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Webinar on

Tobacco Industry Trends for Computer Systems Regulated by FDA

Learning Objectives

- *Tobacco Legislation (FDA)*
- *GxP Predicate Rules*
- *Computer System Validation (CSV)*
- *System Development Life Cycle (SDLC)*
- *A risk-based approach to validation*
- *GAMP V approach to system categorization and validation*
- *Implementation and validation of systems in compliance with FDA*
- *Roles, responsibilities, and training*

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- *Documentation required for FDA compliance*
- *Maintaining a system in a validated state*
- *Data Integrity*
- *The ratio of system cost to compliance with FDA*
- *SOPs required for supporting a validated system*
- *Industry Best Practices*
- *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

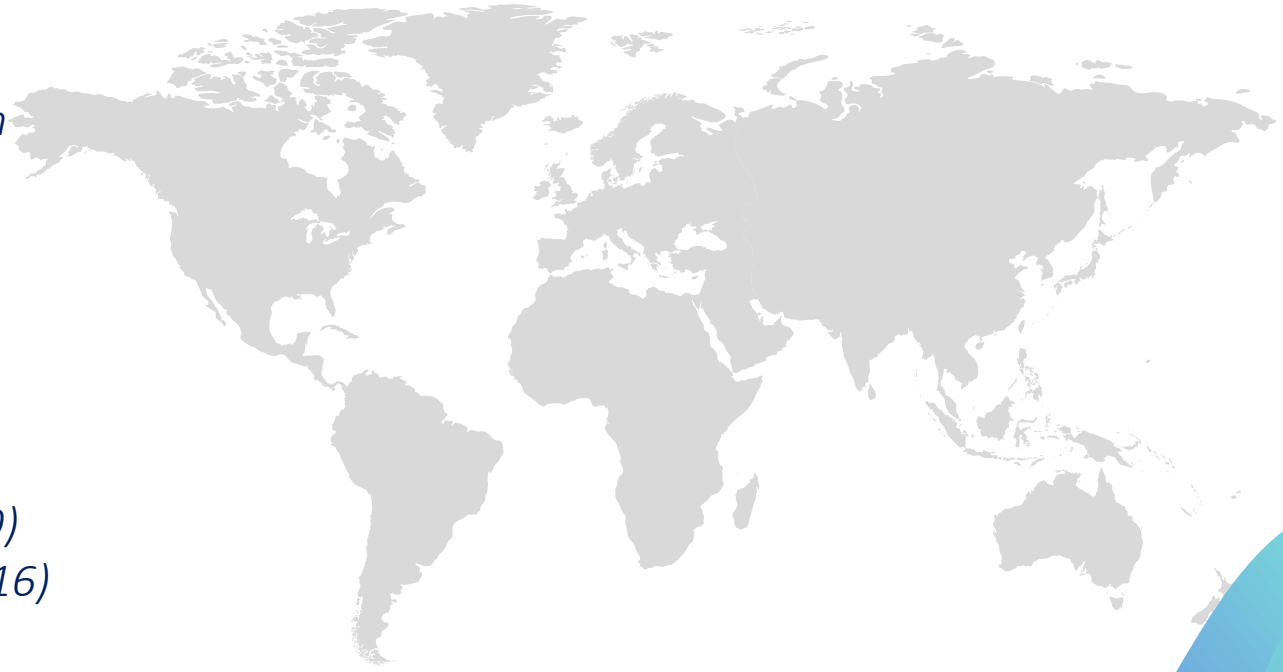
Webinar Description

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

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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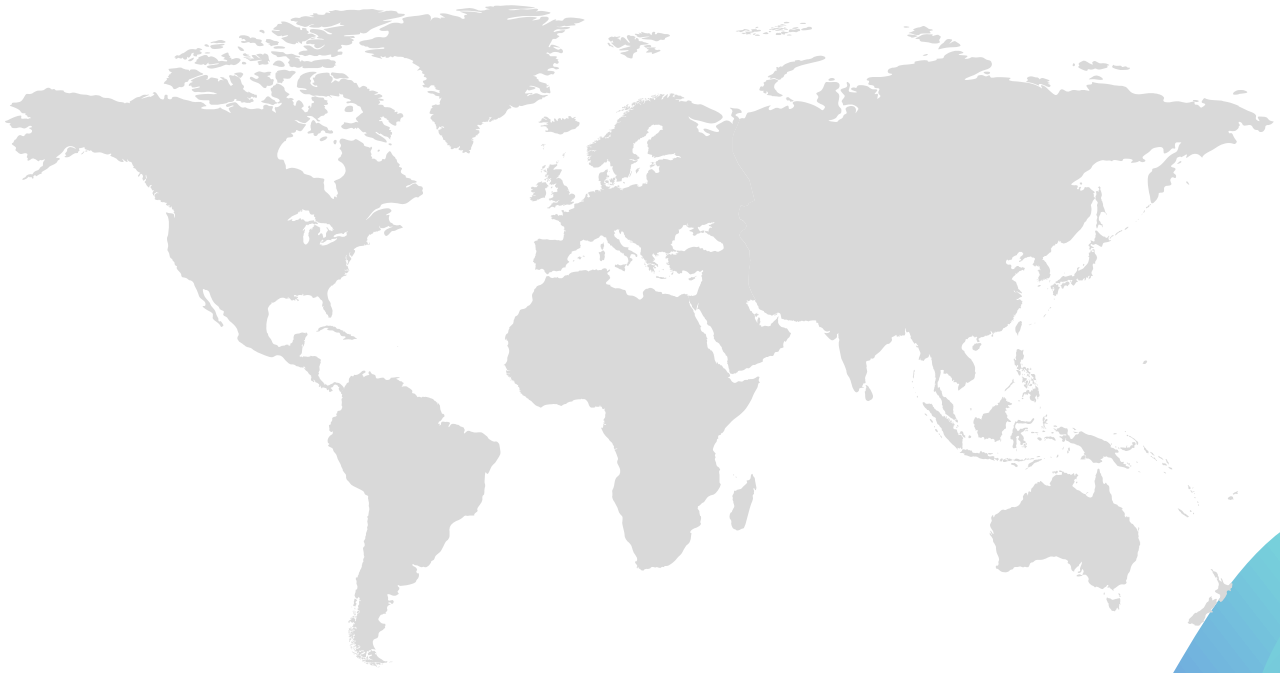
Why Should Attend ?

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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www.grceducators.com
support@grceducators.com
740 870 0321