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Webinar on

Best Practices In Preparation For An FDA Computer System Validation Audit

Learning Objectives

- *Learn about 21 CFR Part 11 and what is required for compliance*
- *Learn about industry best practices related to compliance and computer system validation*
- *Understand strategies for reducing the cost and complexity of compliance with FDA regulations, including 21 CFR Part 11*
- *Understand how the System Development Life Cycle (SDLC) methodology supports the computer system validation process*

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- *Understand how to effectively document the process of computer system validation, 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 invalidation, as the industry progresses and new best practices emerge*
- *Understand some of the industry best practices to apply when following the SDLC methodology*
- *Q&A*

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In this Webinar you will learn how to do FDA Computer System Validation Audit in the most cost-effective manner.

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 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

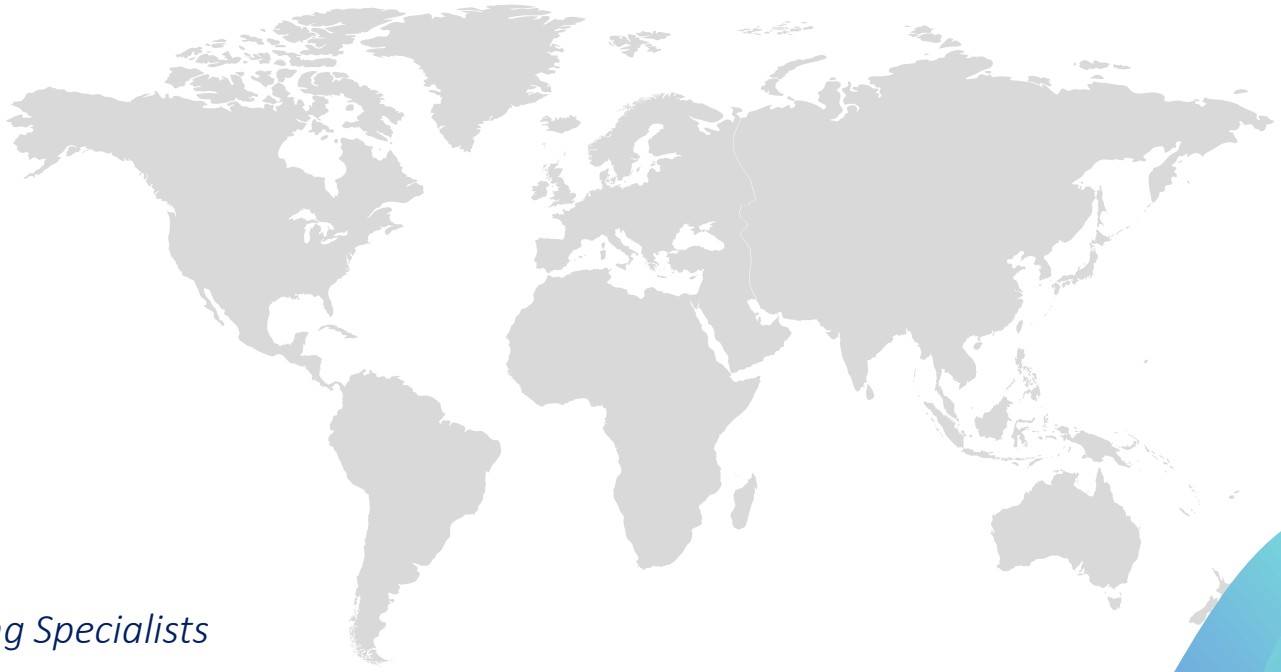
Price: $200

Webinar Description

Effective and compliant computer system validation is critical to any pharmaceutical or FDA-regulated organization. Following best practices for developing a validation program that includes planning, execution and maintenance components will ensure that these efforts will meet all regulatory agency requirements and expectations. Preparedness will improve your relationship with the agency and ensure a more cooperative and successful audit experience. FDA requires that all computer systems used to produce, manage and report on GxP (GMP, GLC, GCP) related products be validated and maintained in accordance with specific rules. You'll learn all about how to prepare your system validation documentation for an FDA audit of your company's computer systems. It is not enough just to validate a computer system and defend your approach to regulatory agencies. You will also need to ensure that the data and information collected, analyzed and reported using the system can be defended effectively, as well. In this course, you will learn how to apply industry best practices to ensure that you and your system users and other stakeholders are fully prepared to defend your systems, data, and information to regulatory agencies. At the same time, you will learn how to do this in the most cost-effective manner.

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.

Who Should Attend ?



Information Technology Analysts

QC/QA Managers, QC/QA Analysts

Clinical Data Managers, Clinical Data Scientists

Analytical Chemists, Automation Analysts

Compliance Managers, Laboratory Managers

Computer System Validation Specialists, GMP Training Specialists

Business Stakeholders responsible for computer system validation planning, execution, reporting, compliance, maintenance, and audit

Consultants working in the life sciences industry who are involved in computer system implementation, validation and compliance

Auditors engaged in the internal inspection of labeling records and practices

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