GRC Online Training Hub
EDUCATORS
Axons Technology and Solutions

Webinar on

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

Learning Objectives

- *Gain an understanding of FDA's 21 CFR Part 11 Electronic Records/Electronic Signatures (ER/ES) guidance document*
- *Develop the ability to apply 21 CFR Part 11 when implementing, validating and maintaining computer systems in your organization*
- *Understand the best practices for maintaining a computer system with ER/ES capability in a validated state*
- *Discuss the best practices necessary to ensure all systems with ER/ES capability are validated appropriately*
- *Learn how to develop the appropriate computer validation strategy, to ensure a good balance of cost vs. risk, as it applies to the use of ER/ES capability*

GRC Online Training Hub
EDUCATORS
Axons Technology and Solutions

- *Understand how to effectively document the process of computer system validation where ER/ES capability exists, and maintain current information about the various systems in your organization and how they are maintained in a validated state*
- *Learn how to gain information about trends in ER/ES validation, as the industry progresses and new best practices emerge*
- *Understand some of the key "pitfalls" to avoid when employing ER/ES capability*
- *Q&A*

GRC EDUCATORS
Online Training Hub
Axons Technology and Solutions

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.

PRESENTED BY:

Carolyn Troiano has more than 35 years of experience in computer system validation in the pharmaceutical, medical device, animal health, tobacco, e-cigarette/e-liquid and other FDA-regulated industries. She is currently an independent consultant, advising companies on computer system validation and large-scale IT system implementation projects.

GRC Online Training Hub EDUCATORS
Axons Technology and Solutions

On-Demand Webinar

Duration : 90 Minutes

Price: $200

Webinar Description

This seminar 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.

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.

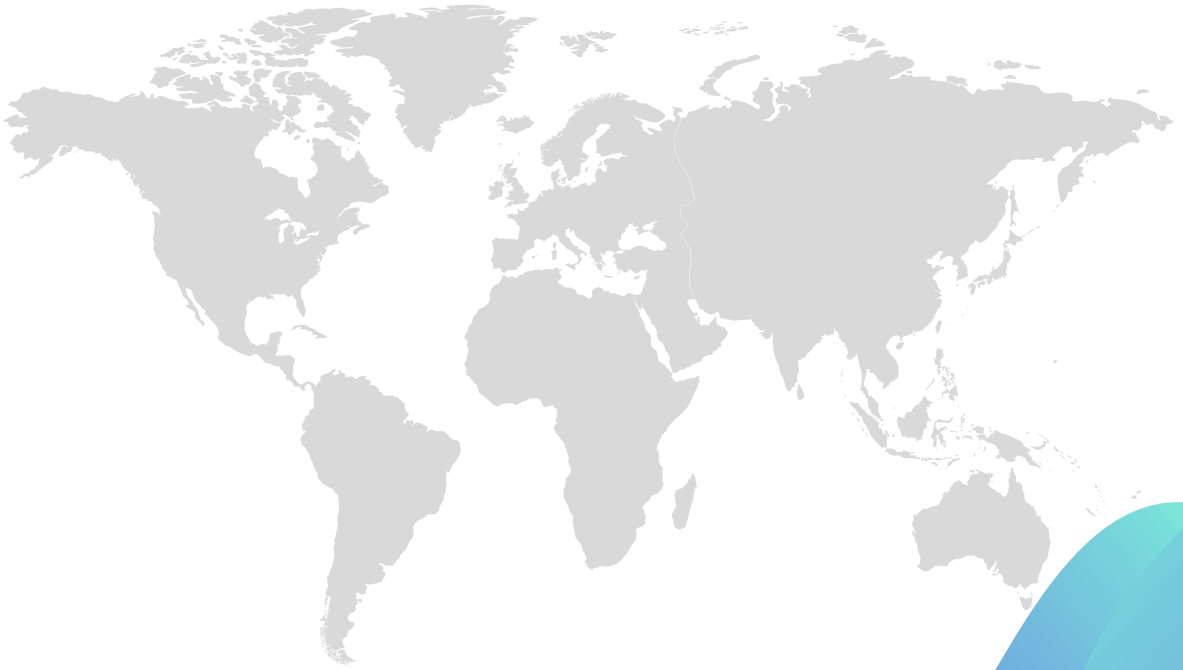
FDA's 21 CFR Part 11 was enacted in the late 1990s and implementation success across the pharmaceutical and other regulated industries have been mixed. There are very specific limitations that arise when using ER/ES capability, such as the elimination of print capability to prevent users from making 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.

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 regulation and provide insight as to the way the company interprets their 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.

Who Should Attend ?

Information technology analysts, QC/QA managers and analysts, clinical data managers and scientists, analytical chemists, compliance managers, lab managers, automation analysts, computer system validation specialists, GMP training specialists, business stakeholders and individuals who are responsible for computer system validation planning, execution, reporting, compliance, maintenance and audit. This webinar will also benefit any consultants working in the life sciences industry who are involved in computer system implementation, validation and compliance.



GRC Online Training Hub EDUCATORS
Axons Technology and Solutions

GRC Online Training Hub
EDUCATORS
Axons Technology and Solutions

To register please visit:

www.grceducators.com
support@grceducators.com
740 870 0321