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Webinar on

C-TPAT Compliance for FDA Regulated Industries

Learning Objectives

- *C-TPAT program overview and tier strategy*
- *Benefits of joining C-TPAT at a variety of levels*
- *Supply chain management, counterfeit, and contraband activities*
- *Security for supply chain management*
- *Standard Operating Procedures (SOPs) and Documentation*
- *Physical and Logical Security*
- *Access, Authentication, and Authorization*

- *Risk Assessment, Mitigation, and Ongoing Management*
- *Vendor and Partner Management*
- *Training Program*
- *Industry Pitfalls and Best Practices*
- *Q&A*

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The market for counterfeit and contraband or “pirated” products can be divided into two important areas.

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 market for counterfeit and contraband or “pirated” products can be divided into two important areas. The primary market provides consumers with counterfeit and contraband products. These consumers believe they have purchased genuine products. However, these products are often below standard and can result in health and safety risks that range from mild to life-threatening. The secondary market provides consumers with products they believe to be a knock-off merchandise offered at bargain prices. They knowingly are buying counterfeit and contraband products.

In either case, contraband and counterfeit products represent several hundred thousand dollars in lost revenue to manufacturers of genuine product, and the profits generated by them is often funneled to groups that fund terrorist activities. Counterfeit and contraband are being produced and consumed in virtually all economies, with Asia emerging as the single largest producing region. In recent years there has been an alarming expansion of the types of products being infringed, from luxury items (such as deluxe watches and designer clothing), to items that have an impact on personal health and safety (such as pharmaceutical products, food, and drink, medical equipment, personal care items, toys, tobacco, and automotive parts).

The Customs-Trade Partnership Against Terrorism (C-TPAT) is a voluntary supply chain security program led by U.S. Customs and Border Protection (CBP). It is intended to improve the security of supply chains of private enterprises against the threat of terrorism, primarily by disrupting counterfeit and contraband activity.

Becoming a partner in C-TPAT can provide your company with distinct benefits, such as entering "green lanes" during shipping and hastening the process for gaining entry to the US with goods from overseas.

In this webinar, we will provide an overview of the Customs and Trade Partnership Against Terrorism:

- *C-TPAT program overview including "Tiered" strategy*
- *Program guidelines and highlights*
- *C-TPAT compliance*

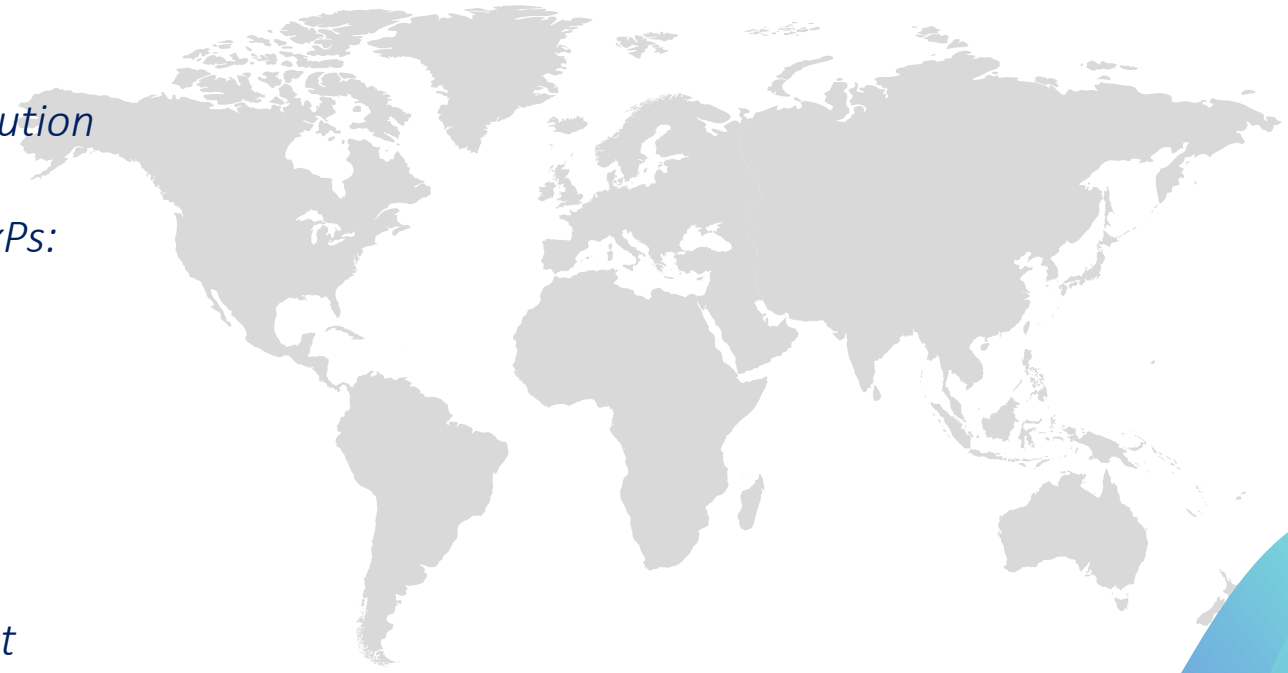
We will also cover the major areas needed to build a successful framework that will support your compliance program:

