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Webinar on

Medical Device Software 62304 Compliance

Learning Objectives

- *Providing safe and effective medical devices is in the best interests of all those involved in developing software for these products, and for those involved in developing medical devices that use software*
- *This session will provide insight into the IEC 62304 standard as it is applied to medical device software*
- *You will learn how to apply this standard to your own work processes*
- *You will also gain insight into the current industry best practices that will help you with IEC 62304 compliance*
- *Q&A*

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The webinar will leave you with the information needed to create and maintain good documentation that meets FDA compliance standards.

PRESENTED BY:

Carolyn Troiano has more than 35 years of experience in computer system validation in the pharmaceutical, medical device, tobacco, and other FDA-regulated industries. She has worked directly, or on a consulting basis, for many of the larger pharmaceutical and tobacco companies in the US and Europe.

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On-Demand Webinar

Duration : 90 Minutes

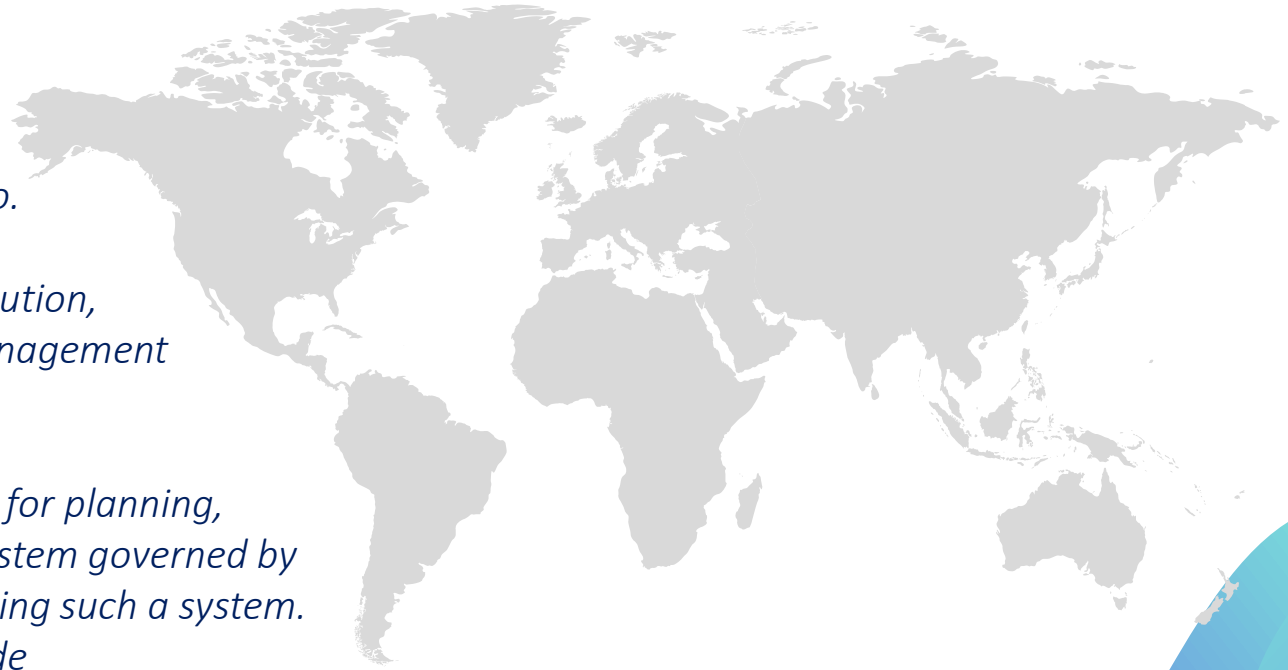
Price: $200

Webinar Description

The webinar will leave you with the information needed to create and maintain good documentation that meets FDA compliance standards. You will learn about what must be done and what must not be done. In addition, you'll learn about the various computer system validation deliverables and how to document them. This session will provide insight into the IEC 62304 standard as it is applied to medical device software.

