GRC Online Training Hub
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Webinar on

9 Valuable Webinars on FDA System Requirements and Data Governance for Regulated Industries

Webinar Description

This webinar bundle covers major system and data governance requirements for computer systems regulated by FDA. It also covers systems classification, best practices to prepare for a system validation audit,21 CFR Part 11 compliance, disaster recovery and business continuity planning, mobile applications, planning of functional requirements, testing of systems regulated by FDA, legal regulatory and policy issues related to validation of computer systems regulated by FDA.

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

This webinar bundle includes below 10 recorded webinars

Data Governance for Computer Systems Regulated by FDA

FDA Compliance and GAMP V Computer System Classification

Best Practices in Preparation for an FDA Computer System Validation Audit

21 CFR Part11 Compliance

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

Disaster Recovery and Business Continuity Planning for Computer Systems Regulated by FDA

Functional System Requirements Planning for Computer Systems Regulated by FDA

In Depth Testing of Computer Systems Regulated by FDA

Legal, Regulatory and Policy Issues Related to Validation of Computer Systems Regulated by FDA

Data Governance for Computer Systems Regulated by FDA

Presented by Carolyn Troiano

Upon completion of this session, attendees will have an understanding of how to tie data governance activities and investments to corporate drivers, strategies, and compliance. They will learn about establishing data governance program objectives, decision-making organizational structures and assigning roles and responsibilities that fit within the organizational culture. It is particularly important to understand the role of data owners vs. data stewards, and the criticality of data identity, trust, security, integrity, accessibility, reliability, and consistency. You will see how best to design data governance processes that encompass people, processes, and technology, and understand the policies and procedures necessary to support the data governance framework. The attendees will have a good grasp of how to leverage the best practices across all systems by creating a standardized program for data governance.

FDA Compliance and GAMP V Computer System Classification

Presented by Carolyn Troiano

Upon completion of this session, attendees will have an understanding of how to classify computer systems in accordance with GAMP V, and develop a sound validation strategy for each system to meet FDA compliance. The attendees will understand the level of testing required for each classification, and the appropriate level of documentation that must be completed to support it. They will also gain an understanding of the training and skills required to both classify systems and work on various classifications of systems to validate or maintain them. The attendees will have a good grasp of how to leverage these practices across all systems by creating a standardized program for classifying systems in accordance with GAMP V.

Best Practices in Preparation for an FDA Computer System Validation Audit

Presented by Carolyn Troiano

Computer System Validation (CSV) and the System Development Life Cycle (SDLC) Methodology are at the core of ensuring that data related to FDA-governed activities is collected, managed and governed in a way that protects the integrity, quality, accessibility, and reliability. All computer systems used for related activities are validated in accordance with the CSV and SDLC methodology. They must also be maintained in a validated state. The validation strategy must take into account the system risk assessment process and GAMP 5 system classification approach. The documentation created throughout the validation process must be in accordance with FDA standards and must be maintained as a set of "living" documents throughout the system's life. An FDA audit of regulated computer systems will explore the documentation that tells the story of how your system was validated and maintained in a validated state. It must tell that story with clarity and accuracy and must reflect best industry practices.

21 CFR Part 11 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.

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.

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.

Disaster Recovery and Business Continuity Planning for Computer Systems Regulated by FDA

Presented by Carolyn Troiano

This course will focus on the key aspects of Disaster Recovery and Business Continuity Planning efforts, including best practices and principles for handling this type of work in an FDA-regulated environment (i.e., the system “touches” product during the manufacturing, testing or distribution of the product, or during any other functional activity). The material will include the various aspects of system and data related concerns, and the result will be a prescriptive approach to helping teams and individuals mitigate risk and reach a higher level of security and compliance.

Computer system validation has been regulated by FDA for more than 30 years, as it relates to systems used in the manufacture, testing, distribution and management of a product in the pharmaceutical, biotechnology, medical device, tobacco and other regulated industries. Disaster recovery activities often include efforts to deal with both system functionality and data integrity, quality, accessibility and accuracy. The specific tasks and deliverables must be completed with care toward maintaining a compliant environment.

Functional System Requirements Planning for Computer Systems Regulated by FDA

Presented by Carolyn Troiano

The course will focus on the key aspects of requirements development and management, including best practices and principles for handling this key component of project work in an FDA-regulated environment (i.e., the system “touches” product during the manufacturing, testing or distribution of the product, or during any other functional activity). The material will include the various aspects of how to develop requirements, and the result will be a prescriptive approach to helping teams and individuals reach a higher level of compliance. It will also provide guidance on how to keep costs low and avoid “scope creep,” which can lengthen the time and require more money to achieve.

FDA guidelines are very specific in terms of how computer systems are to be managed, and each company should have a specific strategy and methodology, along with a set of rigorous tactical processes and procedures that prescribe how third-party participants in projects should be managed.

In Depth Testing of Computer Systems Regulated by FDA

Presented by Carolyn Troiano

We will discuss the importance of applying industry best practices when performing the validation process for a computerized system used in an FDA-regulated environment (i.e., the system "touches" product during the manufacturing, testing or distribution process). Such a system must be validated in accordance with FDA guidelines for computerized systems and documented accordingly. Testing is a very large component of this work, and will be looked at in greater detail.

In addition, we will touch on elements of electronic records and electronic signatures (ER/ES, or FDA 21 CFR Part 11), as these have come under FDA regulations in the late 1990's. Specific criteria must be met in order to consider such a record or signature as valid in the eyes of FDA regulators.

Legal, Regulatory and Policy Issues Related to Validation of Computer Systems Regulated by FDA

Presented by Carolyn Troiano

This course will describe the best practices for developing a strategy and conducting validation work, including roles and responsibilities, and the procedures that should be followed. FDA guidelines are very specific in terms of how this is to be done, and each company should have a specific strategy/methodology, and a set of very rigorous internal policies and procedures that prescribe how this will be planned, executed and documented.

Since 1983, with the issuance of the guidance document from FDA on validation of computerized systems, this topic has applied to pharmaceutical products and the computer systems used to generate, collect, analyze, process and report data. Subsequently, the FDA applied the same guidance to computer systems used in the biologics and medical device industries. More recently, the FDA has brought tobacco products under their regulatory jurisdiction, and has applied guidelines for validation of computer systems used in the manufacture, testing or tracking of tobacco-related products. This includes cigarettes, cigars, e-cigarettes and other forms of smokeless tobacco, such as “pouch” products.

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