

HOW COMPUTER SOFTWARE ASSURANCE (CSA) IS DRIVING TRANSFORMATION AND PATIENT SAFETY IN THE LIFE SCIENCES INDUSTRY.

By: Kelly Harewood, VP of Enterprise and Lab Solutions, Verista

5 Steps to Successfully Implement a Risk-Based Approach to Validation

Quality Assurance experts and other life sciences professionals strive to bring value to patients and business by defining and implementing critical-to-quality parameters and best practices. These teams share a focus on reducing patient risk in environments pressured to continually improve to meet the evolving demands of regulatory agencies, business, and customer needs. This daunting labyrinth mandates a complex strategy to map a safe and timely way through the maze. While controlled change is vital to good governance practices, not changing ossifies. Organizations and individuals, tasked with overseeing computer systems validation practices, need to evolve, too.

Such working environments demand business capabilities that drive the need for new technologies and new ways of working. Often, new technologies and supporting processes bring potential vulnerabilities and threats which must be faced head-on to assure patient safety parameters are met. Companies must also protect the information flowing through these tools and processes so it reaches only those individuals or entities for whom it is intended. Computer Systems Quality Assurance professionals are well positioned to partner with test developers, as well as information security management professionals, to design risks out of new systems by creating forward-thinking strategies that surface, assess, monitor and treat risk.

Computer Software Assurance (CSA) Is a Model That Innovative Companies Deploy to Consistently and Repeatably Deliver Excellence.

For companies new to this journey, bringing together key stakeholders and subject matter experts with the common goal of patient safety and clearly defined parameters for compliance, supports an innovative culture based on openness and trust. This enables the creation of new strategies and optimized processes for projects, which may have been bogged down in the past, via the implementation of newer technologies. Such a model aligns teams for success by equipping them to successfully navigate risk and become effective in surfacing greater efficiencies that deliver safe and effective therapies to market. Validation methods which are nimble, well-managed and controlled,

where necessary, increase project success, save time and free up resources to do more impactful work. **A successful CSA program is skillful in assessing system risk and creating control frameworks to monitor and manage activities which impact patient safety, product quality, end user and customer experiences, as well as third party risk.** CSA requires a re-thinking of the status quo, yet many organizations are still caught in linear processes codified into SOPs. They remain blind to tools and new ways of working which would help them to map new routes to improve product quality and remove unnecessary processes.

The Past – Focus on Regulatory Documentation, Rather than Product Quality, Manufacturing Efficiency and Patient Safety

For years, the focus of Computer System Validation (CSV) processes has been on producing accurate and approved documentation to present information to auditors. Auditors, such as the FDA, require evidence and records. Therefore, the CSV methodology inspires a compliance-mindset rather than an innovative one. As such, existing CSV methodology results in manufacturers spending around 80% of their time producing documentation and only 20% of their time doing actual testing of the software. Instead of assuring product quality, these extensive documentation requirements have become a bottleneck and burden to life sciences companies, deterring investment in more automated IT solutions. While documentation will always be a vital part of the process, it is more important to have a safe, high-quality product that meets patient needs, rather than robust documentation that passes an audit cycle.

CSV guidelines prioritize documentation, primarily to appease auditors, which can be both time-consuming and costly. This emphasis on documentation impedes the application of critical thinking during the validation process, along with opportunities to improve automation via system modernization.

CSA allows organizations to “right size” their validation efforts as it is based on risk that has been assessed and classified, which can streamline processes and save on resources. **This means that while all aspects of the systems used in manufacturing must be tested, only components**

essential to the quality of the product and safety of the patient need to be subjected to full validation rigor. This frees up testing and validation resources to focus on more value-added activities. CSA can benefit start-ups and established life sciences companies by providing guidance on how to manage validation processes in support of the changing landscape of digital transformation. The time-to-journey from CSV to CSA is critical because it helps to ensure the business is keeping up with technology innovation. Electronic solutions allow for a more connected, compliant and efficient organization.

