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Webinar on

Functional System Requirements for Computer Systems Regulated by FDA

Learning Objectives

- *Gain knowledge about how to develop detailed requirements, based on industry best practices that will minimize your operational costs while keeping you in good standing with the FDA*
- *Understand Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) testing to ensure you have thoroughly tested that every requirement is met*
- *Understand the key documentation required throughout the requirements and other computer system validation efforts*
- *Understand the policies needed to support your computer system validation effort*

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- *Understand how to effectively test systems with electronic records/electronic signatures (21 CFR Part 11) capability*
- *Learn how to leverage requirements and other computer system validation documentation for the future when a system is upgraded or enhanced*
- *Learn how to maintain current information about the various systems in your organization and how they are maintained in a validated state*

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This course will provide a condensed overview of the practices that deliver the best results by directing the attendees to the most critical and cost-effective of methods, techniques, and tools available to assure a compliant validation process.

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

We will discuss the importance of applying industry best practices when performing the validation process for a computerized system used in an FDA-regulated environment (i.e., the system "touches" product during the manufacturing, testing or distribution process). Such a system must be validated in accordance with FDA guidelines for computerized systems and documented accordingly. Defining the functional requirements and proving they are working properly through testing are critical components of this work, and will be looked at in greater detail.

In addition, we will touch on elements of electronic records and electronic signatures (ER/ES, or FDA 21 CFR Part 11), as these have come under FDA regulations in the late 1990's. Specific criteria must be met in order to consider such a record or signature as valid in the eyes of FDA regulators.

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.

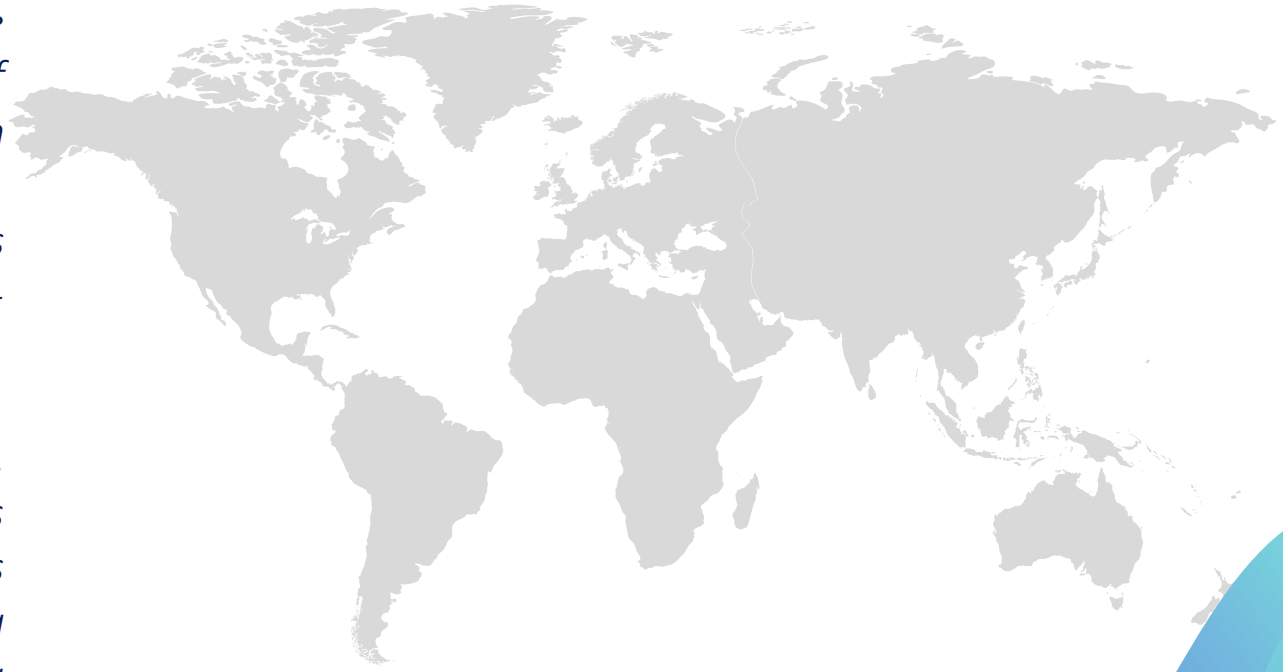
More recently, the FDA has brought tobacco products under their regulatory jurisdiction and has applied guidelines for validation of computer systems used in the manufacture, testing or tracking of tobacco-related products. This includes cigarettes, cigars, e-cigarettes and other forms of smokeless tobacco, such as “pouch” products.

There are specific requirements for the execution and documentation of the computer system validation process, particularly the requirements and testing components. 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.

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.

Effective and compliant computer system validation, particularly as it relates to defining the requirements and developing a commensurate testing strategy, is critical to any FDA-regulated organization, including those manufacturing, testing and distributing regulated products. During the past 30 years, best practices that have been developed will ensure that the cost of building and managing a computer system validation program for this purpose, along with the necessary policies and procedures, will be minimized.



