THE ULTIMATE GUIDE TO

21 CFR Part 11 Compliance

TENFORCE
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INTRODUCTION

Is it any wonder more and more pharmaceutical companies are turning to digital tools to manage regulated processes?

These systems streamline workflows and operations to reduce risks whilst improving efficiency. Better still, they help you comply with regulations such as FDA 21 CFR Part 11.

When it comes to compliance, FDA 21 CFR Part 11 is a big one. With its focus on data integrity, audit trails, system access, and trained users, compliance is key for businesses in the American market if they want to avoid fines, market withdrawal, reputational damage, or even license revocation.

We'll break down key requirements of FDA 21 CFR Part 11, and, best of all, show how TenForce helps you stay compliant.

CHAPTER I

What is the FDA 21 CFR Part 11?

21 CFR Part 11 is an FDA regulation that sets criteria for using electronic records and signatures.

It covers electronic records that are created, modified, maintained, archived, retrieved, or transmitted under FDA requirements.

This regulation applies to any pharmaceutical company in the U.S. using electronic systems for recordkeeping and signatures.

Its main goal is to ensure the integrity, authenticity, and reliability of these electronic records and signatures in FDA-regulated activities.

CHAPTER II

What are the key requirements of the FDA 21 CFR Part 11?

21 CFR Part 11 lays out what you need for electronic records and electronic signatures to be just as trustworthy and reliable as paper records and signatures on paper. Here are some key points to keep in mind:

Electronic records

21 CFR Part 11 guidelines help you create, maintain, and archive electronic records. They focus on keeping records accurate, readable, and easy to access.

Here's what you need to do:

- **21 CFR 11.10 (Closed Systems):** Validate your system, ensure records are easy to access, control access, maintain audit trails, check operations, and train users.
- **21 CFR 11.30 (Open Systems):** Follow the same rules as closed systems, plus add extra security like encryption and digital signatures.
- **21 CFR 11.50:** Include the signer's name, date, time, and meaning of the signature in your records.
- **21 CFR 11.70:** Ensure electronic signatures are linked to records to prevent falsification.

Electronic signatures

21 CFR Part 11 compliance requires electronic signatures to be unique, securely managed, and linked to the right records.

To be valid and legally binding, signatures must follow specific rules to ensure that the signer is really who they say they are, the signature isn't tampered with, and the document is authentic.

Here are some key requirements:

- **21 CFR 11.100:** Signatures must be unique, and the user's identity must be verified.
- **21 CFR 11.200:** You need at least two identification components, like a code and a password, with controls for signing sequences.
- **21 CFR 11.300:** Ensure codes and passwords are unique, have procedures for lost credentials, and safeguard transactions.

CHAPTER II CONTINUED

Audit trails

You need to implement secure audit trails for your electronic records that chronologically document any changes made.

Audit trails help you track any modifications made to electronic records, including who made the changes, when they made them, and what they changed.

Operational controls

You should ensure your system has operational checks to verify that events follow the correct sequence and prevent errors and fraudulent activities in your electronic records.

An automated document creation and approval workflow, that follows a phase-gate process, will help you ensure that documents move through phases in a specific order, and once approved, they can't be edited.

This ensures that the right personnel create, review, and approve records at each stage.

Training

To comply with 21 CFR Part 11.10(i), make sure all your system users have the right education, training, and experience for their tasks.

Train each user thoroughly and document this training well. This way, auditors can easily review the operational audit trail and cross-reference with your training logs.

User authentication and authorization

You need to ensure only authorized individuals access and perform actions on electronic records, such as creating, modifying, or approving them.

You must have robust authentication processes to confirm user identity.

CHAPTER II CONTINUED

Validation

Validate your electronic systems to ensure they perform as intended and meet 21 CFR 11.10(a).

Test and document system functionality, security measures, and data integrity controls regularly to remain compliant.

Data integrity

Maintaining the integrity of your electronic records and signatures is at the heart of FDA 21 CFR Part 11.

Implement adequate controls to prevent unauthorized changes or deletions and keep your records accurate and reliable.

Record retention and retrieval

Ensure your electronic records are available for inspection, review, and copying by the FDA throughout their retention period, as specified by Section 21 CFR 11.10(b).

