WHITE PAPER

NAVIGATING THE COMPLEXITIES OF FDA COMPLIANCE:

A Guide to Effective Software Validation

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BACKGROUND

The Food and Drug Administration (FDA) has created regulations to protect consumers from poor quality, unsafe foods and beverages. To ensure that they are FDA compliant, companies must establish and follow current good manufacturing practices (CGMPs) for the creation and distribution of safe and effective products.[1]

All companies in FDA regulated industries are legally required to validate software if that software could impact product quality, safety, or effectiveness. A modern enterprise resource planning (ERP) system can support FDA compliant systems, especially because ERPs can be highly configurable and relatively easy to update. And while the onus is on the user to configure their ERP to be compliant with any requirements, external advisors and validation partners can help companies ensure that their processes are operating within the established parameters and that their ERP is optimally configured and updated for their unique needs.

WHEN AND WHY IS FDA REGULATION AND SOFTWARE VALIDATION REQUIRED?

Industries that must adhere to FDA regulations include food and beverage manufacturers, pharmaceuticals, botanicals, medical devices, surgical instruments, dental equipment and supplies, ophthalmic supplies, and orthopedics. Companies that manufacture and distribute the parts or ingredients used to produce these goods are also included.

FDA software validation is required when an FDA-regulated company establishes documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes. And while the FDA provides guidelines regarding software validation, it does not tell companies exactly how to do it. Each company must determine how to do so, provide evidence that it has been done, and verify that the software meets FDA requirements. Although most software is purchased from a third-party, the third-party vendor is not responsible for validation. The responsibility lies with the company itself.

Validating software involves establishing documented evidence that proves the software consistently meets predetermined specifications and quality attributes—that is satisfies its intended use. The goal of validation is not only to prove the software works correctly and consistently, but to also identify, document, and mitigate any issues that could negatively impact production of regulated goods or their parts and ingredients.

THE ROLE OF COMPUTER SYSTEM VALIDATION

Computer system validation (CSV) is crucial for companies in FDA-regulated industries. CSV involves verifying the integrity, reliability, and compliance of computer systems used in critical processes. This comprehensive validation process encompasses the entire system lifecycle, including definition of requirements, system design, configuration, testing, installation, operation, and maintenance.

By adhering to regulatory guidelines and industry standards, CSV helps mitigate risks associated with system failures, data integrity issues, and security breaches. It ensures that these systems perform as intended, maintain data accuracy, and comply with regulatory requirements, thereby supporting the safety, efficacy, and quality of products and services in FDA-regulated industries.[2]

IMPLEMENTING COMPUTER SOFTWARE ASSURANCE

The FDA released the Computer Software Assurance for Production and Quality System Software (CSA) guidance in 2022, which provides recommendations for implementing risk-based CSA. Simply put, CSA is crucial in FDA-regulated industries where software systems play a vital role in data creation, management, product production, and regulatory compliance. CSA helps to safeguard data, optimize system performance, and mitigate potential threats, ensuring the highest standards of quality and reliability in software development and implementation.

The 2022 guidance emphasizes the importance of implementing CSA measures to ensure the security, availability, and reliability of computer systems and software used in GxP-regulated activities.[3] While the guidance was issued from the Center for Devices and Radiological Health, the consensus is that the guidance can be leveraged by all GxP industries.

The CSA guidance offers both information and examples on how to implement a process. The guidelines recommend that manufacturers adopt a risk-based approach to CSA, which involves identifying and assessing risks to computer systems and software and implementing appropriate controls to mitigate these risks.

One point on "CSV vs. CSA:" validating your computer system for its intended use is still the law. CSA still requires manufacturers to take steps to ensure the quality of their software.[4] According to a recent article, "Both approaches [CSV and CSA] play a similar role...but have some key differences. Whereas CSV validates that a system does what it is designed to do and complies with regulations, CSA moves beyond compliance only with a risk-based approach that provides high confidence in system performance." [5]

CAN MY COMPANY HANDLE OUR SOFTWARE COMPLIANCE ACTIVITIES INTERNALLY OR DO WE NEED TO WORK WITH AN OUTSIDE PARTNER?

Below are a few questions to consider when making the decision about how to handle your company's FDA software validation compliance needs:

- Do we have the internal resources to ensure that a new ERP or other software is validated in accordance with FDA regulations? Could these resources take on the process as part of a new ERP implementation?
- Can our existing team review and/or modify any future upgrades or changes to our existing systems, including handling the revalidation process, if necessary?
- Are we able to address any audit or inspection findings if a regulatory body uncovers issues related to CSV or CSA?
- Do our employees need training on CSV and CSA? Are they prepared to handle any current and future CSV training needs of new employees?
- Are we prepared to learn of, prepare for, and make changes in response to any regulatory updates?
- Do we have procedures in place to handle risk management, including when launching new products or entering new markets?
- Do we have any long-standing resource constraints that affect our ability to manage CSV and CSA activities?
- Can we prepare for regulatory inspections, including conducting a pre-inspection audit? Can we then identify and proactively address potential CSV or CSA issues? [6]

THE BENEFITS OF USING A MODERN ERP

An integrated, configurable ERP can help your company manage FDA requirements and product recalls through features such as:

- Recipe management with item attribute information which guarantees accurate data
- Ability to account for by-products
- Automated data collection which eliminates manual entry
- Finite capacity scheduling that can adjust the schedules for equipment using dedicated processing lines and side-by-side machines

Again, ERPs and other business management solutions do not carry the responsibility for complying with FDA requirements—these solutions help companies become and remain compliant. Experienced technology and compliance advisors can help food and beverage companies choose and implement the right ERP for their needs, and also can fill crucial knowledge and ability gaps that can make the difference between success and failure to meet standards.[7]

ADDITIONAL BENEFITS OF VALIDATION DURING AN ERP IMPLEMENTATION

Undergoing the validation process during an ERP implementation offers many advantages, including:

- Deepened Understanding of Business Processes: Validation requires comprehensive documentation and understanding of business processes, ensuring that ERP configurations produce expected results.
- Long-term System Consistency: The validation process verifies that procedures are in place to create and maintain master file information correctly, ensuring consistent system behavior long after implementation.

If you have any questions or are ready to take the next step in FDA compliance, simply click here or call us at 1-800-719-3307 to connect with our team of specialists today. We offer personalized advice and support tailored to your business needs, ensuring you stay ahead of compliance requirements.

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7. *Sage. (n.d.). Introduction to Sage X3 FDA compliance and product recalls. Sage X3. http://www.sage.com/na/~/media/site/industry/food-and-bev/pdfs/Managing-product-recalls_FDACompliance*

ABOUT NET AT WORK

Founded in 1996, Net at Work is a leading technology advisor to thousands of small-to-medium sized businesses throughout North America. The award-winning consultancy offers a rich portfolio of technology, expertise, and services to help organizations derive value from the transformative effects of technology. To start unleashing the power of your business, visit www.NetatWork.com.

ABOUT PERFORMANCE VALIDATION

Performance Validation (PV) is a global Commissioning, Qualification and Validation partner for pharmaceutical and medical device manufacturers. Headquartered in Indianapolis, PV specializes in turning compressed timelines into compliant ones across a diverse array of environments, using innovative, adaptive approaches that balance production realities with strict regulatory requirements.

CONNECT WITH US

To learn more about FDA compliance, connect with an expert at Net at Work today:

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