

21 CFR Part 11 (Electronic Records/Signatures) Compliance For Computer Systems Regulated By FDA

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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.

AREAS COVERED IN THIS WEBINAR

- Computer System Validation (CSV)
- System Development Life Cycle (SDLC) Methodology
- Good “Variable” Practice (GxP) (Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP), Good Clinical Practice (GCP))
- Validation Strategy & System Risk Assessment
- GAMP 5 “V” Model & 21 CFR Part 11
- Electronic Records/Electronic Signatures (ER/ES)
- Security, Access, Change Control, and Audit Trail
- Q&A

WHY SHOULD YOU ATTEND

This webinar will help you understand in detail the application of FDA's 21 CFR Part 11 guidance on electronic records/electronic signatures (ER/ES) for computer systems subject to FDA regulations. This is critical in order to develop the appropriate validation strategy and achieve the thoroughness required to prove that a system does what it purports to do. It also ensures that a system is maintained in a validated state throughout its entire life cycle, from conception through retirement. ER/ES capability can vary, and the approach should be based on the specific case and the risk of failing to meet the guidance associated with it.

Topic Background

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. Rules for changing passwords must be rigorously adhered to and the passwords must be kept secure.

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).

A company must have specific policies and procedures in place that explicitly state responsibilities and provide guidance for implementing and using ER/ES capability. These must clarify the 21 CFR Part 11 requirements and provide insight as to the way the company interprets its responsibility for meeting it. As FDA continues to evolve and change due to the many factors that influence the regulatory environment, companies must be able to adapt. New technologies will continue to emerge that will change the way companies do business. While many of these are intended to streamline operations, reducing time and resources, some unintentionally result in added layers of oversight that encumber a computer system validation program and require more time and resources, making the technology unattractive from a cost-benefit perspective.

INSTRUCTOR PROFILE

Carolyn Troiano has more than 40 years of experience in computer system validation in pharmaceutical, medical devices, animal health, tobacco, e-cigarette/e-liquid, and other FDA-regulated industries. During her career, Carolyn worked directly, or on a consulting basis, for many of the larger pharmaceutical companies in the US and Europe, developing validation programs and strategies, and collaborated with FDA and other industry representatives on 21 CFR Part 11, the FDA's electronic record/electronic signature regulation.

CAROLYN TROIANO



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