DATASHEET

Optimizing Validation through a Risk-Based Approach: Leveraging Computer Software Assurance (CSA)

Streamlining validation with forward-thinking approaches

Tired of the mountains of paperwork produced to validate a new or updated system? Frustrated with your company's inability to upgrade existing systems because of the burden of validation? Then let fme help you shift from the traditional computer system validation (CSV) approach to a more streamlined and efficient risk-based method embodied in computer software assurance (CSA).

Little has changed in processes around validation over the past twenty years. By understanding how CSA can be applied in your company, you will leave a large portion of the paperwork traditionally created behind and focus on the important aspects of your software-supported business processes. Learning to optimize your validation activities by focusing on the processes that impact patient health and safety increases your agility to test and adopt new business processes and systems. Read on to learn about fme's methodology, templates and services that accelerate your validation activities and help you stay competitive in the life sciences industry.

Challenge

How have other industries faced challenges that prevented them from innovating or impacted their quality and capabilities? A brief look at the automotive industry provides an interesting example from which we can learn some valuable lessons. Faced with exponentially increasing demand and a manufacturing process that only scaled linearly, Henry Ford was faced with a dilemma. How could he produce more cars, faster, to meet the demand? Hiring more people was an answer, but not efficient enough to achieve the goals. Instead, he had to rethink the approach to increase production – an analysis that ultimately resulted in the invention of the assembly line. Instead of having workers assemble the entire car, they were focused on sub-components, allowing them to focus on efficiencies, improve quality, and achieve the production goals demanded of them.

Life Science companies are facing the same issues – and the innovations Henry Ford applied in the 1930s can be leveraged in similar ways in the context of validation. The traditional CSV methodology demands extensive structure and documentation for every aspect of the system, with little to no scalability. We painstakingly document requirements, phrasing activities such as, »The system shall allow users with proper security to log into the system and prevent non-authorized users from accessing the data.« Or »The system shall promote the status of the regulatory submission to 'approved' when a valid approval date is entered.« Then we build a matrix that follows each requirement through logical

design, functional implementation, and then inclusion and verification in test scripts, capturing screenshots and doubling-up on signatures to demonstrate our complete allegiance to the process.

But is this process working? Are we able to adopt innovative technologies or the latest improvements from our software vendor partners? The challenge is balancing our ability to demonstrate thoroughness in our testing while ensuring the high-risk elements are properly validated. While this might be possible with a traditional CSV approach, the document-laden methodology impacts our agility and focus.

Solution

Adopting a risk-based approach focuses your attention through critical thinking, reducing documentation and scripted testing and emphasizes quality, patient safety and data integrity. Transitioning from CSV to CSA requires new tools, templates and techniques, revised SOPs, and training to embed into your culture the shift to thinking critically rather than dogmatically. Leveraging fme's process expertise and proven toolsets to implement a CSA approach addresses this challenge and accelerates your adoption to a more efficient approach.

We fast-track our client's evolution from CSV to CSA by offering alternatives to manual, labor-intensive validation efforts and establishing a risk-based methodology. By leveraging the best practices of previous decades with the spin towards streamlined approaches, fme offers innovative methods that minimize the impacts validation has traditionally inflicted and establishes new processes for achieving quality results.

By understanding your organization's business and regulatory compliance requirements, we help rightsize your validation SOPs to align with your culture and the needs of the life sciences industry. Empowered with our streamlined tools, you are able to rapidly validate newly implemented computerized solutions and are an enabler, rather than a deterrent, when upgrading existing solutions.

Benefit

- **Reduced validation time** – Accelerate computerized system upgrades through a streamlined CSA approach
- **Decreased validation costs** – Reduce documentation and focus on risk areas
- **Minimized compliance risk** – Avoid scrutiny by aligning your validation approach with health authority guidelines

Our Offering

Our package of CSA SOPs and templates offers a significant return on investment for computerized systems because they enable you to reduce compliance risks, lower costs and strengthen data integrity. We also offer services to revise your existing SOPs and templates. When transitioning from CSV to CSA many areas are impacted, and fme offers solutions to address these key functions:

- Risk Management and Framework
- Data Integrity Governance
- Change Management
- Infrastructure Qualification
- Computer Software Assurance
- Defect and Exceptions Management
- Data Archive and Migration
- Spreadsheet Assurance

Our CSA training options include online, instructorled or a hybrid of eLearning and remote instructor coaching. The eLearning solution includes on-demand videos, quizzes, and infographics and offers better use of time for learning simple to complex topics to understand best practices through collaborative learning.

We are happy to provide you with more detailed information on our validation service offerings and tailor an approach that meets your needs and exceeds your expectations. Please talk to us – we are looking forward to working with you!

CSA Quick Facts

- Can save 80 % of your validation costs
- Provides clarity for FDA's Guidance and methodology
- Drives critical thinking to identify, evaluate, and control potential impact to patient safety, product quality, and data integrity
- Focuses on the ability to leverage vendor qualification activities
- Provides streamlined testing instead of one-size-fits all

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