You will learn about industry best practices for the delivery of reliable and safe software for medical devices.

Who Should Attend ?



This webinar is intended for those working in the FDA-regulated industries, including pharmaceutical, medical device, biological, animal health and tobacco. 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. Examples of who will benefit from this webinar include

Personnel in the following roles will benefit

Information Technology (IT) Analysts, IT Developers, IT Support Staff
QC/QA Managers and Analysts
Quality Managers, Chemists, and Microbiologists
Clinical Data Managers and Scientists

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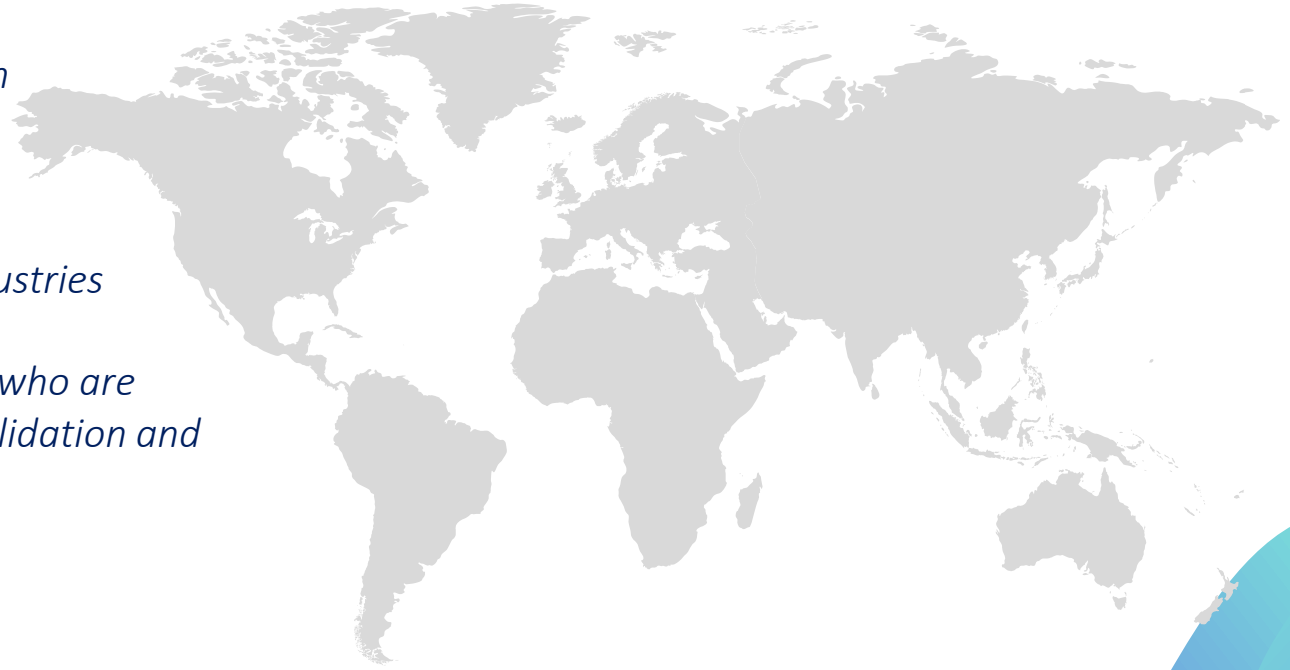
Analytical ChemistsCompliance Managers and Auditors
Lab Managers and Analysts
Atomation Analysts, Computer System Validation Specialists, GMP Training Specialists
Business Stakeholders using Computer Systems regulated by FDA, Regulatory Affairs Personnel
Consultants in the Life Sciences and Tobacco Industries
Interns working at the companies listed above
Consultants working in the life sciences industry who are involved in computer system implementation, validation and compliance



