DATASHEET

compliance center™
powered by CARA

With its tedious testing and documentation, the traditional CSV (Computer Software Validation) model has finally given way to a risk-based CSA (Computer Software Assurance) approach. But this doesn't mean validation is easy to execute or document. Are you tired of long implementation times for your systems? Do you wish you could have quicker go-live dates, increased quality, less documentation, and more? fme can help implement your computerized systems with our built-for-purpose tool that combines our proven methodology in a flexible, easy-to-use online platform: **fme compliance-center™, powered by CARA.**

Based on the CSA guidelines and our 25 years of working with global pharmaceutical, medical, and other industries with strict compliance requirements, fme compliance-center™ is specifically built to streamline validation workflows with an efficient risk-based methodology.

The Challenge

When validating a solution using a paper-based process, it can take multiple days or weeks to obtain the many approval steps, signatures, and paper-based screen-shots required. Reviewing documents, correcting errors, controlling versions, and identifying and getting time with signatories add time and complexity, increasing the potential for errors and rework.

In fact, the FDA conducted a Case for Quality initiative to determine why so few companies were investing in automated solutions and why so many continued running long-outdated software versions.

This is what they concluded:

- Companies are focused more on compliance than on overall quality
- By directing activities towards creating documentation to remain "compliant," less attention was placed on activities and investment in overall quality
- The burden of performing document-centric compliance activities of rigorous and exhaustive testing has prevented the progression to more advanced automated manufacturing and other improved quality practices
- Study participants reported that the burden of computer software validation was, in some cases, twice the cost of the new system

The Solution

fme compliance-center™ is a pre-configured solution purpose-built to eliminate these issues and more using an electronic-based, paperless CSA validation method. Unlike other online tools, fme compliance-center™ uses a risk-based methodology to validate systems and processes. Using this methodology, we can determine which requirements and system functionalities matter the most, like patient safety and product quality. This risk-based methodology saves users time and money, typically performing less testing and documentation, allowing for faster implementations, and delivering a higher-quality product.

fme compliance-center™ allows users to do system level risk assessments to determine the appropriate validation approach. Assessments are based on:

1. **Technical risk**

a. Risk Level 1: (GAMP category 1) infrastructure software

b. Risk Level 2: (GAMP category 3) Standard purchased products that is not configurable

c. Risk Level 3: (GAMP category 4) Standard purchased products that are configured

d. Risk Level 4: (GAMP category 5) Custom software

2. **Operational Risk (examples taken from FDA guidance document**)

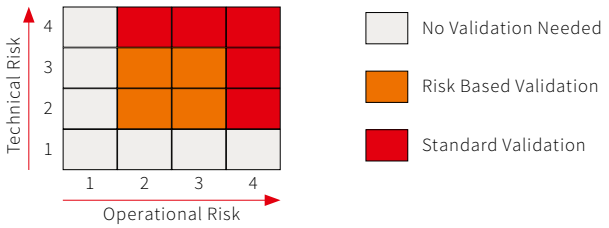
a. Risk Level 1: no impact to patient safety, product quality, or data integrity (ex.: general business process or operations software)

b. Risk Level 2: small impact (ex: production/qms support software)

c. Risk Level 3: moderate impact (ex: production/qms software)

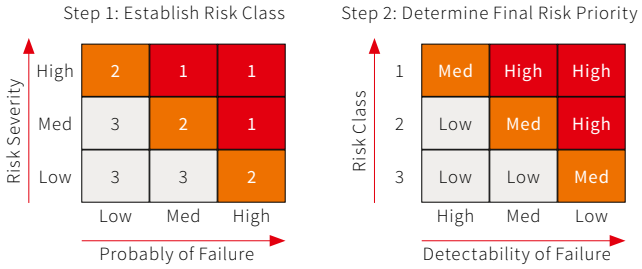
d. Risk Level 4: high impact (ex: Medical Device software)

System Risk Assessment



It also enables process risk assessment based on the severity, probability, and likelihood of detection to determine validation requirements.

Process Risk Assessment



fme compliance-center™ delivers:

- Paperless Validation
- Risk-Based Validation Methodology
- Cloud-based QMS
- Audit Trail History
- Automated Reporting
- Document Reviews & Approvals
- No Browser Limitations

Benefit

- **Increased Quality** – Focusing efforts on high-risk processes allows for a better overall system quality
- **Decreased Risk** – Following the updated guidelines provided by the health authority reduces the risk of issues
- **Less Documentation** – More time is spent on critical thinking, and less time editing, reviewing, and printing documents
- **Lower Costs** – Less time spent on tedious tasks translates to a more efficient and cost-effective process that saves time and money
- **Faster Implementation** – A more efficient process also means a quicker review, approval, and go-live date

Summary

fme compliance-center™ is the premier platform for executing your validation requirements while leveraging the efficiency of the newest CSA methodology. This solution can help reduce overall costs and bring your product to market quicker and with higher quality. The team at fme can expertly validate any solution for you and can provide fme compliance-center™ as a QMS to use for your own projects.

› Contact us to set up a free demonstration and overview of fme compliance-center. We would love to show you how you can streamline and accelerate your validation processes. We look forward to working with you!