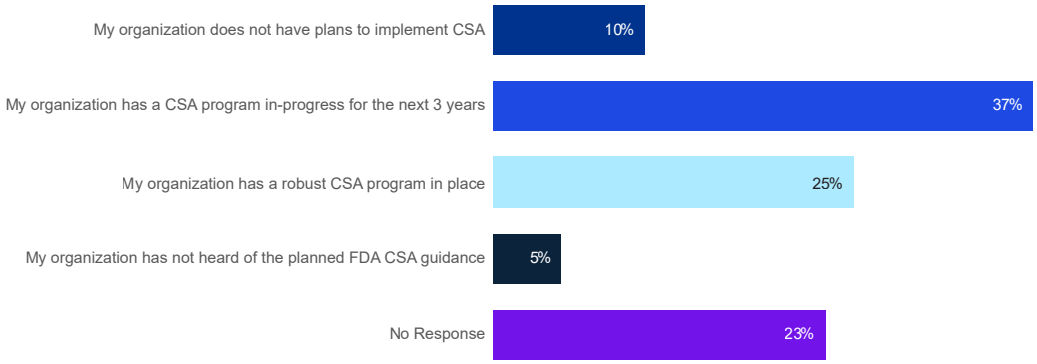
Percentage figures are rounded off to whole number

Theme #2: Readiness and mindset change

Key finding: Although the majority of life sciences organizations have most of the key systems and governance requirements in place to start the transition to CSA, cultural barriers could make the road a bumpy one.

CSA strategies are in place: Although our conversations with life sciences organizations indicate many are not yet executing risk-based assurance to the fullest, our survey findings show that the majority are at least on the way to adopting CSA: About two-thirds of respondents say their organization has a CSA program in place (25 percent) or in progress (37 percent). Further, 72 percent of respondents say their organizations currently have a CSV policy that allows for a risk-based approach—the foundation of the model.

How would you gauge your organizations strategy for implementing CSA?



About two-thirds of respondents feel that their organization has either robust CSA program in place or CSA program in progress for next three years.

Percentage figures are rounded off to whole number

CSV policies need consistency: While some corporate policies support a relatively seamless transition to CSA, others need to be revisited to help clear the path forward: One sign of readiness is that more than half (52 percent) of organizations have one corporate CSV policy, rather than individual policies within business units/divisions or local sites. A single policy supports harmonization and standardization of quality assurance processes, which are a key starting point for quick, compliant CSA adoption—the next phase of the journey. On the other hand, only about one-third (36 percent) of organizations have a flexible CSV policy that allows for implementation of new technologies. Neutral or restrictive policies—which hinder risk-based critical thinking and often lead to excessive, compliance-driven testing and documentation—are more prevalent. For organizations in this category, it could be more difficult to introduce new technologies.

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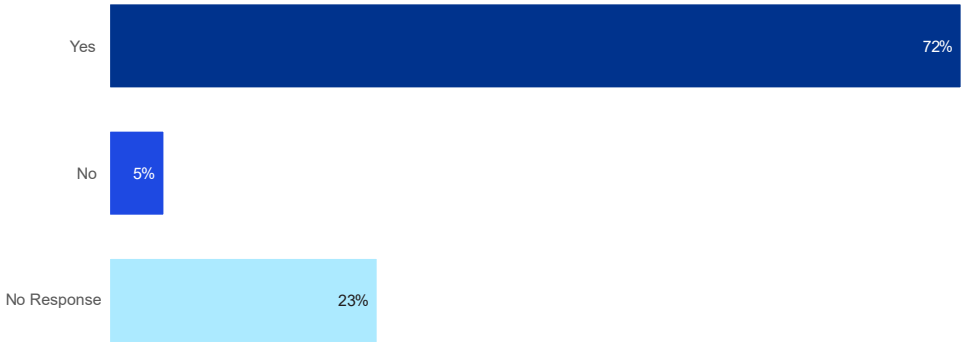
There will need to be a cultural paradigm shift on how quality and business functions operate within the CSA framework. They must align on the risk levels and intended use to truly embrace CSA, and there should be dedication to change management, said Arya of Bristol-Myers Squibb.

