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Webinar on

Developing a Strategic Approach to FDA Compliance for Computer Systems

Learning Objectives

- *System Development Life Cycle (SDLC) Methodology*
- *Computer System Validation (CSV)*
- *Good "Variable" Practice (GxP)*
- *Good Manufacturing Practice (GMP)*
- *Good Laboratory Practice (GLP)*
- *GAMP 5 Guidance for System Classification*
- *Risk Assessment and Management*
- *Validation Strategy*

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- *Change Control and Audit Trails*
- *User Requirements Specification (URS) & Functional Requirements Specification (FRS)*
- *System Design Specification (SDS) and System Configuration Specification (SCS)*
- *Test Planning, Execution, and Documentation (IQ/OQ/PQ)*
- *Requirements Traceability Matrix (RTM)*
- *System Acceptance, Release Notification, and Deployment*
- *System Retirement*
- *Data Governance Archival*
- *Q&A*

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This webinar will help you understand in detail Computer System Validation (CSV) and how to apply the System Development Life Cycle (SDLC) Methodology when validating computer systems subject to FDA regulations.

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.

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On-Demand Webinar

Duration : 90 Minutes

Price: $200

Webinar Description

This webinar will help you understand in detail Computer System Validation (CSV) and how to apply the System Development Life Cycle (SDLC) Methodology when validating computer systems subject to FDA regulations. This is critical in order to develop the appropriate validation strategy and achieve the thoroughness required to prove that a system does what it purports to do. It also ensures that a system is maintained in a validated state throughout its entire life cycle, from conception through retirement. We will discuss the phases within the SDLC, and how these form the basis for any CSV project. The importance of the sequence of steps will also be covered.

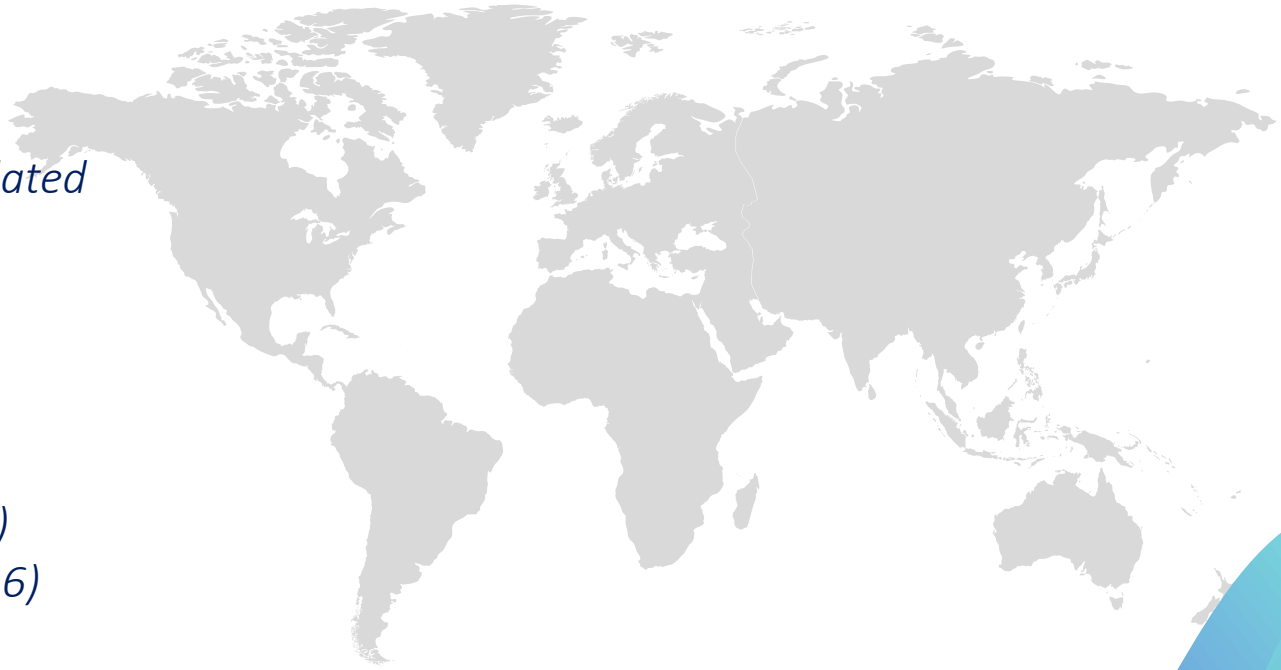
Effective and compliant computer system validation is critical to any FDA-regulated organization. During the past 30 years, best practices have been developed and, if followed, can ensure laboratory computer systems are validated efficiently and in compliance with FDA regulations. This webinar will provide guidance for planning, executing and validating a laboratory computer system, and managing the system in a validated state through the end of the system life cycle.

