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Webinar on

A Complete Guide For 21 CFR Part 11

Webinar Description

FDA's 21 CFR Part 11 was enacted in the late 1990s and implementation success across the pharmaceutical and other regulated industries have been mixed. There are very specific limitations that arise when using ER/ES capability, such as the elimination of print capability to prevent users from making decisions based on a paper record as opposed to the electronic record. It also requires very specific identification of users that ensures the person signing the record is the same person whose credentials are being entered and verified by the system. The rule for changing passwords must be rigorously adhered to and the passwords must be kept secure.

Webinars in this bundle will focus on the importance of ensuring that electronic record/electronic signature (ER/ES) capability built into FDA-regulated computer systems meets compliance with 21 CFR Part 11.

The webinar format is 1-1.5 hours of audio-visual presentation, including a brief Q&A session.

This webinar bundle includes below 2 recorded webinars:

21 CFR Part 11 (Electronic Records/ Signatures) Compliance for Computer Systems Regulated by FDA

21 CFR Part11 Compliance

21 CFR Part 11 (Electronic Records/ Signatures) Compliance for Computer Systems Regulated by FDA

Presented by Carolyn Troiano

The Webinar will focus on the importance of ensuring that electronic record/electronic signature (ER/ES) capability built into FDA-regulated computer systems meets compliance with 21 CFR Part 11. This includes the development of a company philosophy and approach and incorporating it into the overall computer system validation program and plans for individual systems that have this capability.

It is also critical that the system specify the exact meaning of the signature. It may be that the person conducted the work, recorded the result, reviewed the result, or approved the result. A person may simply be attesting to the fact that they reviewed the work and the signatures, and there was appropriate segregation of duties (i.e., the person recording the result is not the same as either the person reviewing or the person giving final approval)

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21 CFR Part11 Compliance

Presented by Edwin Waldbusser

This Webinar will explain what 21 CFR Part 11 is, why it is important to FDA regulated companies and how conformance to Part 11 differs from just having good IT security. Procedures for controlling electronic signatures and electronic records will be explained. FDA regulated companies want to transition to electronic records for economy and efficiency. FDA, because of its concern for patient safety, wants to prevent electronic records from being compromised with possible resulting harm to the patient. FDA has set up regulations that address both data security and patient safety. We will show how 21 CFR part 11 considers both.

Companies want to transition to electronic records but are afraid of compromising their quality system and receiving 483's at their next inspection. Part of this fear originates from confusion. FDA originally published a rather severe 21 CFR Part 11. After industry complaints, the FDA acknowledged that the regulation, as written, would result in nobody attempting to convert to electronic records. But, instead of rewriting the regulation, FDA said it would "selectively enforce" sections of the regulation. This webinar will explain what all these means.

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