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Webinar on

21 CFR Part11 Compliance

Learning Objectives

The attendees will gain knowledge on:

- *Company certification*
- *Records covered*
- *Audit trails*
- *Open /closed system access rules*
- *Electronic signatures*
- *Training requirements*

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This Webinar will explain what 21 CFR Part 11 is, why it is important to FDA regulated companies and how conformance to Part 11 differs from just having good IT security.

PRESENTED BY:

Edwin retired from the industry after 30 years in management of the development of medical device products and development of company Quality Systems. He was involved in the development of products such as IVD devices, kidney dialysis systems, and inhalation devices.

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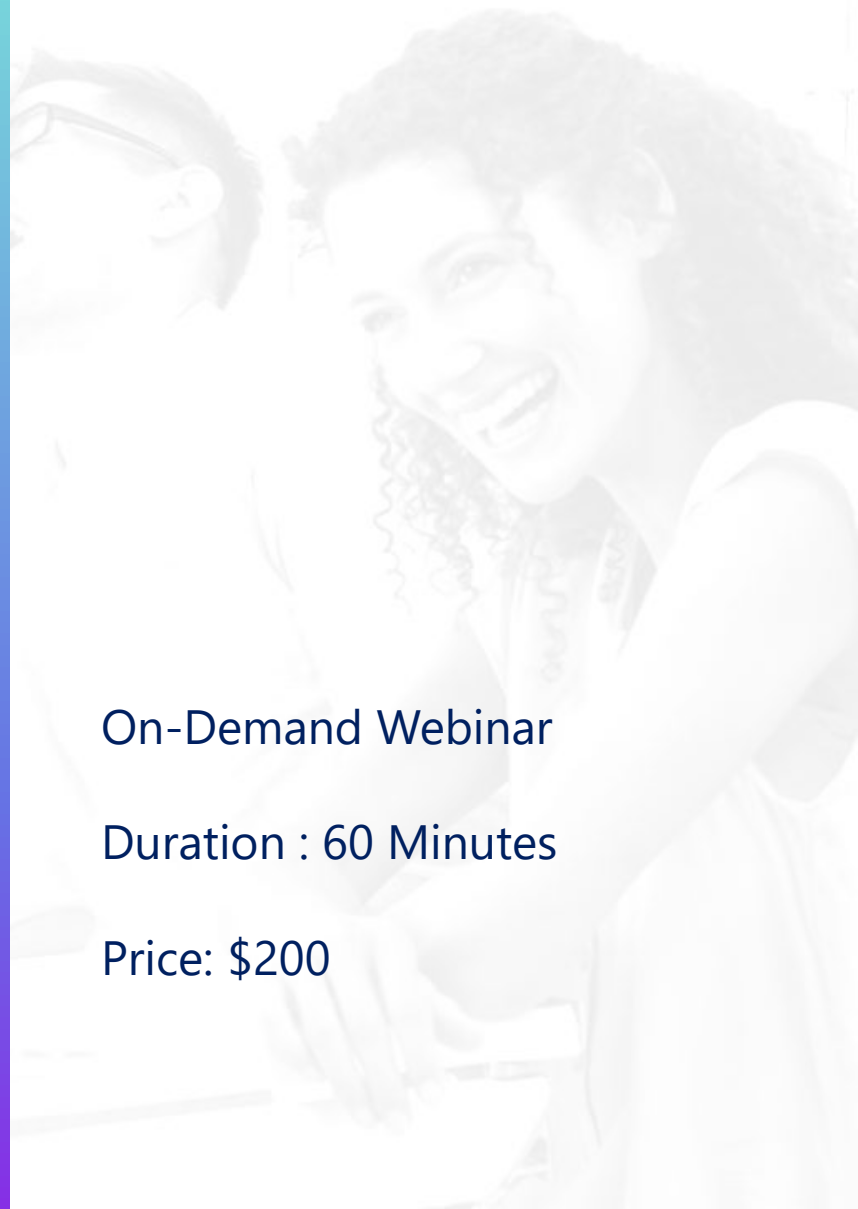


