KPMG

From theory to practice

Adopting Computer Software Assurance for today's technologies in life sciences

KPMG life sciences computers system assurance survey 2023

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Executive summary

In September 2022, the US Food and Drug Administration (FDA) released draft guidance encouraging life sciences companies to take a more risk-based approach to verifying that their computer systems are performing as intended.

With the draft guidance, the FDA is urging life sciences companies to adopt the Computer Software Assurance (CSA) approach to control computer systems used for product quality, patient safety, and data integrity and move away from the currently used Computer Systems Validation (CSV), which is seen as rigid, slow, documentation heavy, expensive, and conservative.

In the year since, many in the industry are asking: How companies are progressing in applying the CSA principles? How is industry as a whole adapting to these principles? And how are they applying these guidelines to modern technologies such as artificial intelligence and machine learning?

Earlier this year, we surveyed life sciences companies to determine how they could benefit from CSA; how ready is the industry to adopt the CSA principles; and how would companies' digital capabilities help or hinder the transition process. More recently, KPMG, in collaboration with KENX, a life science conference and training network, again surveyed life-sciences companies' leaders to determine how their organizations have responded to the CSA guidance, and how far along they are in adoption.

CSA is a set of activities or actions to be performed to give confidence that the software functions as intended and meets the organization's needs. The principles drive critical thinking, risk-based approaches, and modernized delivery and testing techniques.

Overall, our survey found that industry is moving forward to adopt CSA principles when implementing GxP IT solutions. A majority said that more than half of their IT systems were GxP relevant. The one notable challenge is artificial intelligence (AI) and machine learning (ML). More than half said that they haven't implemented either the CSV or CSA principles to their AI/ML solutions, although about a third said their company has resources dedicated or available for a knowledge base related to AI/ML GxP use cases.

Many respondents are implementing AI/ML solutions and see the technology as benefiting the operations around manufacturing, quality, and clinical trials. AI/ML can bring real benefits to consumers—for example, by making products better, cheaper, and more widely available. But AI/ML also raises the risk of injuring, misleading, or otherwise harming Americans. To address these issues, the White House recently issued an executive order on the use of AI. The order called for the responsible use of AI in healthcare and the development of affordable and life-saving drugs and instructed the Department of Health and Human Services to establish "a safety program to receive reports of—and act to remedy—harms or unsafe healthcare practices involving AI." As the use of AI/ML in the life science industry increase, the importance of CSA will grow as well as it allows for a risk-based approach to validate the technology.

In the following pages, we offer details of the survey and an analysis of the results.

> I don't think we can ever turn back to the traditional CSV approach. Once people see the benefits of CSA, the industry will not want to give it up.
>
> **—Joanne Goldberg, Medtronic**

Survey methodology

In June 2023, the KPMG Life Science Advisory Practice and KENX, a life science conference and training network, surveyed life sciences company executives on their progress to meet the CSA guidelines set forth by the FDA. About half of the respondents describe their job role involves Computer System Validation, Quality Assurance, or Executive Management. More than half of the companies represented had total annual revenue of $500 million or more. Respondents' companies included manufacturers of pharmaceuticals (37 percent), medical devices (21 percent), biologics (14 percent), software as a medical device (10), and combination products (12 percent).

Survey results and analysis

Theme No. 1: CSA moving forward; most IT systems are GxP relevant

Key finding: Life science companies are moving forward with CSA around AI/MI. Respondents also report their companies' IT systems are GxP compliant. However, only 31 percent of respondents said that their company has resources dedicated or available for a knowledge based related to AI/ML GxP use cases.

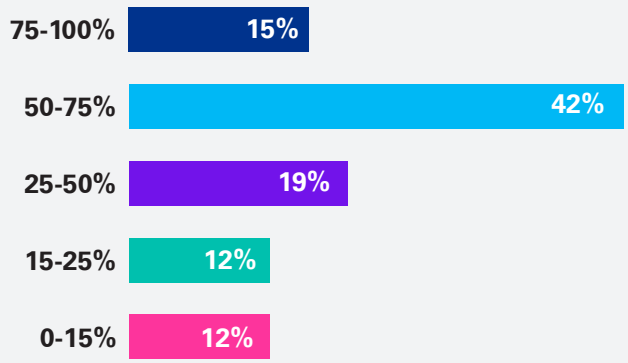
CSA adoption for AI/ML: Our survey found that life sciences companies have started their CSA rollout around AI/ML, with 38 percent of respondents saying they have leveraged CSA principles within their AI/ML framework. Of those, 23 percent said it took less than six months to implement this framework, while 15 percent said it took more than a year.