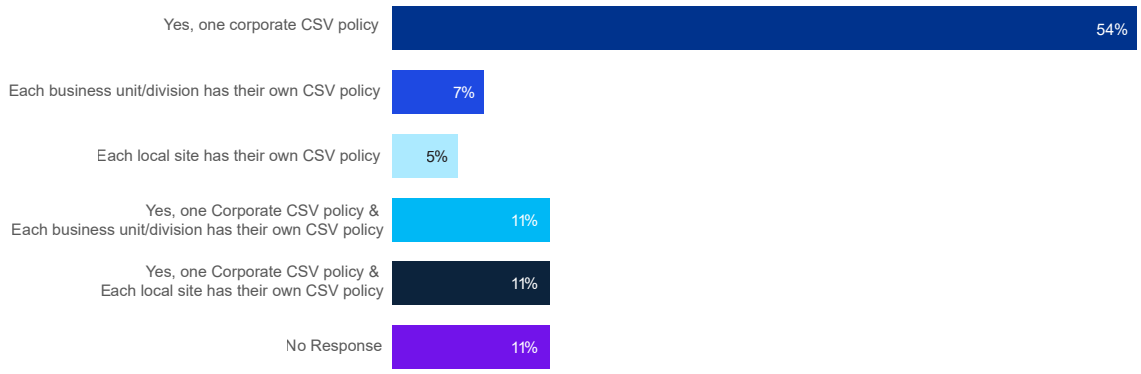
Does your organization currently have a CSV policy that allows for a risk approach?



About three-quarters of respondents believe that their organization's current CSV policy allows for a risk approach.

Percentage figures are rounded off to whole number

Does your organization have a corporate CSV policy?

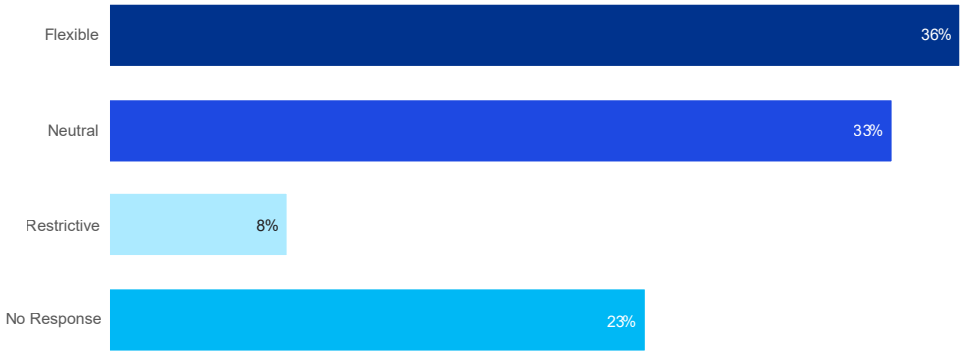


At least 54 percent of the respondents believe that their organization has one corporate CSV policy.

At least 12 percent of respondents believe that their organization has own CSV policy at each business unit/division and local site.

Percentage figures are rounded off to whole number

How would you describe your organization's current CSV policy to allow for implementation of new technologies?



About one-third of the respondents believe that they are using some form of automation tools to support the validation testing activities.

