GRC Online Training Hub
EDUCATORS
Axons Technology and Solutions

Webinar on

Legal, Regulatory And Policy Issues Related To Validation Of Computer Systems Regulated By FDA

Learning Objectives

Upon completion of this session, attendees will have an understanding of the FDA regulations for computer systems used in the manufacture, clinical and quality testing, distribution, and post-marketing surveillance of pharmaceutical, medical device, biological, tobacco and related products. The attendees will understand how the FDA regulations have evolved and what to expect. You will:

- *Learn about FDA oversight, how the agency operates, and what that means for your organization*
- *Gain knowledge about how to develop a compliance strategy, based on industry best practices that will minimize your operational costs while keeping you in good standing with the FDA*

GRC Online Training Hub
EDUCATORS
Axons Technology and Solutions

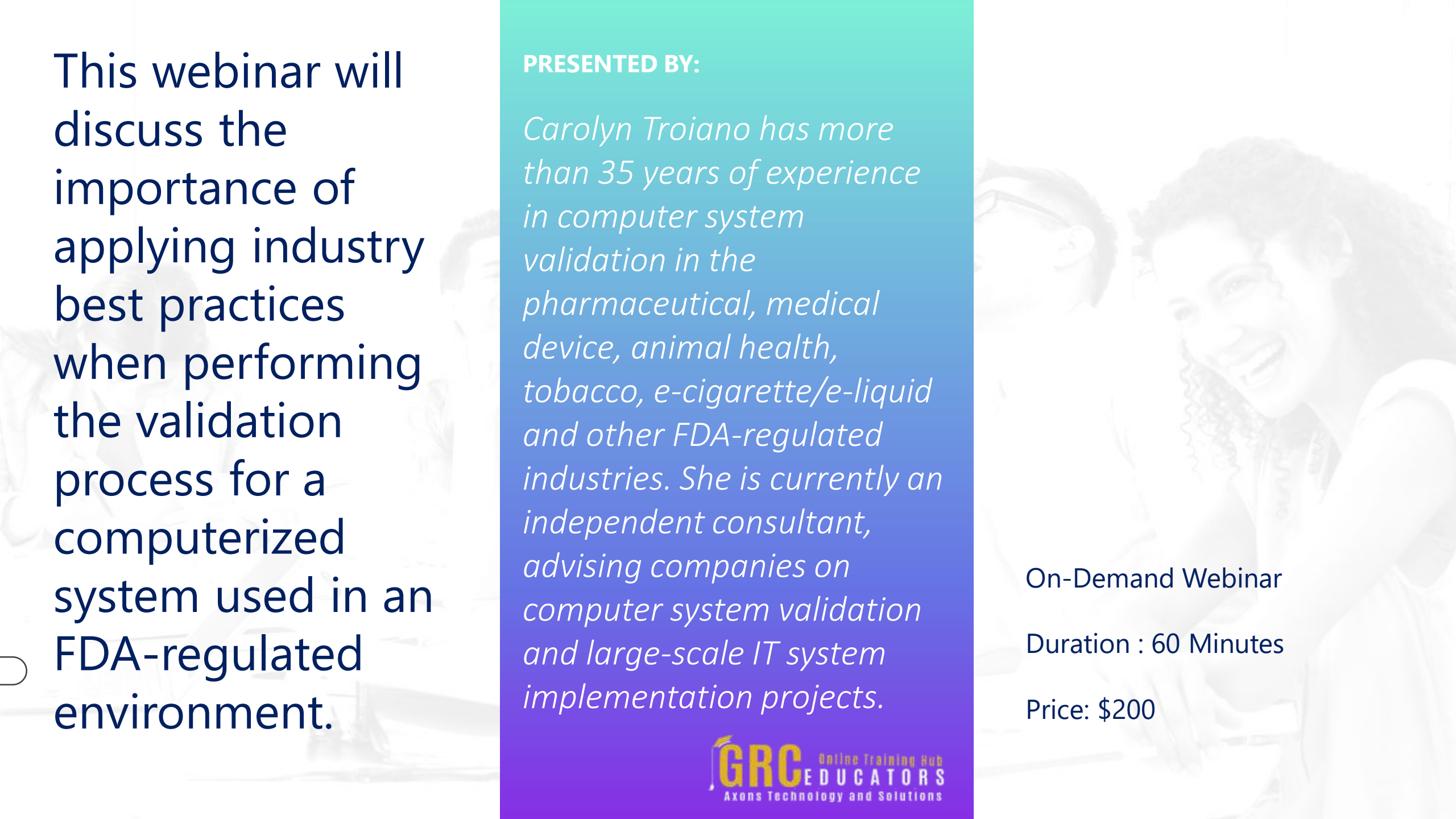
- *Understand the policies needed to support your computer system validation effort*
- *Understand how to effectively document the process of computer system validation where ER/ES capability exists, and maintain current information about the various systems in your organization and how they are maintained in a validated state*

This webinar will discuss the importance of applying industry best practices when performing the validation process for a computerized system used in an FDA-regulated environment.

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.

GRC Online Training Hub EDUCATORS
Axons Technology and Solutions



On-Demand Webinar

Duration : 60 Minutes

Price: $200

Webinar Description

We will discuss the importance of applying industry best practices when performing the validation process for a computerized system used in an FDA-regulated environment (i.e., the system "touches" product during the manufacturing, testing or distribution process). Such a system must be validated in accordance with FDA guidelines for computerized systems and documented accordingly. There are legal, regulatory and policy implications that will be covered.