In addition, 57 percent of respondents said that more than half of their IT systems were GxP relevant. Of those systems, 30 percent of respondents said that more than half of them were SaaS solutions, while 36 percent of respondents put the percentage of SaaS solutions at between 25 and 50 percent. The survey also found that many organizations are opting for custom-made IT solutions compared with out-of-the box applications. About a third of respondents said that between a quarter and a half of their GxP solutions were custom-made, while 26 percent said custom-made applications accounted for more than half of their solutions.

Nevertheless, when it comes getting up to speed around AI/ML and GxP, life-sciences companies may still have some work to do. Only 31 percent of respondents said that their company has resources dedicated or available for a knowledge based related to AI/ML GxP use cases.

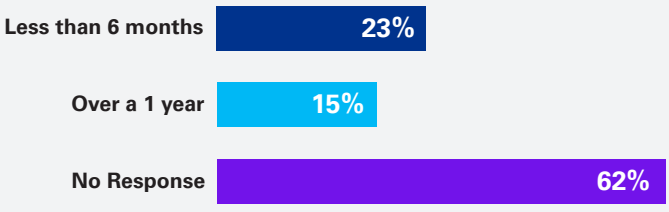
> We have adapters, and we have resisters. Some of the focus will have to be on the resisters because fear may be the leading cause of their resistance. In the coming years, we have to make sure we listen to the cause of their fears, and then we make sure a framework is being put out there that helps them in adopting the CSA principles.
>
> **—Geetanjali Abbi, Alkermes**

What percentage of your organizations IT System are GxP relevant?



About half of the respondents believe that their organization IT System are more than 50% GXP relevant

How long did take your organization to implement this AI/ML framework?



About 1/4th of the respondents took less than 6 months to implement AI/ML framework in their organization

Theme No. 2: Some AI/ML applications without CSV framework

Key finding: Our survey uncovered that most respondents don't have a Computer Systems Validation (CSV) framework for AI/ML. Buy they are working toward implementation.

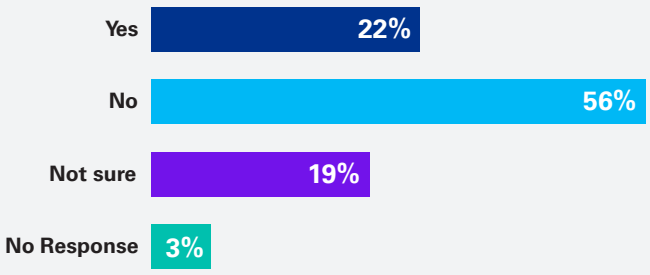
CSV application is possible for AI/ML, but adoption is slow so far: As the life-sciences industry moves toward CSA controls to ensure their computer systems' reliability, security, and performance, companies are relying on CSV during the transition.

However, even as life sciences companies implement AI/ML programs, a sizable number of respondents indicated their organizations have yet to implement a CSV framework for their AI/ML solutions within GxP environments. Only 22 percent of respondents said they had such a CSV framework in place, compared to 56 percent who said they didn't. Of the respondents who did, about a quarter leveraged their current CSV software lifecycle, while 15 percent said they created a separate CSV lifecycle for AI/ML.

The good news is that progress is being made. Nearly half of the respondents (47 percent) said that an AI/ML CSV framework is in their one-to-three-year technology roadmap.

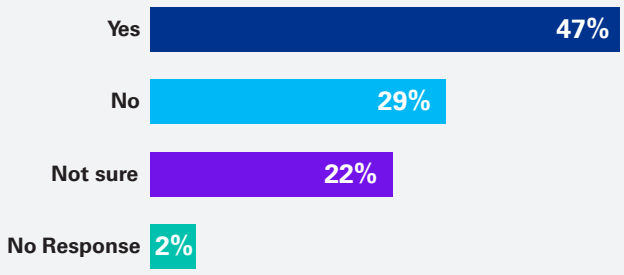
> The discussion shouldn't be about CSA in the future. Rather it should be around the actual approach taken to demonstrate intended use is being met through a risk-based approach.
>
> **—Francisco Vicenty, FDA**

Does your organization have a computer System Validation (CSV) framework to implement AI/ML based solutions in a GxP environment?



About half of the respondents do not have a CSV framework to implement AI/ML based solutions in a GXP environment

Is building an AI/ML CSV Framework in your 1-3 year Roadmap?