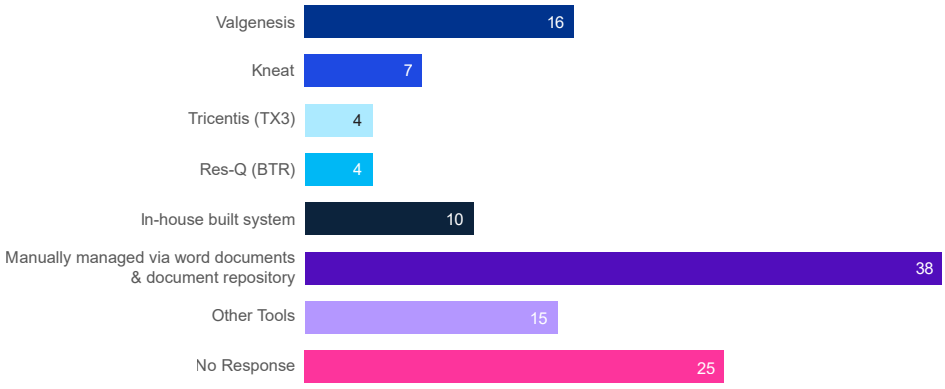
Percentage figures are rounded off to whole number

Theme #3: The transition to digitalization

Key finding: Continued reliance on manual, paper-based processes, as well as a lack of automation in validation activities, indicates that many life sciences organizations are not yet capable of taking full advantage of CSA methodologies.

Slow adoption of VLM tools: Digitalized processes are required to unlock the true value of CSA, enabling organizations to complete risk-based assurance activities quickly and efficiently. However, our survey findings show that digital maturity is trailing the industry's CSA adoption ambitions. The majority of surveyed organizations (56 percent) say they use Validation Lifecycle Management (VLM) tools—configurable workflows used to perform the system review and approval cycle in an efficient, reproducible way. However, 38 percent—a notably high number—conduct VLM manually, via Word documents and document repository. As paper-based systems are slower, less efficient, and less scalable than digital ones, they are significant obstacles on the road to CSA.

Does your organization use any Validation Lifecycle Management (VLM) tools to support validation activities?



Other tools:

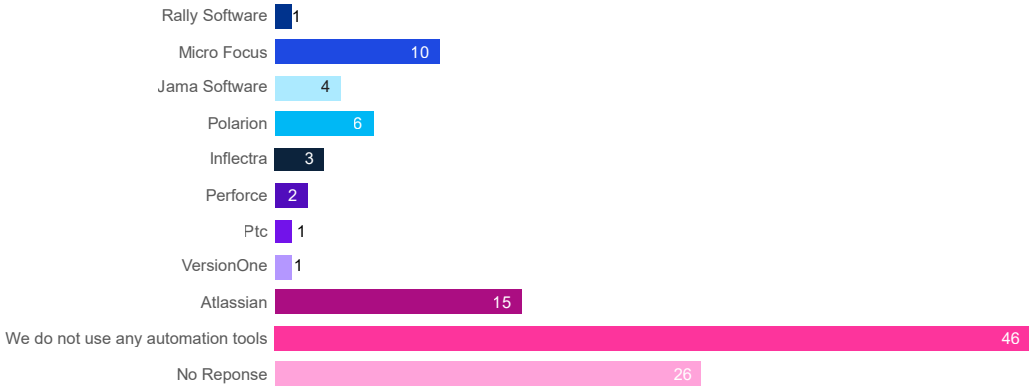
- ACE Essentials
- ALM Tools
- Veeva
- HP ALM
- Polarion
- Simploud
- TestComplete
- ValidationMaster

The majority of respondents identify that their organization uses some form of Validation Lifecycle Management (VLM) tools to support validation activities.

Multiple Reponses were given by respondents

Even slower adoption of automation tools: It is rarer still for organizations to use automation tools such as ALM, electronic testing, VLM, and DevOps to support validation testing activities. While using these tools could help reduce costs, increase quality, and simplify the process of transitioning to CSA, it is concerning that nearly half of respondents (46 percent) say their organizations do not use any automation tools for validation testing.

Are you using any automation tools to support validation testing activities (e.g., ALM, electronic testing, VLM, DevOPS)?



About one-third of the respondents believe that they are using some form of automation tools to support the validation testing activities.

Multiple Reponses were given by respondents

Getting there: Four steps for making the shift to CSA

Transitioning to CSA is much more than a technical exercise—it is a full organizational transformation process. To move the needle, processes, people, and technology must all adapt. How can your organization get ahead of the curve and build your CSA capability?