This course will describe the best practices for developing a strategy and conducting validation work, including roles and responsibilities, and the procedures that should be followed. FDA guidelines are very specific in terms of how this is to be done, and each company should have a specific strategy/methodology, and a set of very rigorous internal policies and procedures that prescribe how this will be planned, executed and documented.

In addition, we will touch on elements of electronic records and electronic signatures (ER/ES, or FDA 21 CFR Part 11), as these have come under FDA regulations in the late 1990's. Specific criteria must be met in order to consider such a record or signature as valid in the eyes of FDA regulators.

Since 1983, with the issuance of the guidance document from FDA on validation of computerized systems, this topic has applied to pharmaceutical products and the computer systems used to generate, collect, analyze, process and report data. Subsequently, the FDA applied the same guidance to computer systems used in the biologics and medical device industries. More recently, the FDA has brought tobacco products under their regulatory jurisdiction and has applied guidelines for validation of computer systems used in the manufacture, testing or tracking of tobacco-related products. This includes cigarettes, cigars, e-cigarettes and other forms of smokeless tobacco, such as "pouch" products.

There are specific legal and regulatory requirements for the execution and documentation of the computer system validation process. There are also policies needed to support these efforts.

Who Should Attend ?

You should attend this webinar if you are responsible for planning, executing or managing the validation of a system governed by FDA regulations, specifically in relation to pharmaceutical, medical device, biologics, tobacco and related products. This includes cigarettes, as well as the more recently developed e-cigarette products and smokeless tobacco products.

Effective and compliant computer system validation is critical to any FDA-regulated organization, including those manufacturing, testing and distributing regulated products. During the past 30 years, best practices that have been developed will ensure that the cost of building and managing a computer system validation program for this purpose, along with the necessary policies and procedures, will be minimized. There is an enormous body of documentation and information available that can be overwhelming. This course will provide a condensed overview of the practices that deliver the best results by directing the attendees to the most critical and cost-effective of methods, techniques, and tools available to assure a compliant validation process.

GRC Online Training Hub
EDUCATORS
Axons Technology and Solutions

Manufacturing Analysts and Supervisors, Marketing Analysts and Managers

Information Technology Professionals, QC/QA Analysts and Managers

Laboratory Analysts and Managers, Compliance and Audit Managers

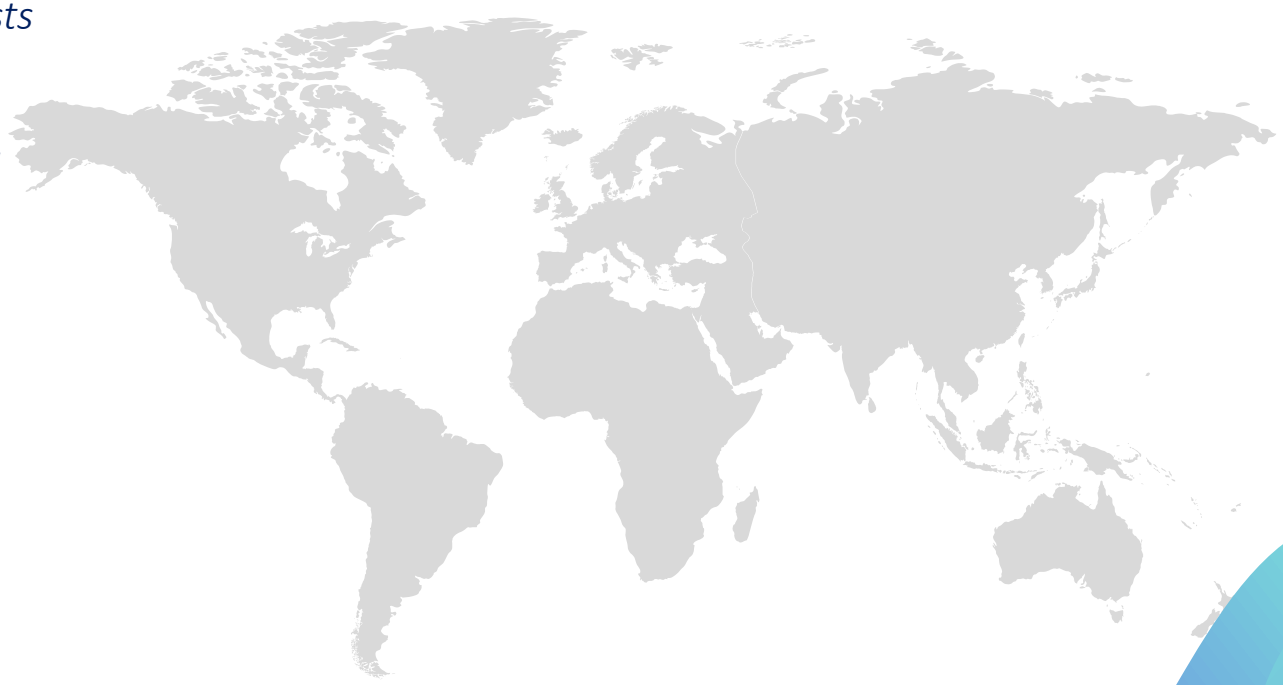
Automation Analysts and Managers, GMP Training Specialists

Computer System Validation Specialists, Business Stakeholders/Subject Matter Experts

Business System/Application Testers, Warehouse Managers

Legal and Regulatory Affairs professionals

Finally, anyone who is acting as a consultant or contractor to a company in an FDA-regulated industry should attend to ensure they are able to bring the most current knowledge and expertise to their assignment.



GRC Online Training Hub EDUCATORS
Axons Technology and Solutions

GRC Online Training Hub
EDUCATORS
Axons Technology and Solutions

To register please visit:

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