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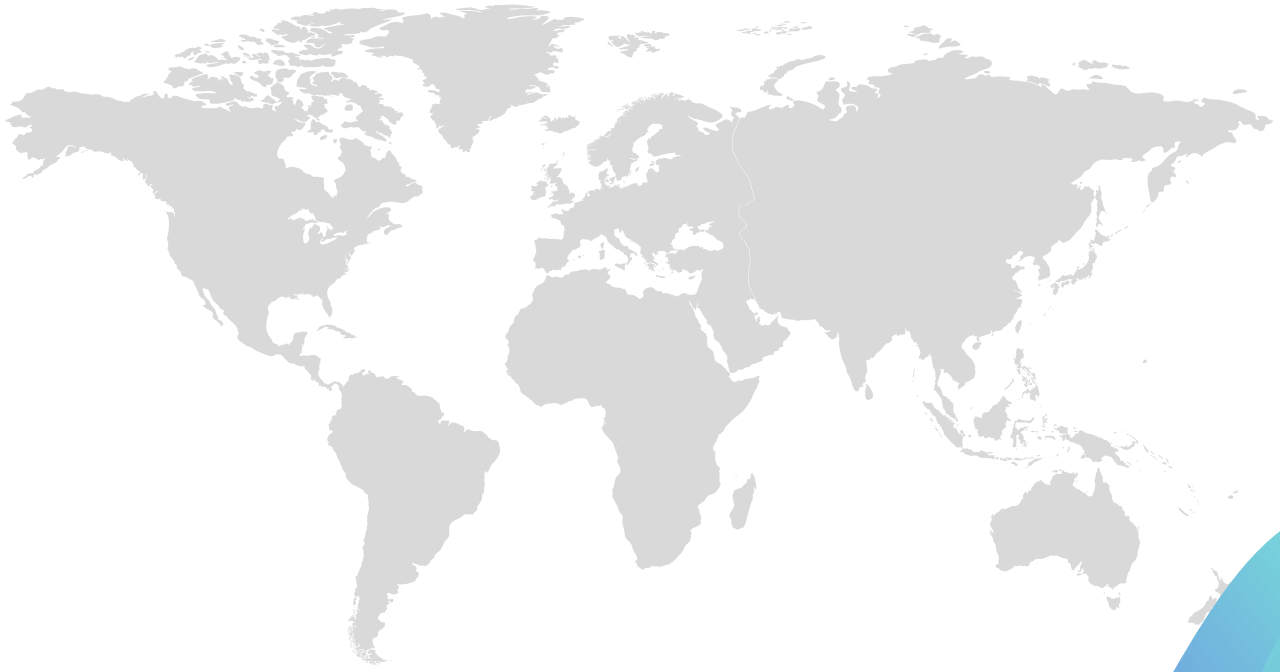
There is an enormous body of documentation and information available that can be overwhelming. This course will provide a condensed overview of the practices that deliver the best results by directing the attendees to the most critical and cost-effective of methods, techniques, and tools available to assure a compliant validation process.



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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
Warehouse Managers
Legal and Regulatory Affairs professionals

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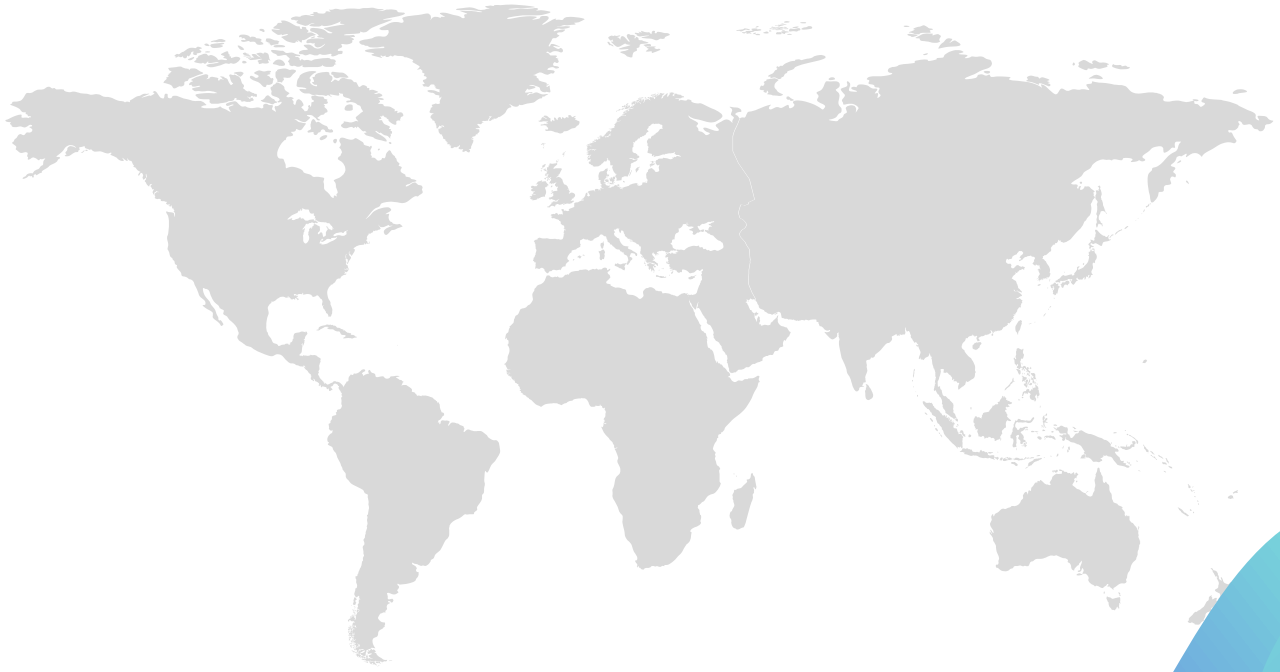
Finally, anyone who is acting as a consultant or contractor to a company in an FDA-regulated industry should attend to ensure they are able to bring the most current knowledge and expertise to their assignment.



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