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Webinar on

New FDA and EMA Labeling Requirements for Regulated Industries

Learning Objectives

- *Learn what product labeling material is subject to FDA and EMA regulation*
- *Understand the specifics of FDA and EMA regulations for product labeling and how to comply*
- *Learn how to establish and maintain a well-organized system for product labeling, and provide quality assurance for the data included*
- *Learn the importance of developing a consistent system for locating labeling records, and preparing them for regulatory inspection*
- *Learn about best practices and industry standards*

This webinar includes the FDA and EMA are implementing a set of rules for the electronic submission of labeling content.

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. She is currently an independent consultant, advising companies on computer system validation and large-scale IT system implementation projects.

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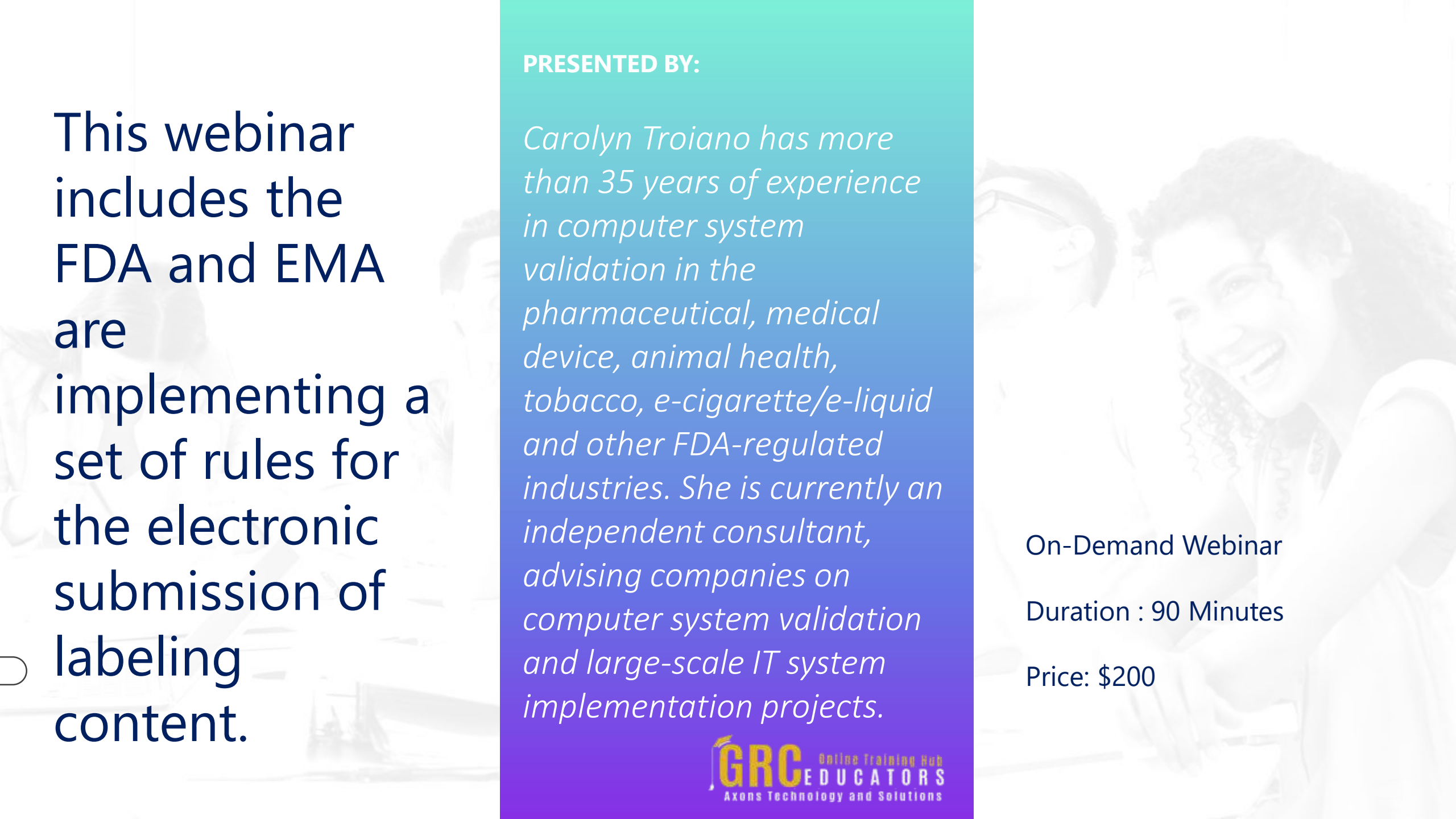


On-Demand Webinar

Duration : 90 Minutes

Price: $200

Webinar Description

This webinar will help you understand in detail the new requirements for labeling from FDA and EMA, including a set of rules for electronic submission of labeling content, and strategies and actions for meeting the new challenges posed.

