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Webinar on

Data Governance For Computer Systems Regulated By FDA

Learning Objectives

- *Establishing a data governance framework and program for data that is collected, analyzed, stored or reported using a computer system subject to FDA regulations*
- *How to use a data governance framework as a logical structure for classifying, organizing and communicating complex activities involved in making decisions about and taking action on enterprise data*
- *How to ensure that data governed by FDA adheres to the principles of Computer System Validation (CSV), System Development Life Cycle (SDLC) Methodology, and Electronic Records and Signatures (21 CFR Part 11), as applicable*
- *How to leverage industry best practices in developing an overall data governance framework and program*
- *How to ensure your data & Q&A*

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This webinar is intended for those working in the FDA-regulated industries, including pharmaceutical, medical device, biological, animal health, organ donation, and tobacco.

PRESENTED BY:

Carolyn Troiano has more than 35 years of experience in computer system validation in the pharmaceutical, medical device, tobacco and other FDA-regulated industries. She has worked directly, or on a consulting basis, for many of the larger pharmaceutical and tobacco companies in the US and Europe. Carolyn developed validation programs and strategies and participated in the review of 21 CFR Part 11, or the FDA's electronic record/electronic signature (ER/ES) regulation.

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On-Demand Webinar

Duration : 90 Minutes

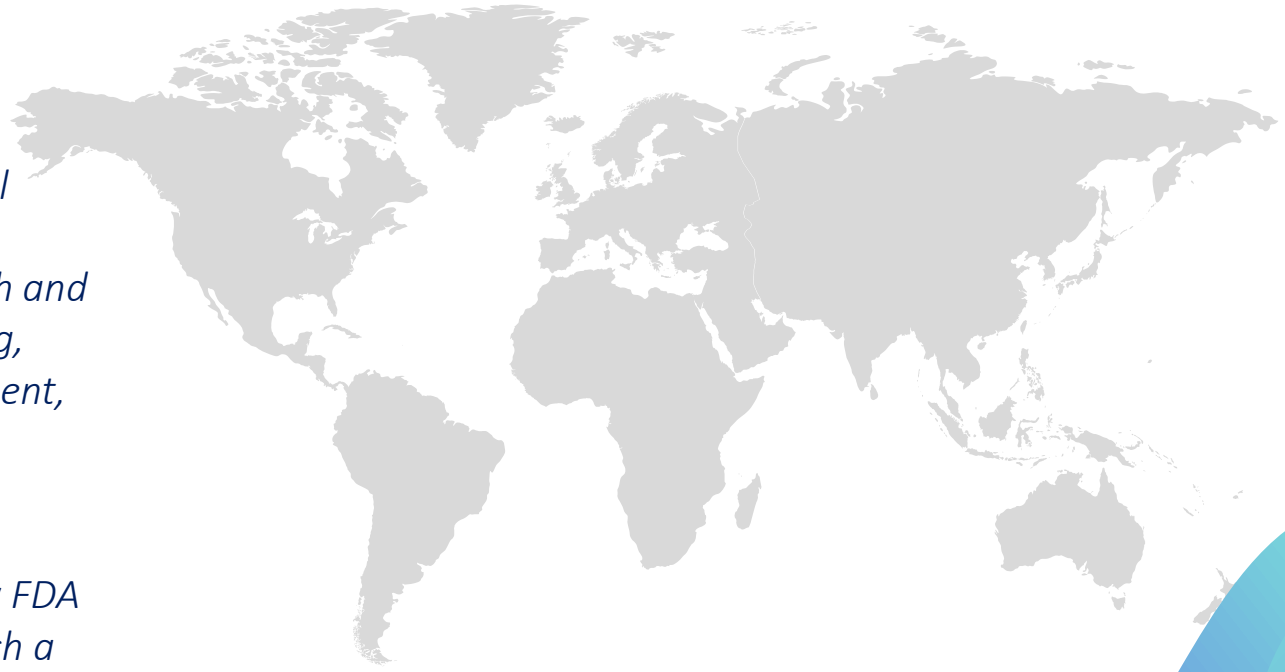
Price: $200

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.

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.

Who Should Attend ?