Your system should be able to generate and export copies of stored records and provide both electronic copies and paper printouts.

Security

Protect your electronic records from unauthorized access, alteration, or destruction with robust security measures.

Use both procedural safeguards, like access controls, and technical safeguards, such as encryption.

For full details, and to ensure compliance, refer to the official information in the FDA 21 CFR Part 11 regulations.

CHAPTER III

What are the benefits of using a 21 CFR Part 11 compliant system?

- **Better data integrity:** protecting the integrity of electronic records helps you generate accurate and reliable data throughout the record lifecycle, supporting data analysis tasks such as monitoring KPIs and continuous improvement.

- **Regulatory compliance:** compliance helps you avoid serious repercussions such as warning letters, fines, and penalties, product recalls or import alerts, legal action, reputational damage, and increased scrutiny from the FDA.

- **More efficient processes:** a digital system simplifies electronic recordkeeping and signatures, saving you time, resources, and manual effort.

- **Closer collaboration:** a compliant system enables authorized users to share information across departments and locations, ensuring a controlled environment for project collaboration and data exchange.

- **Improved auditability:** track electronic records and signatures with time-stamped, computer-generated audit trails, reducing errors, ensuring traceability and accountability, and supporting accurate investigations.

- **Increased security:** strong security measures like access controls, user authentication, and data encryption help you protect sensitive information from unauthorized access, ensuring data confidentiality.

- **Simplified recordkeeping:** eliminate paper records and cut storage costs with a compliant document management system. Easily manage, access, and retrieve electronic records, improving your data accessibility and long-term retention.

CHAPTER IV

How does TenForce support your compliance with 21 CFR Part 11?

Meeting 21 CFR Part 11 guidelines is easier with a digital document and process management system like TenForce.

Our software simplifies compliance, unifying your quality and manufacturing goals to turn regulatory compliance into a competitive edge. Here's how we can help:

Controlled, audit-ready documents

With TenForce, authorized users can access electronic records in the secure document repository from anywhere. Users can search for and immediately retrieve records using a search feature that searches in document titles and content.

We support copying and exporting records for audits and regulatory inspection, including printable documents, and our controlled documents capability ensures that printouts are tracked.

User authentication and authorization enforcement

TenForce enforces user authentication and authorization with system access controls like password protection and role-based access.

Only authorized individuals can access electronic records and signatures. Each user has a unique ID and password, ensuring secure access and protecting the confidentiality of your records.

CHAPTER IV CONTINUED

Reliable electronic signatures

TenForce provides the fields required for FDA 21 CFR Part 11–compliant signatures, including name, date, time of signing, and meaning of signature. Each signature is linked to its record, ensuring it can't be removed, copied, or transferred to falsify the record.

Comprehensive training and training records

TenForce offers comprehensive training on using our system during implementation, with refresher sessions available upon request.

Our Competence Management module streamlines training management by creating plans, assigning training and evaluations, monitoring progress, and sending automated notifications when qualifications are due for renewal.

Accelerated validation

You need to validate your systems to make sure they're accurate, reliable, and can spot any invalid or altered records, as required by 21 CFR 11.10(a). Regular validation checks are essential.

We make this easy for you by handling all software validation, saving you time and resources. Every time we release a new version or apply updates, we revalidate the software, so you don't have to worry about it.

Automated audit trail capture

TenForce automatically captures secure, computer-generated, and timestamped audit trails, recording the date and time of all activities, including creation, modification, and deletion of records. These audit trails are exported in a human-readable format and cannot be modified.

CONCLUSION

Next steps for your compliance journey

TenForce's eQMS software makes it easy for pharmaceutical companies to comply with 21 CFR Part 11. Our quality management suite ensures your data is accurate, your operations run smoothly, and you easily meet all regulatory requirements.

With features like secure document management, reliable electronic signatures, automated audit trails, and strong user authentication, you can confidently manage compliance.

Why stress about compliance when you can turn it into an advantage? With TenForce, staying compliant becomes a seamless part of your workflow, protecting your business and reputation.

Curious to see how it works? Book a demo today and chat with our friendly experts to discover how TenForce can simplify your quality management.