How much time are your resources focusing on repeat actions for low-risk, low-probability scenarios? How much time are your resources documenting without assessing for and classifying the risk, then matching the amount of testing due to risk classification? What if their focus was on more testing, testing for proof of concept, or proof of intended use to find potential unforeseen issues prior to documentation? How much time could be saved over a project lifecycle if techniques for validation efforts were planned upfront? With CSA, long gone are the days of creating validation documentation for the sake of documentation. Real testing. Real time. More Automation. Less documentation. Is the life sciences industry ready to take the journey?

The Risk Journey

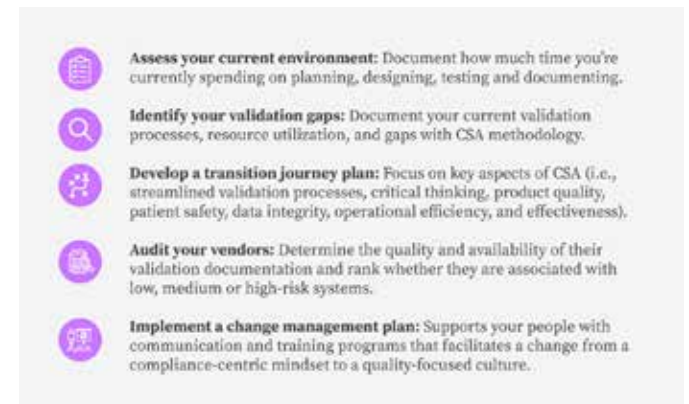
Software providers and other technology for life sciences organizations have been created to be easily implemented. Off-the-shelf applications enable companies to be more efficient and strategic, all while being compliant with regulations. Applications for use in regulatory environments must be assessed, then validated, if there is GxP impact. Cloud-based applications are created and often managed with vigorous regulations, standards, and controls. The key here is assessing the governance, risk controls and information security practices used in the creation and ongoing monitoring of software. The CSA model puts the focus on testing the features being utilized for the intended purpose. This method of testing ensures that organizations understand the real risks, and assist in maintaining data integrity, along with product quality and safety.

The life sciences industry has changed significantly over the years, and product launch timelines have been cut from years to months. Testing and validation efforts require similar improvements in project turnaround times, all while demonstrating real risk

reductions. CSA allows for less documentation while allocating more time to implement other improvements in the systems management lifecycle.

What Is Stopping the Journey to CSA?

The industry has the knowledge that electronic tools work; we understand risk and risk classification. So, why is it hard to transition from CSV to CSA? Is the industry holding on to legacy processes because they are ‘safe’ practices? CSA does not mean less safe, but more efficient with right-fit testing based on risk assessment. Change is intimidating in the life sciences environment; one small change can set off a paper blizzard which can take weeks to clear a path through. To be more efficient and to keep up with innovative technologies in the digital transformation landscape, the adoption of CSA is critical to the industry.



Steps to a Successful Transition

Organizations that follow the CSA approach can reduce costs and increase profits because it helps them right-size their validation efforts for intended use. It allows them to focus on quality throughout the product lifecycle, from concept to retirement. Not only can it reduce the validation time, it can also provide a competitive edge.

To transition to CSA, we recommend the following:

As the FDA prepares to release its new CSA guidance, life sciences companies need to be proactive and develop a strategy to transition to the new CSA methodology that focuses on patient safety, product quality, and data integrity. **CR**

About CIOReview

CIOReview is a leading technology magazine that is at the forefront of guiding enterprises through the continuously varying business environment with information about the solutions and services. The magazine serves as a trustworthy knowledge source as well as a platform for the C-suite executives, industry experts, technology buyers, and other decision-makers to share their valuable insights about new technology trends in the market.

CIOReview stands out with its learn-from-our-own-peers approach, enabling the senior management of a company to select from a wide range of choices available in the tech arena. The technology magazine bridges the gap between enterprise technology vendors and buyers by presenting the vetted content and community resources. The content of CIOReview includes insights, opinions of C-suite executives and leaders that are changing the paradigms in the business arena.

In recent years, technological tools act as a backbone for firms across various industries and allow them to execute operations without any hindrance. The podium of CIOReview allows the senior management to learn and share their experiences about a product, helping their peers to choose the most efficient solution which suits their requirement. The editorial mission of CIOReview is to provide influential technology and business executives with real-life, engaging opportunities and targeted, in-depth coverage of topics most critical to their success.