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Webinar on

FDA Deeming Rule for Tobacco Related Products and Recent Actions: eCigarettes, eLiquids, Cigars

Learning Objectives

- *FDA Tobacco Control Act and "Deeming Rule"*
- *Extension of FDA oversight to Vapor, e-Cigarette, Cigar and other industries*
- *Details of the August 8, 2016, FDA Regulation*
- *PMTAs and Requirements*
- *How to Build a Compliance Strategy*
- *Minimizing Cost while Maximizing Compliance*

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- *Industry Best Practices*
- *Know the policies and procedures that must be developed and maintained to support the clinical trial system in operation*
- *Understand how to leverage the vendor and other external resources to apply the best industry practices and avoid potential pitfalls when validating a clinical trial system*
- *Know about FDA trends in oversight and audit and how to keep abreast of these*
- *Q&A*

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This course will describe the best practices for developing a compliance strategy, including roles and responsibilities, and the policies and procedures that should be followed to ensure compliance

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 is intended for those working in the FDA-regulated tobacco and related industries, including e-liquids (vapor), e-cigarettes, cigars, and smokeless tobacco products. 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.

An effective and compliant strategy is critical to any FDA-regulated organization, including those in the tobacco-related industries. Knowing the regulations is the first step toward ensuring compliance, and learning about industry best practices is a sure way to learn how to balance compliance with a cost.

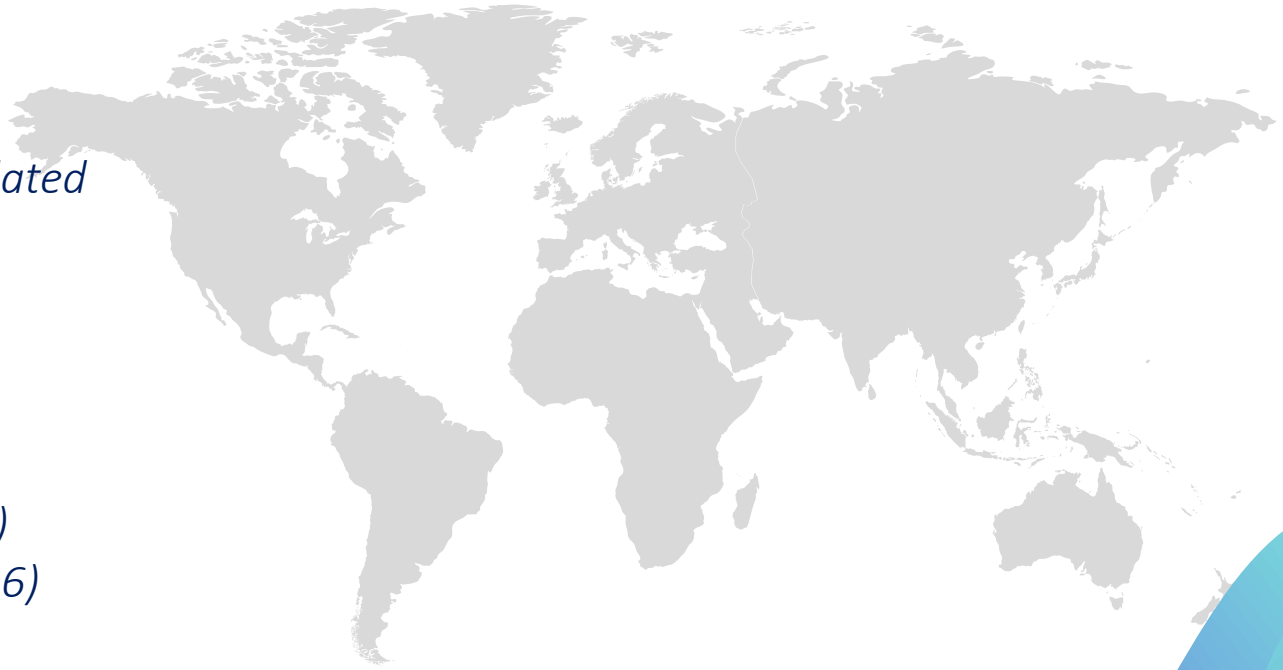
The Tobacco Control Act went into effect by the FDA on June 22, 2009. Through this ruling, the FDA regulated cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco, but in 2016, the FDA finalized a rule, Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, which extends the FDA's authority to include the regulation of electronic nicotine delivery systems (such as e-cigarettes and vape pens), all cigars, hookah (water pipe) tobacco, pipe tobacco and nicotine gels, among others. The rule went into effect on August 8, 2016.