This webinar is intended for those working in the FDA-regulated industries, including pharmaceutical, medical device, biological, animal health, organ donation, and tobacco. Functions that are applicable include research and development, clinical sample manufacturing, packaging, labeling and distribution, clinical testing and management, adverse events management and post-marketing surveillance. You should attend this webinar if you are responsible for planning, executing or managing the implementation of any clinical trial system governed by FDA regulations, or if you are maintaining or supporting such a system. Examples of who will benefit from this webinar include:

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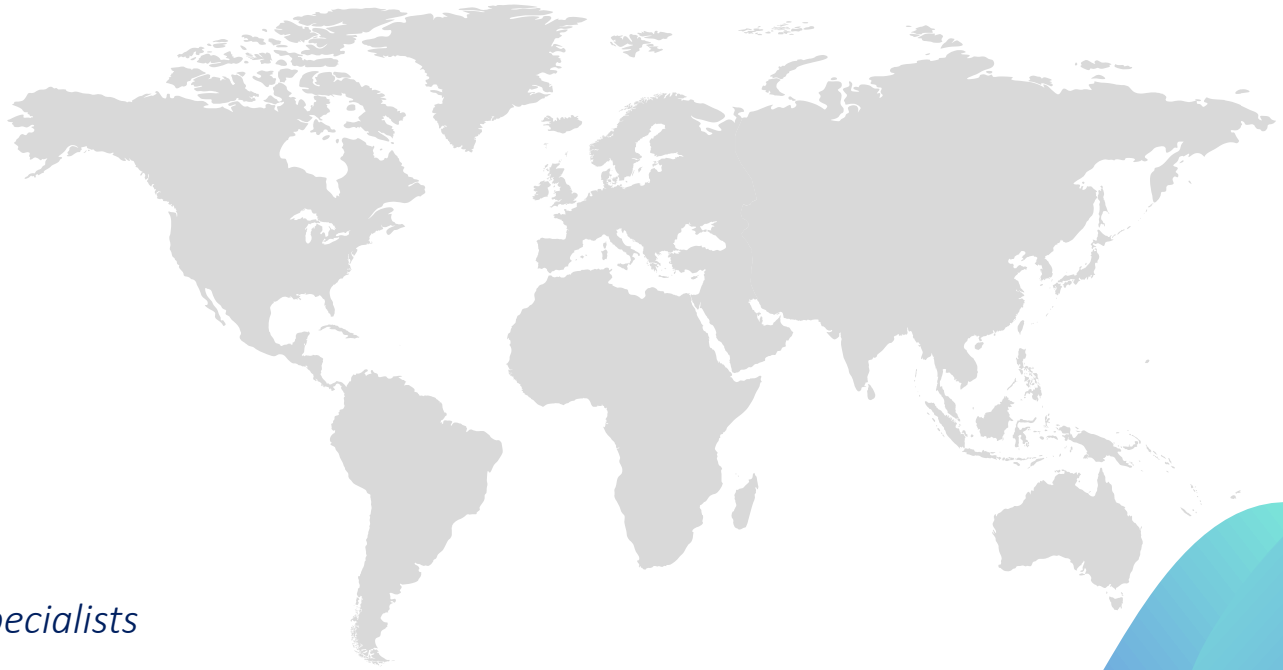
- *Data “Owners”*
- *Data “Stewards”*
- *Information Technology Analysts*
- *Information Technology Developers and Testers*
- *QC/QA Managers and Analysts*
- *Clinical Data Managers and Scientists*
- *Analytical Chemists*
- *Data Analysts and Managers*
- *Compliance and Audit Managers*
- *Laboratory Managers*
- *Automation Analysts*
- *Computer System Validation Specialists*
- *GMP Training Specialists*
- *Business Stakeholders/Subject Matter Experts*
- *Business System/Application Testers*
- *System Implementation, Integration and Validation Specialists*



Anyone who is involved in the development, testing, manufacturing, storage, handling and distribution of product must understand and conform to FDA requirements for data quality and integrity. 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. This webinar will also benefit any consultants working in the life sciences industry who are involved in computer system implementation, validation and compliance.

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