The webinar will take you through the validation process, indicating key aspects of the approach, including GAMP 5 System Classification, Risk Assessment and overall development of a sound validation strategy. We will cover the actual validation phases, deliverables and key points to ensuring the work is in accordance with FDA requirements for computer system validation, while also making sure the approach is cost-effective for your organization.

The webinar will also address roles and responsibilities, the timing of phases and deliverables, business process reengineering, organizational change management, change control, and audit trails, training, and documentation. You will learn what is required not only to validate your laboratory system but maintain it in a validated state until it is retired or otherwise no longer in use.

There is an enormous body of documentation and information available on computer system validation, which 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 methods, techniques, and tools available.

Who Should Attend ?



Manufacturing, Testing, Packaging and Distribution companies in the following industries that are regulated by FDA are required to follow GxPs:

Pharmaceutical
Medical Device
Biologicals
Tobacco (based on the Tobacco Control Act of 2009)
E-Liquid/Vapor (based on the "Deeming" Act of 2016)
E-Cigarette (based on the "Deeming" Act of 2016)
Cigar (based on the "Deeming" Act of 2016)
Third-Party companies that support those in the above industries

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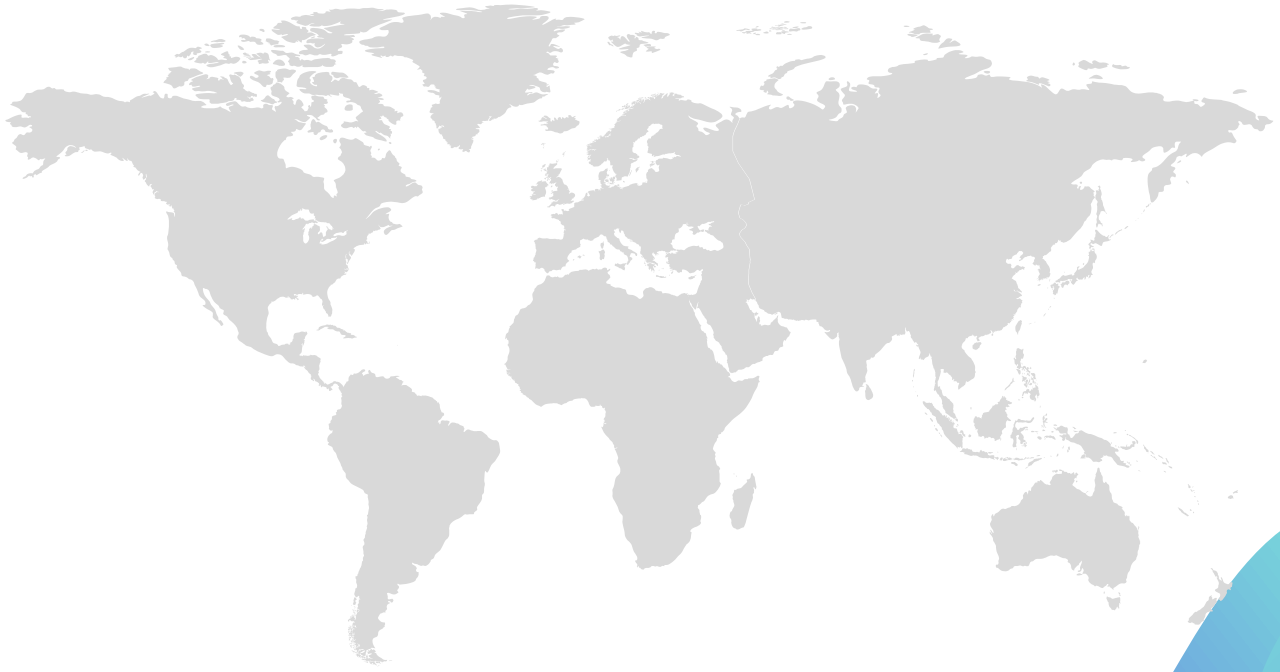
Personnel in the following roles will benefit:

- *Information Technology Analysts*
- *QC/QA Managers*
- *QC/QA Analysts*
- *Clinical Data Managers*
- *Clinical Data Scientists*
- *Analytical Chemists*
- *Compliance Managers*
- *Laboratory Managers*
- *Automation Analysts*
- *Manufacturing Managers*
- *Manufacturing Supervisors*
- *Supply Chain Specialists*
- *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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