All FDA-regulated industries

Biologicals (companies with a combination medical device and biological products)
Medical Device (manufacturers, software developers)
Tobacco (companies with a combination medical device and tobacco products)
Tobacco-related products (e-cigarettes, e-liquids, cigars)
Pharmaceutical (companies with combination medical device and pharmaceutical products)

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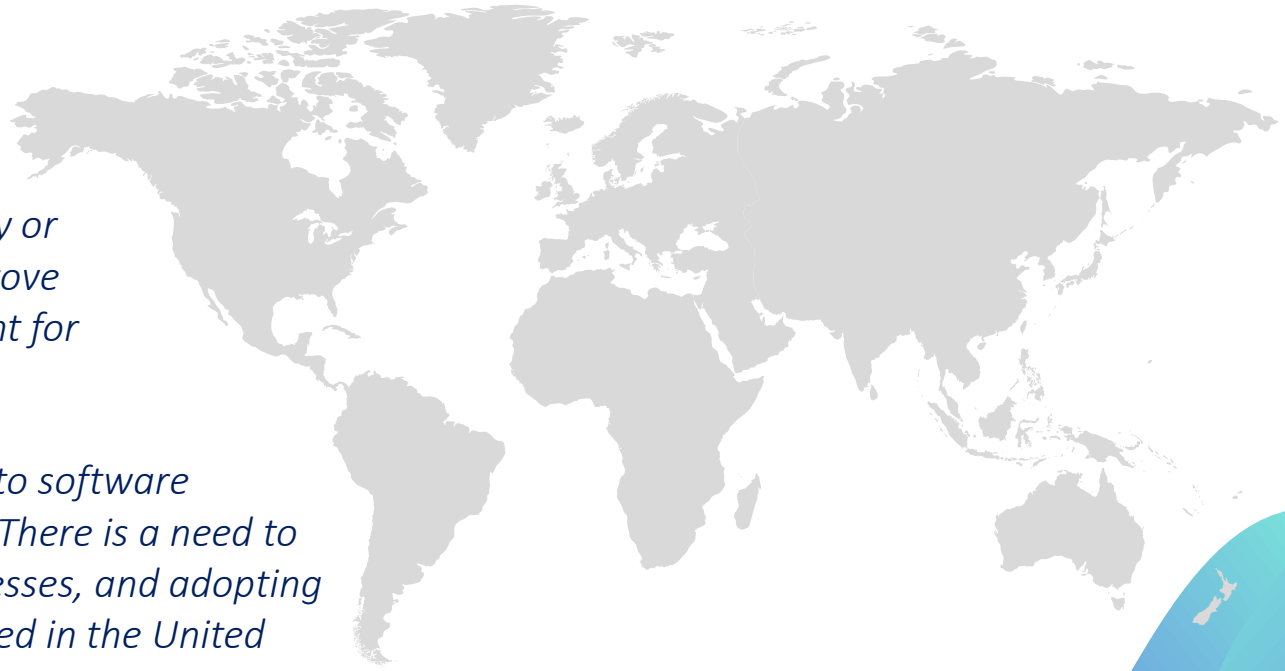
Topic Background

This webinar will focus on medical devices, IEC 62304, and what is required for compliance. Medical devices can use very complex software applications, and any failure to function properly could lead to potential injury or death of a consumer or patient. There is a need to improve overall standards for medical device software to account for this high-risk potential.



The majority of software recalls in the 1990s were due to software defects that were a result of software being upgraded. There is a need to restructure medical device software development processes, and adopting IEC 62304 provides a standard for design that is accepted in the United States (US) and European Union (EU).

IEC 62304 is a risk-based approach to compliance that ensures the standards followed are appropriate for their potential assessed risk. IEC 62304 is a lifecycle approach that defines the activities and tasks required to ensure software for medical devices will be safe and reliable. Applying IEC 62304 will reduce your overall rate of software failure and improve your bottom line.

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