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Webinar on

FDA Compliance And GAMP V Computer System Classification

Learning Objectives

- *Gain an understanding of GAMP V computer system classifications, Q&A*
- *Develop the ability to apply GAMP V in classifying computer systems in your organization*
- *Understand the level of computer system validation required, based on the classification as determined using GAMP V*
- *Discuss the best practices necessary to ensure all systems are classified properly and validated appropriately*

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- *Learn how to develop the appropriate computer validation strategy, including the level of testing required for the given computer system classification, as determined by GAMP V*
- *Understand how to effectively document the process of computer system classification and how to maintain current information about the various systems in your organization and how they are validated*
- *Learn how to gain information about trends invalidation, as the industry progresses and new best practices emerge*
- *Understand the level of training required for the various GAMP V computer system classifications, and the skills and expertise necessary to make the classification determination*

The attendees will understand the level of testing required for each classification, and the appropriate level of documentation that must be completed to support it.

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.

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On-Demand Webinar

Duration : 90 Minutes

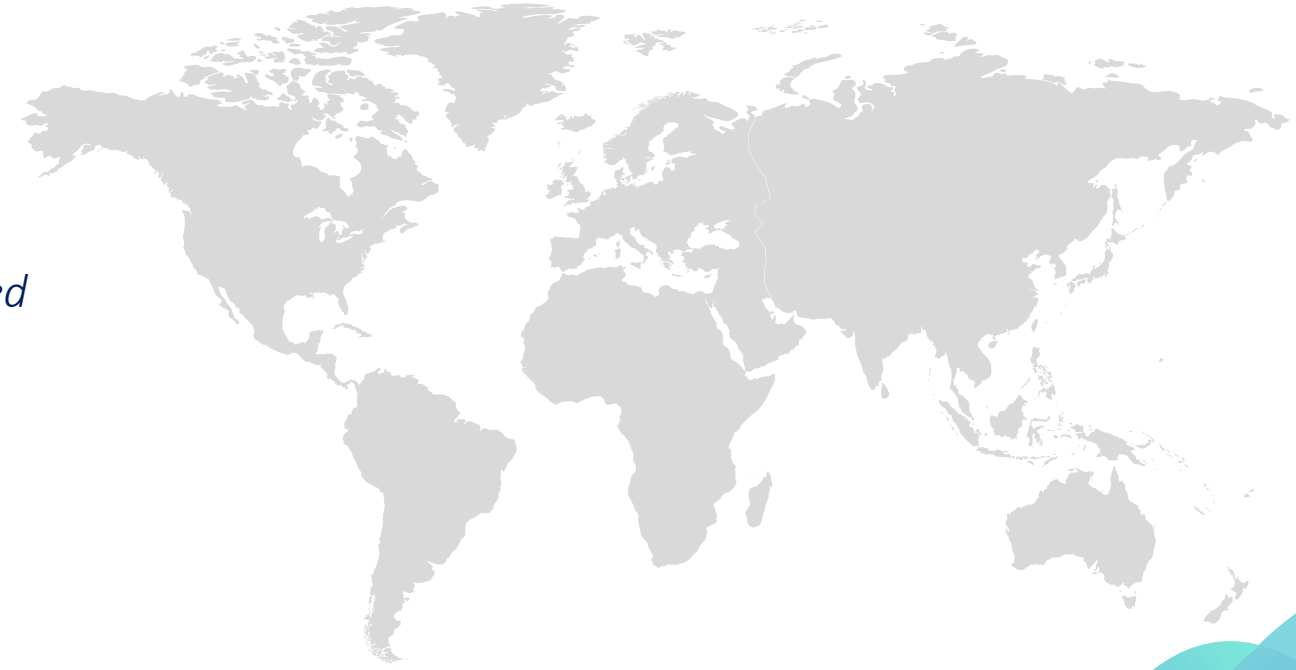
Price: $200

Webinar Description

We will discuss the importance of classifying computer systems subject to FDA regulations in accordance with GAMP V. 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 you do not go beyond what is required for a specific classification of the system so as to be cost-effective.