- *Policies*
- *Standard Operating Procedures (SOPs)*
- *Documentation*
- *Training*

Who Should Attend ?

Manufacturing, Testing, Packaging and Distribution companies in the following industries that are regulated by the 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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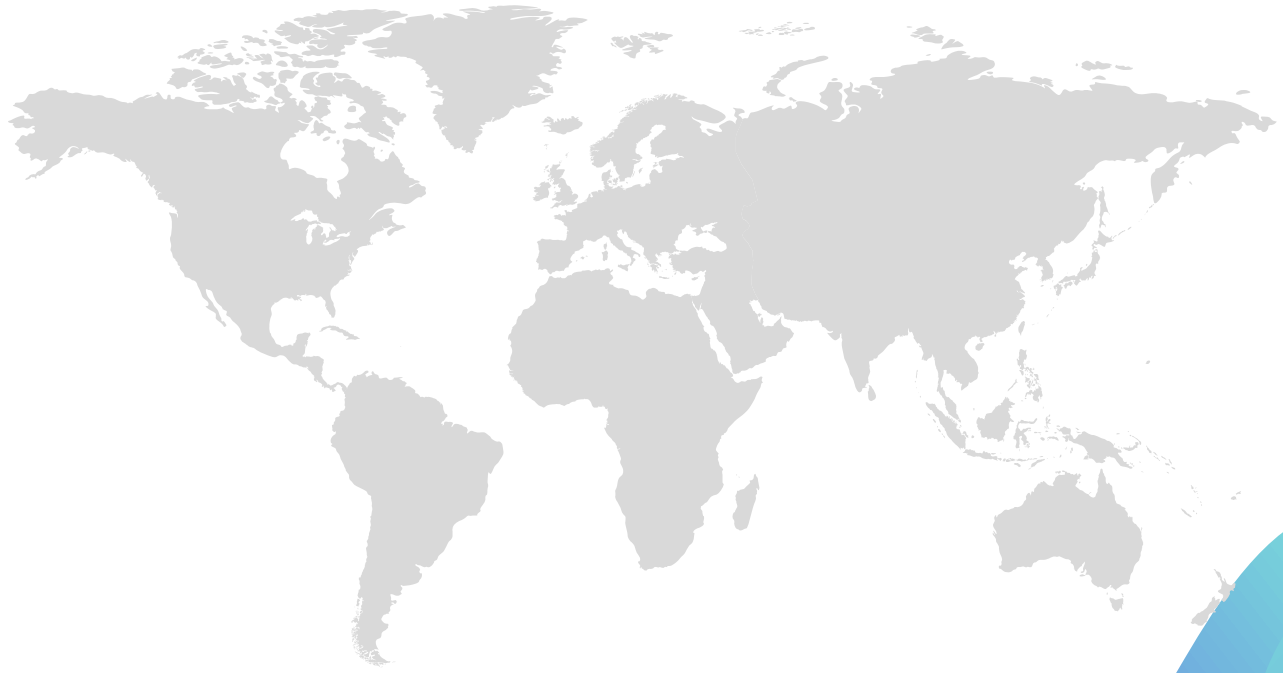
Personnel in the following roles will benefit:

- *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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