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Webinar on

Functional System Requirements Planning For Computer Systems Regulated By FDA

This webinar intended to provide specific guidelines for coaching attendees on the best practices for developing requirements for computer systems regulated by FDA.

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 : 60 Minutes

Price: $200

Webinar Description

This course is intended to provide specific guidelines for coaching attendees on the best practices for developing requirements for computer systems regulated by FDA. There are several key types of requirements that will be covered, including user, functional, performance, system, environmental and other categories.

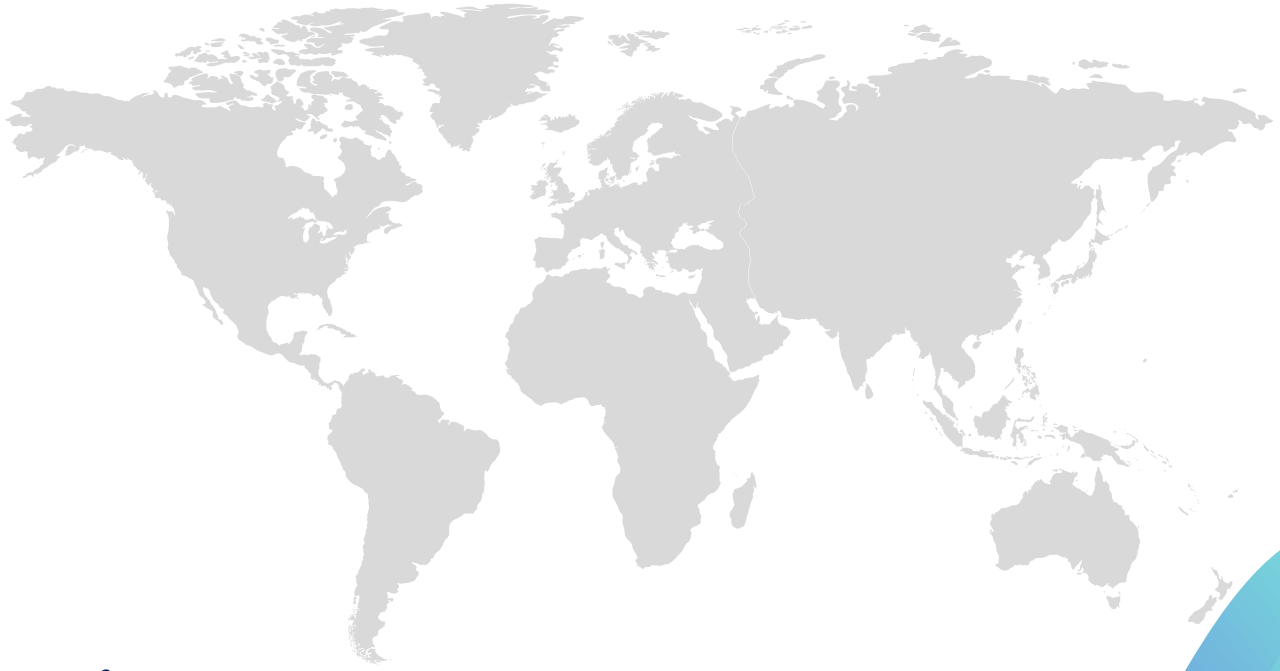
The attendee will learn about the requirements for planning, executing and documenting the requirements and the Requirements Traceability Matrix (RTM), along with who is responsible and how these should be timed within the overall validation execution.

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.

Who Should Attend ?

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



Anyone who is involved in the development, testing, manufacturing, storage, handling, and distribution of product must understand and conform to FDA requirements for computer system validation.

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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To register please visit:

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