FOXIT ESIGN FOR FDA 21 CFR PART 11 COMPLIANCE

INTRODUCTION

Using digital PDF documents and electronic signatures is increasing in frequency with FDA-regulated industries such as manufacturing and pharmaceuticals. Because the work conducted by organizations in these industries can impact health and safety, proper document processes and workflows that are also FDA-compliant are essential. This is where electronic signatures come in. The FDA has determined that while adherence to compliance with ESIGN and UETA is essential, further guidelines must be followed to maintain safety, consistency, and proper audit trails. 21 CFR Part 11 is an FDA regulation that outlines compliance requirements for electronic signatures and electronic records in these industries. By using Foxit eSign for electronic signatures, companies can streamline their paperwork processes and ensure correct and thorough FDA compliance.

WHY MORE BUSINESSES ARE CHOOSING FOXIT ESIGN FOR THEIR COMPLIANCE SOLUTION

When FDA-regulated companies need a reliable signing solution, they turn to Foxit eSign. When you complete documents with Foxit eSign, you sign with confidence knowing we meet industry regulations, integrate with current technologies, understand 21 CFR Part 11 requirements, and keep sensitive information always secured. Key features and benefits of Foxit eSign include:

Rely on Comprehensive Compliance

- Foxit eSign works with industry specialists to guarantee the most reliable and secure eSign technology and processes for easy and superior FDA 21 CFR Part 11 compliance.

- HIPAA compliance, UETA, ESIGN, and eIDAS acts are adhered to, ensuring legally binding documents that will stand in court.

Ensure Data Security

- Investing in Foxit eSign software offers organizations a sophisticated alternative to keep their documentation secure with SOC 2 Type II compliance, 256-bit encryption, cloud servers in trusted US and EU data centers, and more.

- From limiting access to certain users to password-protecting sensitive documents and restricting when and where a document can be edited or signed, Foxit eSign does it all.

Improve Sales & Sample Management

- Sales teams can easily collect signatures online and from any internet-enabled device using Foxit eSign.

- Regardless of where a customer is situated, a sales or sample transaction can take place, meaning there's never a slowdown due to paperwork.

Simplify Vendor Approvals

- Ensure smooth material ordering by sending requests for approvals and supplies electronically.

Ensure Comprehensive Audit Trails

- Foxit eSign has system audit tools to thoroughly monitor document history and current status by tracking who had signed, when and where signatures took place, who has accessed the document, and where a document may be in the process of completion.

- Thorough audit trails with Foxit eSign allow FDA-compliant companies to more easily accommodate documentation requests and audits from the FDA and trace problems to the source faster when they occur.

Helpful Functionality in Various Languages

- To support pharmaceutical and manufacturing companies that span national borders, Foxit eSign offers functionality in 16 languages and growing.

Better Paperwork Accuracy and Validity

- Signer delegation and sequences can be easily set in place with Foxit eSign to ensure the correct persons sign off on approvals and procedures, thus reducing inaccuracies.

- With electronic signatures used as opposed to wet ink signatures, documents are ensured to be less vulnerable to forgery, tamper-proof, and more easily verifiable as valid.