

SharePoint Essentials for Successful

CFR 21, Part 11

& GAMP 5

Compliance



EXECUTIVE SUMMARY

Anyone that is part of an industry that is regulated by The Food and Drug Administration is very familiar with CFR-21, Part 11 compliance requirements. These include drug makers, medical device manufacturers, biotech companies, biologics developers, CROS and others.

CFR-21, Part 11 is a regulation set forth by the FDA that must be followed in regards to electronic records and electronic signatures. More specifically, it requires companies to implement controls, including audits, system validations, audit trails, electronic signatures, and documentation for software and systems involved in processing electronic data. GAMP5 (Good Automated Manufacturing Practice) is a validation method for CFR- 21. It is essentially a set of document management requirements to ensure patient safety, product quality and data integrity in manufacturing.

There has been a strong focus on data integrity generated in regulated quality control laboratories since the Able Laboratories and Leiner Health Products fraud cases in 2005 and 2006. One major compliance issue stemmed from the fact that paper copies of records differed, sometimes radically, from the electronic records maintained in the data system. The FDA revealed massive record falsification and mismanagement in an effort to avoid detection of several defective medications. In the Leiner Health case, they pleaded guilty to giving a false appearance that a batch of drugs had passed quality tests and allowed the nonconforming drugs to be shipped to customers.

The consequences can be dire for companies who fail to comply. The FDA may give a warning letter (FD-483), or a more serious reprimand such as a Consent Decree that may result in significant delays to regulatory approval, time-to-market, product recalls or facility closures. Continued noncompliance may result in possible criminal and civil actions under various Federal and State statutes.

Overcoming the challenges of data integrity is a high priority for many companies, it is crucial to use a system that will maintain compliance requirements in the most effective way.

SharePoint offers an applicable solution for compliance requirements

Staying in compliance with mandated regulations for FDA-regulated industries is crucial. Microsoft SharePoint offers easy, effective solutions that comply with CFR-21, Part 11 and GAMP5 requirements.

How SharePoint solves compliance issues for FDA-regulated industries

SharePoint 2013 is a browser-based collaboration and document management platform from Microsoft. It has a built in workflow engine and can be configured to meet various business requirements, including electronic document management and records management. SharePoint 2013 is a configurable application and is considered a Category 4 type system as defined in GAMP5.

SharePoint validation of CFR-21, Part 11 requirements

The following features of SharePoint explain how it is compliant to CFR-21, Part 11 and GAMP5 requirements.

Active Directory Integration. SP integrates with active directory to ensure only authorized accounts can access the system.

Prevention of Unauthorized Users. SharePoint is able to prevent unauthorized users from accessing areas of the system where electronic records are created and maintained. It is possible to configure the record center with separate access controls.

Restrict Access to System Administration. For additional safety; SharePoint can also restrict access to system administration and configuration by setting up security groups or permissions.

Protect Data Records. SharePoint can protect data records from deletion and enable their accurate retrieval. Administrators can set up the SharePoint Information Management Policy feature and apply retention policies to various content types for a required period of time. In addition, the record center can be configured with separate access controls and independent permissions to prevent deletion of records. Versioning can also be added to ensure that changes to a document's metadata are versioned.

Other features of SharePoint that make it extremely beneficial for compliance include:

- Well defined, granular permissions and access controls
- Information Management Policies. This feature enables you to control who can access your organizational information, what they can do with it, and how long to retain it. These policies can be attached to content types, document libraries and lists in collaborative and record spaces so that once policies are applied, all content will automatically be managed in accordance with that policy.
- Version control
- Comprehensive audit trails
- Manage lists and track information centrally
- Design electronic forms for the collection of data for everyday operational activities
- Manage distribution of information and collaboration between geographically dispersed teams
- Manage processes better with interactive workflows in line with SOP
- Provide real time metrics through dashboards to facilitate decision making

Add ShareKnowledge for comprehensive compliance coverage

Out-of-the-box SharePoint compliance features are great, adding a software system like ShareKnowledge to the mix can assure that compliance for CFR-21, Part 11 and GAMP5 is thoroughly covered.

Here is an example of a situation where ShareKnowledge enhances the compliance areas that may be lacking in SharePoint™.

Example Use Case - Using SharePoint to generate submission ready electronic PDF records that will be submitted to the FDA as part of their INDs (required by predicate rule).

Requirements - The system should be able to:

- Allow electronic signature of records
- Invalidate an e-signature if the signed record is modified
- Manage the version number of records
- Rendering final records read-only

With ShareKnowledge, you can attach an e-signature to ensure a learner has read and understood the training content. Choose from a two-part authorization using name and password or simply a check box. In addition, with ShareKnowledge, you can automatically put restrictions on any changes to a document that has an e-signature requirement. Additional training requirements can also be added along with an e-signature.

Scheduling recurring events in ShareKnowledge for refreshment trainings makes it easy to ensure all requirements are completed each year or time interval. With the PowerSync feature, it makes it easier than ever for the right people to receive the right training. PowerSync automatically adjusts training needs with promotions, transfers and team changes without any additional staff work. ShareKnowledge is able to work with all of your organizational data, HRIS and Active Directory to keep training applicable to your employees. ShareKnowledge provides easy to use advanced reporting features that can be customized to fit your specific business needs.

Conclusion

FDA-regulated industries must comply with CFR-21, Part 11 and GAMP5 requirements or face severe penalties. Choosing to utilize the functionality of SharePoint and combining it with a comprehensive LMS like ShareKnowledge offers a complete solution to ensure full compliance.

SharePoint's comprehensive content management capabilities including workflows, versioning, auditing and system validations make it the first choice for any industry looking to enhance their quality assurance program. Going one step further and linking SharePoint with ShareKnowledge, a software system built on SharePoint, is a winning compliance match.