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Webinar on

FDA's Recent Clarification on Guidance for Managing Data Integrity for Regulated Systems

Learning Objectives

- *Tie data integrity management activities and investments to corporate drivers, strategies, and compliance*
- *Establish data governance program objectives, decision-making organizational structures and assigned roles and responsibilities that fit within the organizational culture to ensure data integrity is maintained throughout its life cycle*
- *Understand the role of data owners vs. data stewards in establishing and maintaining data integrity*

Data integrity is at the heart of good compliant data management and decision-making in an FDA-regulated organization, and must be maintained throughout its entire life cycle.

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.

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On-Demand Webinar

Duration : 90 Minutes

Price: $200

Webinar Description

Effective and compliant computer system data management is critical to organizations in the pharmaceutical, biologics, vaccines, tobacco, animal health, medical device or other FDA-regulated industry. During the past 30 years, best practices have been developed to ensure computer systems used in these environments can be cost-effectively managed while meeting all aspects of FDA compliance. To take this a step further, we are now looking at ways to ensure the data that resides on these systems is also managed in a compliant manner and one that will provide the best results for operations at the lowest cost.

After attending this course, you will understand data governance as a quality control discipline for assessing, managing, using, improving, monitoring, maintaining, and protecting organizational information. It is a system of decision rights and accountabilities for information-related processes, executed according to agreed-upon models which describe who can take what actions with what information, and when, under what circumstances, and, finally, using what methods.

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.

There are specific requirements for the execution and documentation of the computer system validation process, particularly maintaining data integrity through good governance over the life cycle of the data. It is crucial that you build a solid program that can be defended during an FDA audit or inspection. There are also policies needed to support these efforts.

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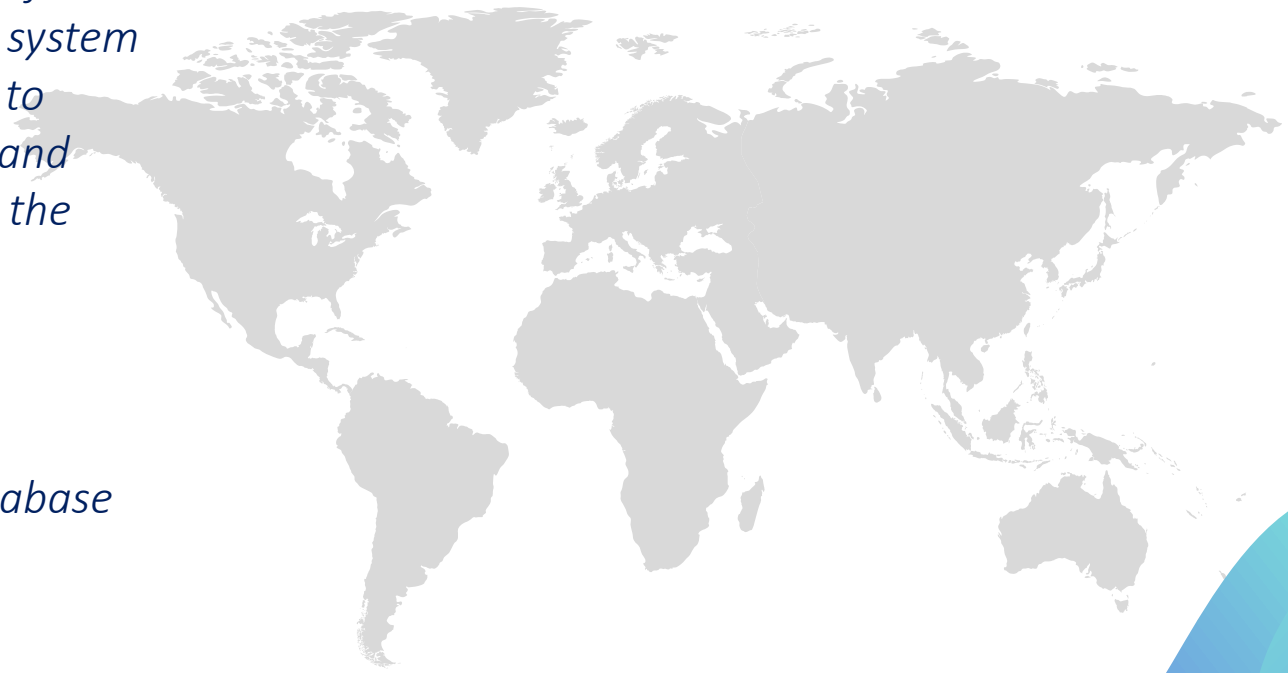
Who Should Attend ?

You should attend this webinar if you are responsible for planning, executing or managing the validation of a system governed by FDA regulations, specifically in relation to pharmaceutical, medical device, biologics, tobacco, and related products. This includes cigarettes, as well as the more recently developed e-cigarette products and smokeless tobacco products.



Manufacturing Analysts and Supervisors
Information Technology Professionals, including Database Specialists
QC/QA Analysts and Managers
Laboratory Analysts and Managers
Compliance and Audit Managers
Automation Analysts and Managers
GMP Training Specialists
Computer System Validation Specialists
Business Stakeholders/Subject Matter Experts
Business System/Application Testers
Supply Chain Managers/Analysts

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Finally, anyone who is acting as a consultant or contractor to a company in an FDA-regulated industry should attend to ensure they are able to bring the most current knowledge and expertise to their assignment.

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