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Webinar on

How To Prepare For And Host A FDA Inspection And Respond To 483’S

Learning Objectives

- *Personnel preparation*
- *Procedure to follow during audit- what to do/ what not to do*
- *Facility requirements to support inspection*
- *Behavior during inspection-what not to sign*
- *Internal/ mock audits*
- *483/ Warning Letter response*

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In this webinar you will learn about the types of FDA inspections, preparations, facility requirements and how to respond to 483s and warning letters.

PRESENTED BY:

Edwin Waldbusser is a consultant retired from the industry after 20 years in management of the development of medical devices (5 patents). He has been consulting in the US and internationally in the areas of design control, risk analysis and software validation for the past 8 years. Mr. Waldbusser has a BS in Mechanical Engineering and an MBA. He is a Lloyds of London certified ISO 9000 Lead Auditor and a member of the Thomson Reuters Expert Witness network.

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On-Demand Webinar

Duration : 60 Minutes

Price: $200

Webinar Description

In this webinar you will learn about the types of FDA inspections, preparations such as assigning dedicated personnel to specific tasks for the inspection, facility requirements to support the inspection (front room, back room), the value of mock audits, how personnel should conduct themselves, the inspection process and how to respond to 483s and warning letters. How to respond and when is critically important. Also covered will be the FDA's rights during the inspection and documentation you are not required to show them.

Who Should Attend ?

Engineering personnel

Engineering management

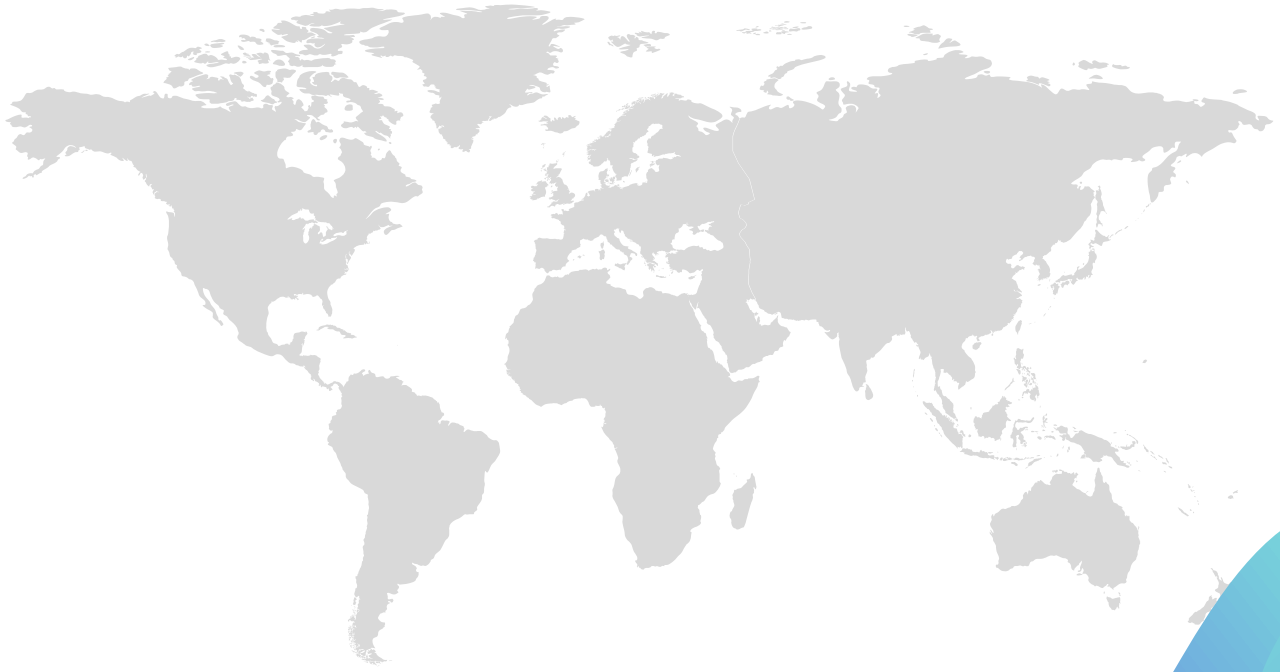
Quality/ Regulatory Management

Corporate Management

Manufacturing Management

Division management

Legal counsel



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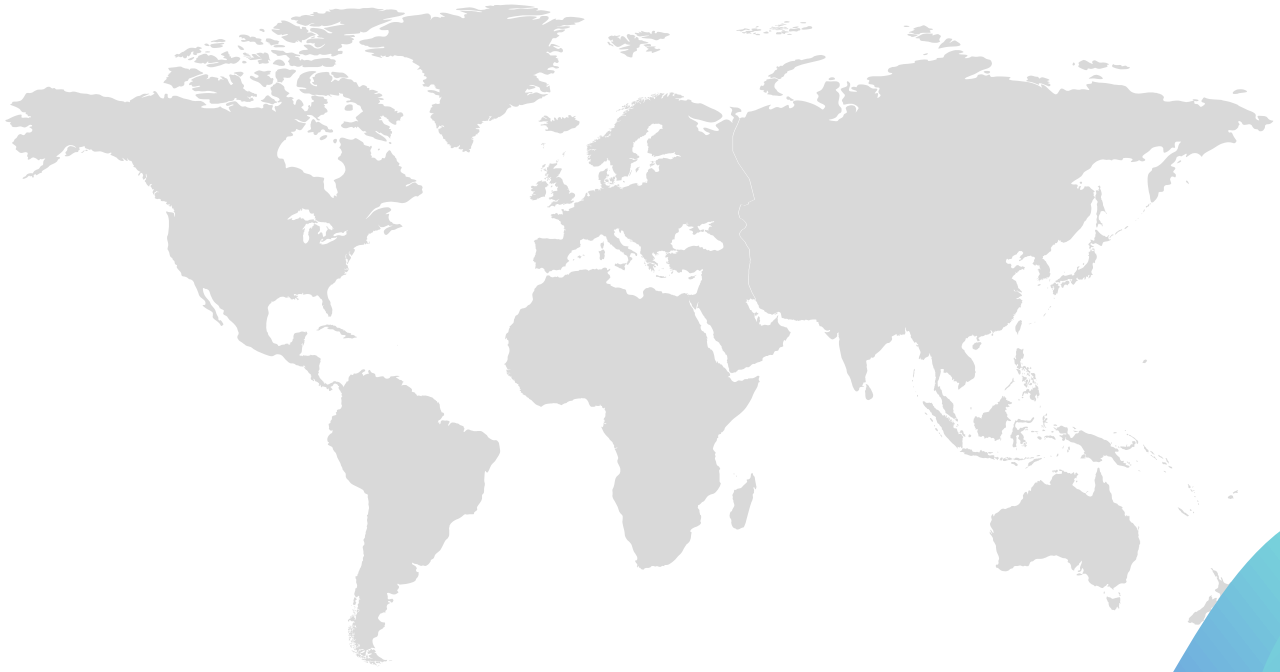
Why Should Attend ?

FDA is required to conduct an inspection every two years. A company that is prepared for the inspection is less likely to receive 483's than a disorganized company. If a 483 is received knowing how to respond will lessen the chances of receiving a Warning Letter.



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