We offer four recommendations for life sciences organizations to get started.

1. Conduct a gap analysis

To prepare your organization to adopt CSA methodologies, first conduct a gap analysis—a detailed examination of your current versus ideal state. This will help you understand opportunities for improvement to best achieve your objectives, acting on facts, not assumptions. Gather and analyze input, data, and key performance indicators, KPIs from stakeholders involved in CSV activities to answer questions such as:

- What are the intended uses of our computer systems?
- What are the highest-risk features, operations, and functions?
- What is the specific value of CSA adoption for our organization?
- How can we build a business case to present to leadership?

2. Transform your processes

Once you identify organizational shortcomings, it's time to establish a strategy to close the gaps. Adjustments to your current software lifecycle (SLC) process will be a critical focal point, as existing CSV processes will need to align to the CSA methodologies.

To transform your processes by Identifying, reviewing, and revising policies and procedures that define the SLC process, include:

- Definition of CSA
- Roles and responsibilities across quality, validation, business owners, and technology groups, including documentation owners and approvers
- Risk levels of system features related to product quality, patient safety, and data integrity
- Definition of out-of-the-box (OOTB) configuration and customization system features
- Definition of testing strategies based on system feature category and risk levels for scripted and unscripted testing, although all testing is documented

This establishes an overall risk-based approach for the organization based on intended use of the system as related to product quality and patient safety.

3. Address people and change

Teams will also be impacted by the transition to a CSA approach. Help create a culture and mindset focused on quality over compliance by:

- Evaluating the current state of quality culture within the organization and establishing strategic business partner relationships
- Building collaboration between quality, validation, business owner, and technology groups to ensure shared ownership of system development and implementation
- Training all functions on the CSA risk-based approach as defined in the latest guidance.

4. Accelerate advanced technology adoption

Finally, next-generation technology capabilities that enable your organization to automate manual processes will help with not only the initial transition to CSA, but also efforts to drive greater value in terms of cost, speed, and quality. Modernize and digitalize the technologies that support your assurance activities by:

- Assessing current technologies and manual processes used for CSV activities
- Identifying opportunities to reduce documentation and gain process efficiencies through implementation of technology tools
- Using Validation Lifecycle Management (VLM) tools for automation or simplification (e.g., ValGensis, HP ALM)
- Using DevOps tools to reduce manual process discrepancies and increase overall quality with systems such as Jira, ALM automated testing, and Tricentis Tools.

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How KPMG Life Sciences Advisory can help

KPMG LLP is a leading adviser to the healthcare and life sciences industry, providing a wide range of strategy, advisory, audit, and tax services to assist our clients in growing their businesses, enhancing performance, and managing risks. Our client focus, commitment to excellence, global mindset, and consistent delivery allow us to build trusted relationships that are at the core of our business and reputation. Across the healthcare and life sciences sector, we are viewed as trusted advisers in the following areas:

- Strategy and new business models
- Diligence, separations, and integrations
- Tax compliance and governance
- Disruptive technologies and advanced analytics
- Risk management and regulatory compliance
- Independent audit and attestations services

In a rapidly evolving environment, our forward-thinking professionals focus on the horizon as well as the here and now, anchoring our experience in today's realities while helping healthcare and life sciences organizations anticipate and prepare for tomorrow's possibilities.

Get in touch

Madhavi Ganesan is a director in the Life Sciences Advisory practice at KPMG LLP. A strategic IT quality assurance leader, she has more than 25 years of experience working with multinational life sciences companies (medical device, pharmaceuticals, biologics, biotechnology) to develop and drive computer systems validation strategic compliance initiatives related to design controls, manufacturing, testing, distribution, packaging, and labeling. Using her in-depth knowledge of CSV industry rules, standards, and enforcement trends, and extensive experience working with U.S. and E.U. regulators, Madhavi has an excellent record of closing remediation activities, implementing strategies for data integrity, and helping ensure compliance with evolving requirements.

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