Pharmaceutical companies must manage the process of designing and creating product labels that meet regulatory requirements. This includes product-labeling documents such as Packet Inserts (PIs), Summaries of Product Characteristics (SmPCs) and Core Data Sheets (CDSs). A large number of product strengths, dosage forms, and product presentations result in a large number of labeling records that must be maintained and kept synchronized.

The FDA and EMA are implementing a set of rules for the electronic submission of labeling content. The FDA requires companies to submit XML labeling content in Structured Product Labeling (SPL) format. The EMA requires companies to submit product information documents in QRD-compliant format. Companies in the regulated life sciences industries must develop and implement systems and processes that will ensure compliance with these standards for their global labeling content. They must also take a longer-term view as to how best to minimize the complexity and cost of doing so. In this webinar, we will discuss ways to overcome these regulatory challenges and understand how companies in the life sciences industries are doing so through best practices.

Who Should Attend ?

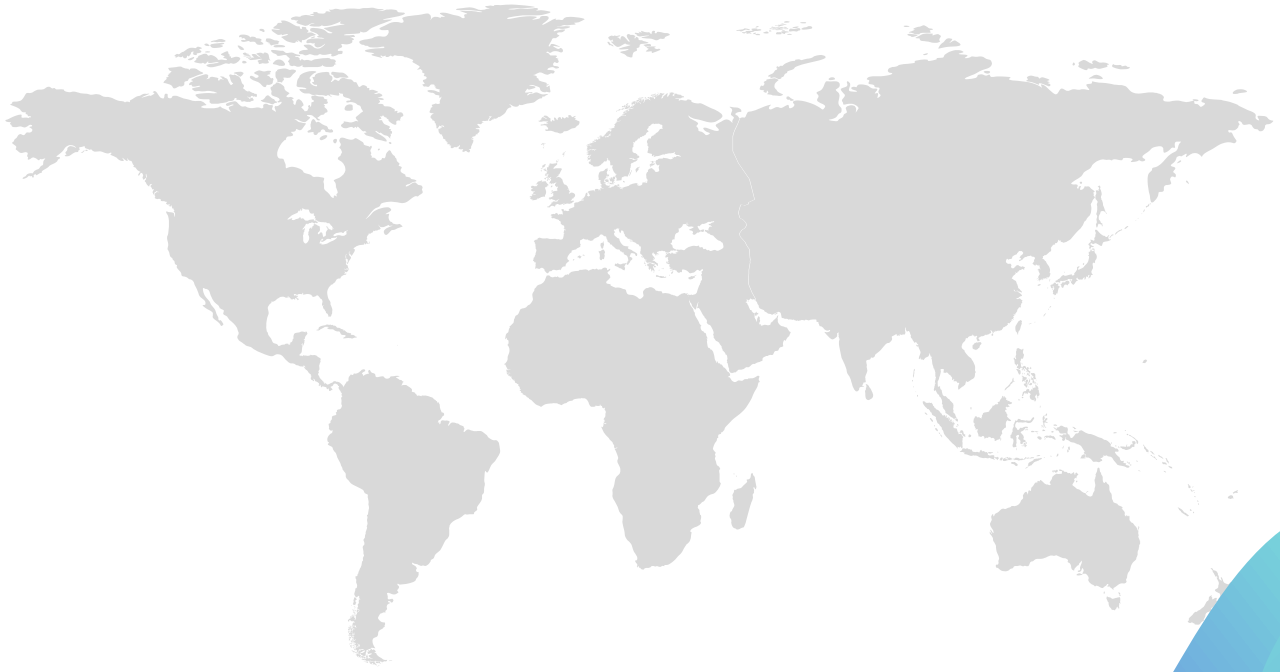
Those responsible for designing, creating and maintaining product labels and labeling records

Manufacturing and Quality Assurance professionals responsible for labeling content, format, and management

IT professionals involved in the conversion of label content formats for electronic labels

Quality Assurance Personnel

Auditors engaged in the internal inspection of labeling records and practices



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