About half of the respondents do consider to have a CSV framework in 1-3 year roadmap

> While we do not have a framework yet, we do have a structure for collecting and sharing experiences across the organization; the guidance will come out of that. The possibilities are exciting, and I think it is going to lead to some really terrific growth. At this point we are encouraging people to dream and to share.
>
> **—Joanne Goldberg, Medtronic**

> Define a risk-based approach model for your company, document it, follow it, and be ready to defend it. What helped us tremendously is doing a lot of change management. Making sure you have change managers assigned and ready to go helping you along the way is critical. Educating people and raising awareness on what CSA is.
>
> **—Louis Rayal, GlaxoSmithKline**

Theme No. 3: Companies are adopting AI and ML

Key finding: Life sciences companies are increasing their use of AI and ML. These tools hold the promise of increasing productivity and efficiencies and can be incorporated in all aspects of the product lifecycle. However, fewer than half of respondents have leveraged CSA principles for their AI/ML framework.

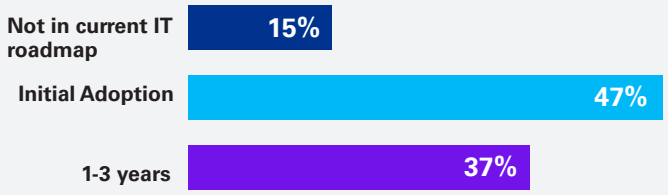
AL/ML usage on the rise: AI and ML are increasingly taking a larger share of the spotlight among organization's technology solutions. Life sciences companies are no exception, with many exploring the use of AI applications over the past one to three years. AI and ML have the potential to be incorporated in all aspect of the product lifecycle, from development to manufacturing to clinical trial to marketing. Respondents put manufacturing, quality, and clinical trials as the top three product development stages they believe would benefit most from AI/ML.

In our survey, nearly half of the respondents (47 percent) said they were in the initial stages of adopting AI and ML, while 37 percent said that they were already 1 to 3 years into their adoption. Only 15 percent indicated that AI and ML weren't a part of their current IT roadmap. As to whether their AI/ML solutions were built in-house or were vendor solutions, respondents were evenly split at 46 percent. (Eight precent gave no response.)

Use of ChatGPT

ChatGPT raised the profile of AI with the wider public and demonstrate the potential for generative AI has for business, education, and other aspects of life. However, the use of ChatGPT isn't without major risks—exposure of IP, inaccurate results, and bias responses, to name a few. Hence, organization have wary of allowing its use by employees for company business. This would seem to be the case among, life sciences companies, with a large majority (71 percent) of respondents saying that that their organization isn't using ChatGPT.

Within your current IT roadmap, where is your organization's adoption of Artificial Intelligence (AI)/Machine Learning (ML) Capabilities?



About half of the respondents organization's are in initial adoption of AI/ML capabilities

Percentage figures are rounded off to whole number

> ChatGPT is a tool, you are responsible for the outputs of the tool, not the tool itself.
>
> **—Daniel Walter, FDA**

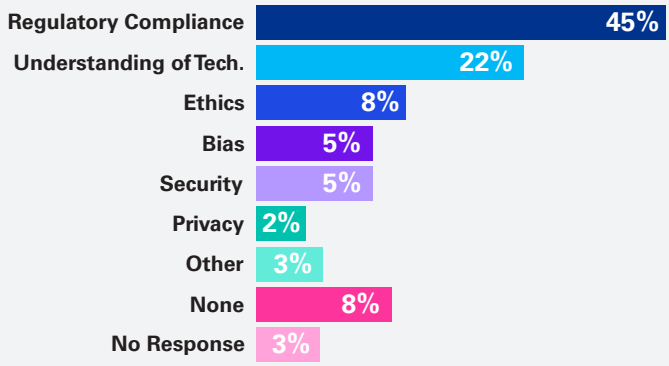
Theme No. 4: Regulatory compliance around AI/ML a chief concern

Key finding: AL and ML aren't without risks. For life sciences executives, regulatory compliance was the chief worry.

Managing AI/ML Risks: Although life sciences companies are pushing forward with their use of AI/ML, they do recognize a number of challenges. Most prominent among these is regulatory compliance around the need for the FDA to validate these solutions, which was cited by 45 percent of respondents.

The rise of AI—and generative AI in particular—has also raised other risk concerns. Among the potential challenges cited by respondents for AI/ML use were security (17 percent), ethics (11 percent), and bias (10 percent). Similarly, when asked if they had already encountered or anticipated any challenges with AI/ML adoption, 45 percent cited regulatory compliance, while 22 percent said understanding technology. That compares with 8 percent for ethics, 5 percent each for bias and security, and only 2 percent or privacy.

Have you encountered or do you anticipate any challenges with AI/ML adoption?