Upon completion of this session, attendees will have an understanding of how to classify computer systems in accordance with GAMP V, and develop a sound validation strategy for each system to meet FDA compliance. The attendees will understand the level of testing required for each classification, and the appropriate level of documentation that must be completed to support it. They will also gain an understanding of the training and skills required to both classify systems and work on various classifications of systems to validate or maintain them. The attendees will have a good grasp of how to leverage these practices across all systems by creating a standardized program for classifying systems in accordance with GAMP V.

Who Should Attend ?



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

- *Third-Party companies that support those in the above industries*

- *Colleges and Universities offering programs of study in Computer System Validation and Regulatory*

- *Affairs/Matters related to FDA*

- *Information Technology (IT) Analysts IT Developers, IT Support Staff*

- *QC/QA Managers and Analysts, Clinical Data Managers and Scientists*

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- *Analytical Chemists, Quality Managers, Chemists, and Microbiologists*

- *Compliance Managers and Auditors*

- *Lab Managers and Analysts*

- *Automation Analysts*

- *Computer System Validation Specialists*

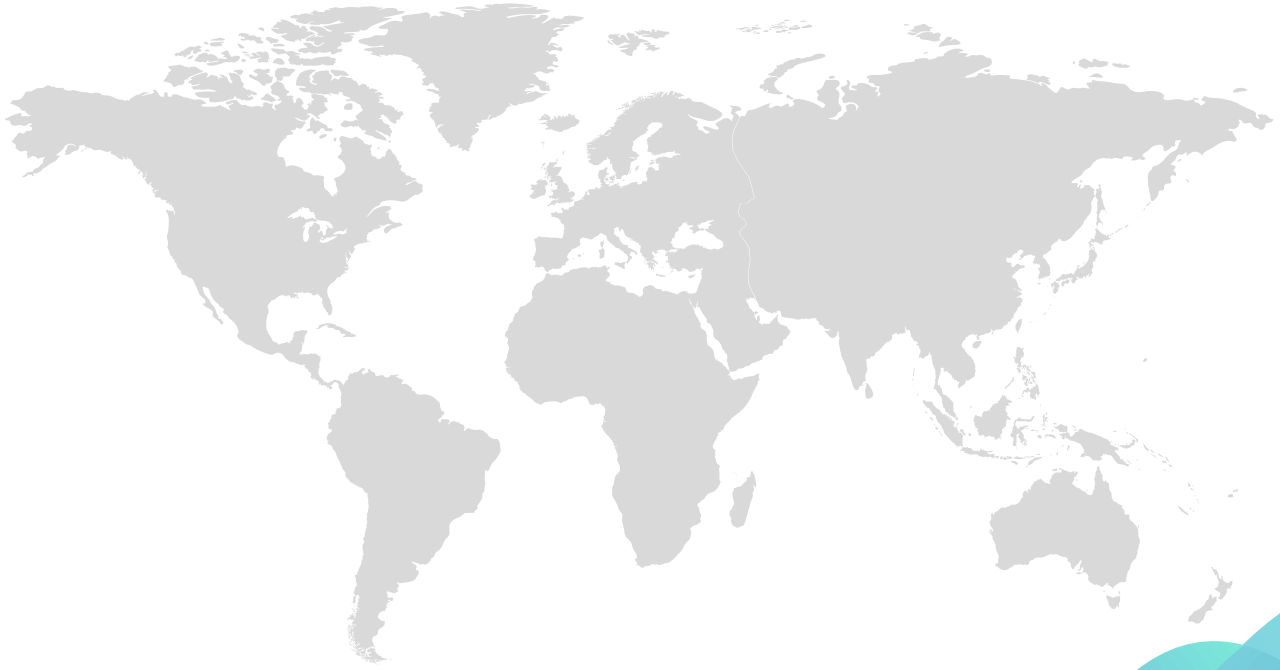
- *GMP Training Specialists*

- *Business Stakeholders using Computer Systems regulated by FDA*

- *Regulatory Affairs Personnel*

- *Consultants in the Life Sciences and Tobacco Industries*

- *Interns working at the companies listed above*



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