This action is a milestone in consumer protection – going forward, the FDA will be able to:

- Review new tobacco products not yet on the market
- Help prevent misleading claims by tobacco product manufacturers
- Evaluate the ingredients of tobacco products and how they are made
- Communicate the potential risks of tobacco products

We will provide an overview of the regulations as they pertain to the manufacturing, marketing, distribution and other operational activities engaged by companies in the tobacco industry. This course will describe the best practices for developing a compliance strategy, including roles and responsibilities, and the policies and procedures that should be followed to ensure compliance

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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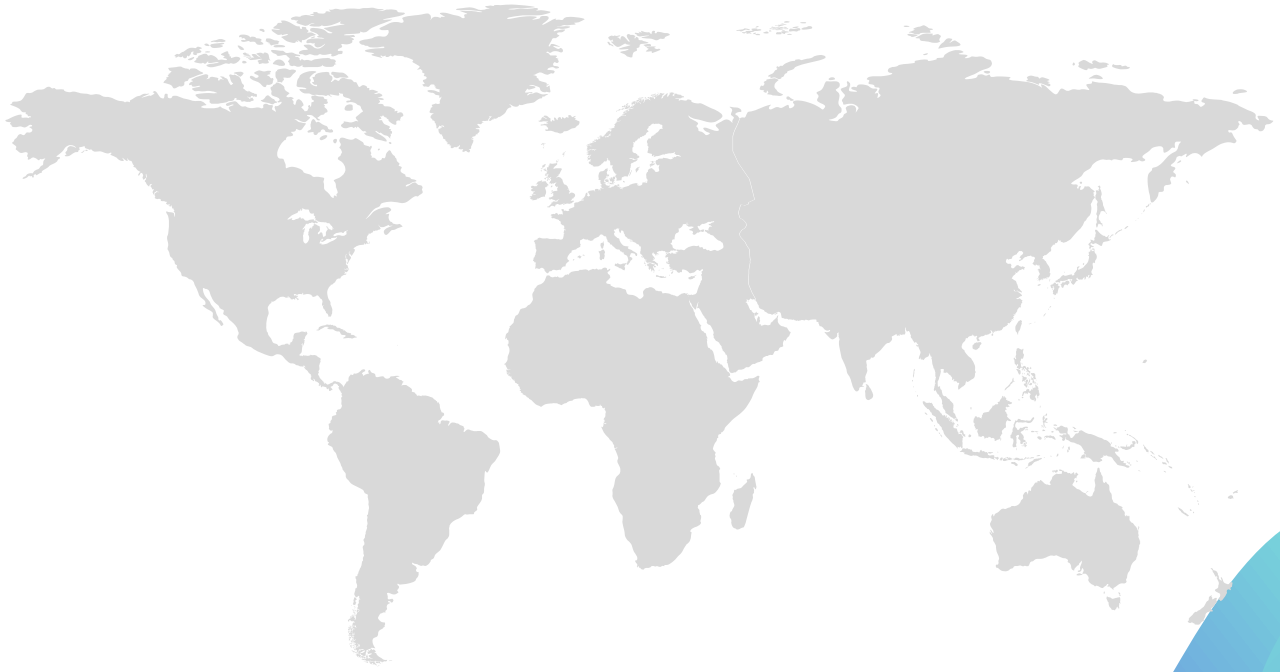
Personnel in the following roles will benefit:

- *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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