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Webinar on

Good Documentation Practices (GDPs) to Support FDA-Regulated Computer System Validation (CSV)

Learning Objectives

- *Learn the requirements for documenting efforts related to systems governed by FDA*
- *Discuss the best practices for documenting computer system validation efforts, including requirements, design, development, testing and operational maintenance procedures*
- *Review examples of incorrect, incomplete, or otherwise inappropriate and non-compliant documentation and understand why these are not acceptable*
- *Learn how to prepare a procedure that will capture the best practices for FDA compliant documentation*
- *Discuss the importance of training as it relates to good documentation practices to ensure FDA compliance, Q&A*

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This webinar includes the information needed to create and maintain good documentation that meets FDA compliance standards.

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.

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On-Demand Webinar

Duration : 90 Minutes

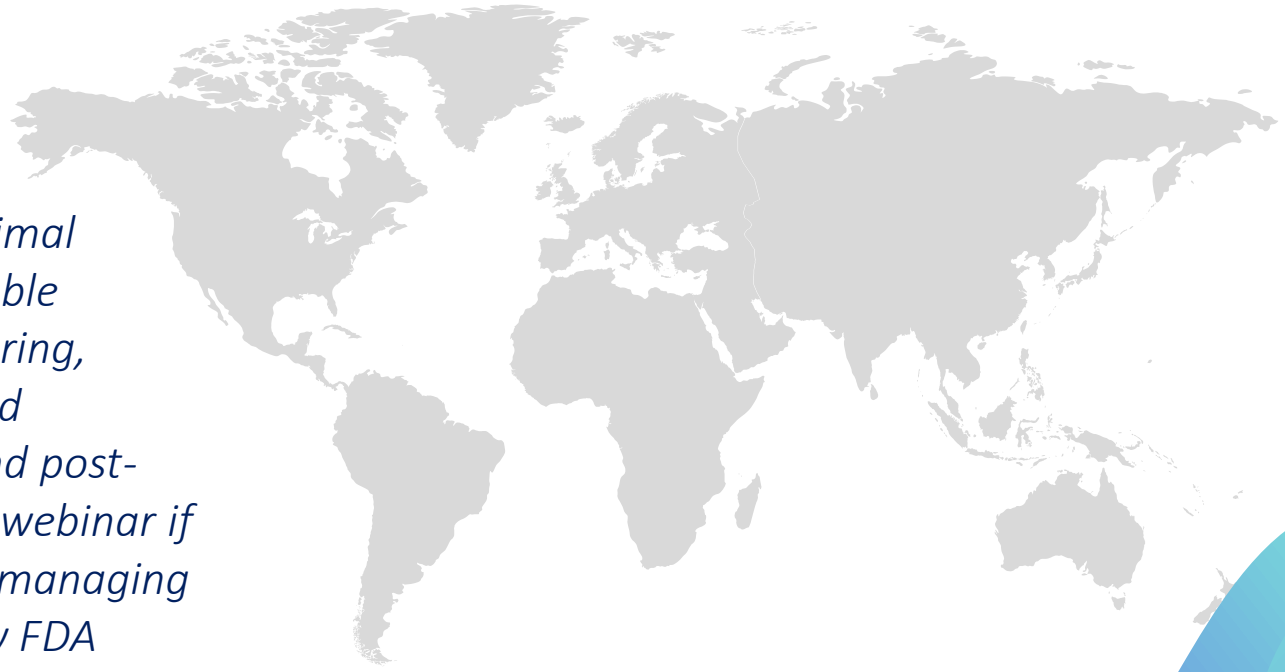
Price: $200

Webinar Description

The webinar will leave you with the information needed to create and maintain good documentation that meets FDA compliance standards. You will learn about what must be done and what must not be done. In addition, you'll learn about the various computer system validation deliverables and how to document them.

Computer system validation has been regulated by FDA for more than 30 years, as it relates to systems used in the manufacturing, testing and distribution of a product in the pharmaceutical, biotechnology, medical device or other FDA-regulated industries. The FDA requirements ensure thorough planning, implementation, integration, testing, and management of computer systems used to collect, analyze and/or report data. Electronic records and electronic signatures (ER/ES) came into play through guidelines established by FDA in 1997 and disseminated through 21 CFR Part 11. This code describes the basic requirements for validating and documenting ER/ES capability in systems used in an FDA-regulated environment. All of the FDA-regulated computer systems that are validated in your organization must include documentation to support the fact that these were done in accordance with good documentation practices. The documents must be created, managed and stored in a manner that will ensure integrity through the entire lifecycle of the computer system.

Who Should Attend ?



This webinar is intended for those working in the FDA-regulated industries, including pharmaceutical, medical device, biological, animal health and tobacco. Functions that are applicable include research and development, manufacturing, Quality Control, 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 system governed by FDA regulations, or if you are maintaining or supporting such a system.

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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Information Technology Analysts

Information Technology Developers and Testers

QC/QA Managers and Analysts

Analytical Chemists

Compliance and Audit Managers

Laboratory Managers

Automation Analysts

Computer System Validation Specialists

GMP Training Specialists

Business Stakeholders/Subject Matter Experts

Business System/Application Testers

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