About half of the respondents do consider to have a CSV framework in 1-3 year roadmap

Main points of the FDA's CSA guidance:

The FDA's draft guidance on CSA for life sciences companies is aimed at promoting the use of advanced technologies to improve the quality and efficiency of the value chain (discovery, research and development, manufacturing, and commercial) to improve product quality and drive patient safety. The draft guidance encourages companies to focus more on critical thinking and risk-based approaches rather than on documentation, as is the case with CSV.

The key points include:

1. Emphasizing the importance of risk management in the software development process. This includes identifying potential risks, assessing their impact, and implementing strategies to mitigate them.
2. Encouraging a shift from compliance-based approaches to quality and performance-based approaches. This means focusing on the actual performance and functionality of the software, rather than just compliance with regulations.
3. Promoting the use of automated technologies to improve efficiency and reduce errors. This includes the use of software tools for data analysis, process control, and decision-making.
4. Encouraging a culture of continuous improvement and learning. This includes regularly reviewing and updating software assurance processes to ensure they remain effective and efficient.
5. Recognizing the importance of collaboration and communication among all stakeholders, including software developers, users, and regulators.

Moving forward with CSA: Understanding roles and responsibilities are key

The life-sciences industry has encountered some hurdles in its efforts to implement CSA principles. One significant challenge is around companies' culture and resistance to changing from the traditional methodologies that FDA has deemed compliant to CSA's more risk-based approach.

Moving beyond this challenge demands a clear understanding of the roles and responsibilities of the different parties involved. Applying CSA principles requires communication and collaboration between the multiple functions that participate in the software development process—including IT, quality, and regulatory affairs. Knowing who is included in the process and what they are responsible for is critical to guaranteeing that all processes are compliant with regulatory requirements and that they are safe and effective.

What's needed are clear guidelines and training around CSA principles and best practices to ensure that individuals fully understand what they are attempting to achieve. Silos cause confusion about which department should take responsibility for implementing CSA. Therefore, collaboration and interaction among all team members are crucial and need to be strongly encouraged.

Although the business owner is ultimately responsible for ensuring that the software meets regulatory requirements and ensures product safety and efficacy, it is equally important for everyone in all departments of the company to follow the regulations to maintain quality.

> We have some teams that have fully transitioned to CSA. We have other teams that I would describe as in the process of transitioning. We are certainly continuing to see teams make changes to their ways of working.
>
> **—Joanne Goldberg, Medtronic**

As life sciences companies move forward with their implementation of CSA principles, gaining an understanding of the following principles can help navigate the process.

- Ensure people understand the "big picture" and the rationale behind the changes.
- Encourage employees to shadow those already implementing these principles, sharing success stories from past inspections, and recognizing that change takes time can help employees successfully adapt to the new approach.
- Emphasize the importance of change management and stakeholder involvement when implementing CSA principles. Addressing the "what's in it for me" aspect—the return on investment—in change management discussions is vital for successful CSA implementation.
- Creating a vision and involving a broader group of stakeholders can make deploying new processes smoother and encourage buy-in.
- Demonstrate the benefits and practical results of adopting the new CSA approach, such as reduced errors and increased effectiveness in testing. Communicating these outcomes to team members can help them understand the rationale behind the changes and be more willing to adopt them.

Since the FDA's draft guidance, organizations have taken a renewed interest in CSA, and there has been an uptick in its adoption. Clear guidelines and training around CSA can help tackle remaining challenges and ensure the successful adoption and implementation across the organization.

> There is a lot of education that needs to happen before you go on your journey. Then as you start the journey make sure you communicate often as far as the value and how it impacts the organization moving forward and what it means from a regulatory and business perspective.
>
> **—Louis Rayal, GlaxoSmithKline**

> One of the hardest challenges to overcome is people not understanding their roles and responsibilities. Everyone needs to understand their roles and responsibilities when they come to the table.
>
> **—Geetanjali Abbi, Alkermes**

> The biggest challenge is the culture. It has been a challenge to shift the mindset to focus on risk rather than documentation.
>
> **—Louis Rayal, GlaxoSmithKline**

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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 US and EU 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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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 busine trusted relationships that are at the core of our business and reputation. Across the healthcare and life sciences sector, we are viewed as trusted advisors 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.

> For a long time, people only focused on documentation and testing, when it is all about showing the system is fit for its intended use.
>
> **—Francisco Vicenty, FDA**

> As people become more comfortable with the concepts of CSA and see it in execution, there will be a greater acceptance of the general approach.
>
> **—Daniel Walter, FDA**

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