On-Demand Webinar

Duration : 60 Minutes

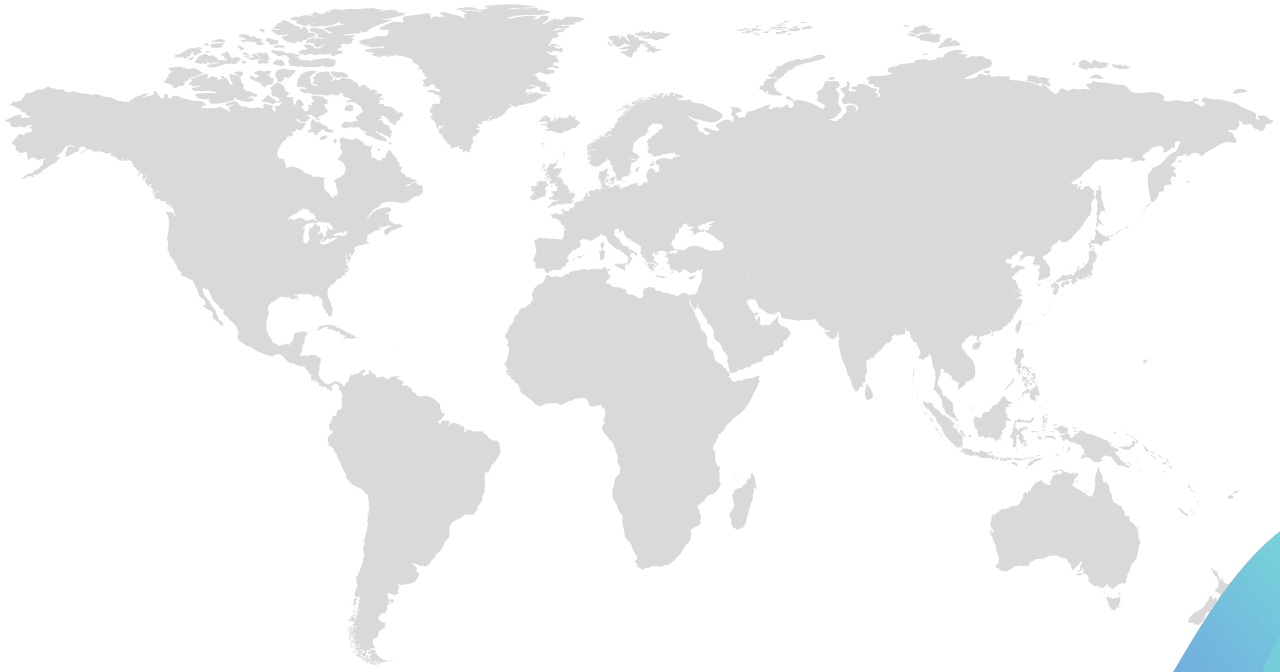
Price: $200

Webinar Description

This Webinar will explain what 21 CFR Part 11 is, why it is important to FDA regulated companies and how conformance to Part 11 differs from just having good IT security. Procedures for controlling electronic signatures and electronic records will be explained. FDA regulated companies want to transition to electronic records for economy and efficiency. FDA, because of its concern for patient safety, wants to prevent electronic records from being compromised with possible resulting harm to the patient. FDA has set up regulations that address both data security and patient safety. We will show how 21 CFR part 11 considers both.

The confusion over the original FDA regulation and its subsequent “selective enforcement” will be explained.

Who Should Attend ?



Quality Managers

Quality Engineers

Small Business Owners

GxP Professionals

Consultants

Quality VPs and IT VPs

Engineering personnel

Management

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Why Should Attend ?

Companies want to transition to electronic records but are afraid of compromising their quality system and receiving 483's at their next inspection. Part of this fear originates from confusion. FDA originally published a rather severe 21 CFR Part 11. After industry complaints, the FDA acknowledged that the regulation, as written, would result in nobody attempting to convert to electronic records. But, instead of rewriting the regulation, FDA said it would "selectively enforce" sections of the regulation. This webinar will explain what all these means.

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