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Webinar on

Medical Device Complaints And Corrective And Preventative Action (CAPA)

Learning Objectives

- *Sources of information (complaints), Verification/Validation of CAPA action*
- *Information gathering & proactive information gathering*
- *Information evaluation (is it a Complaint, is it a CAPA, should it be investigated)*
- *Risk analysis applied to CAPA, Root cause determination*
- *CAPA Investigation Report & CAPA action Plan*
- *Post-closing effectiveness check, CAPA program metrics*

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This webinar will explain the CAPA process from information gathering through MDR and Recall decision making to final CAPA closing.

PRESENTED BY:

Edwin Waldbusser is a consultant retired from the industry after 20 years in management of the development of medical devices (5 patents). Mr. Waldbusser has a BS in Mechanical Engineering and an MBA.

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On-Demand Webinar

Duration : 60 Minutes

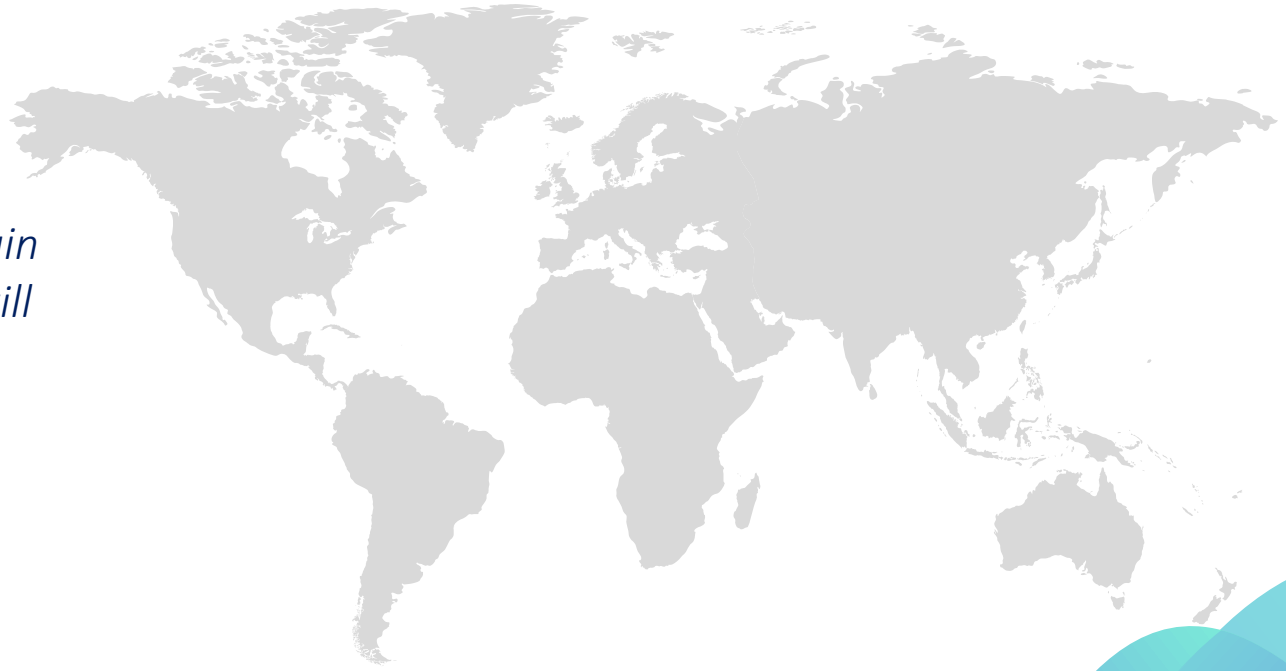
Price: $200

Webinar Description

Complaint handling and Corrective and Preventative Action (CAPA) is considered by the FDA to be two of the most important areas to assure medical device safety and efficacy. They are in the top five areas where FDA finds problems during inspections and issues 483's. Medical device developers must understand the complicated Complaint and CAPA process and have a strong CAPA program. A key understanding is striking a balance between too many CAPA's (strangles the system) and too few (problem areas escape fixing).

This webinar will explain the CAPA process from information gathering through MDR and Recall decision making to final CAPA closing. Post-closing effectiveness evaluation is required and will be explained. Preventative Action is often neglected and will be discussed. Post distribution product monitoring including customer surveys will be explained. Integration of manufacturing non-conformities with the CAPA program will be discussed.

Who Should Attend ?



After this course, you will be able to construct and maintain a strong but manageable Complaint/ CAPA system that will satisfy FDA requirements.

Templates of the Complaint Evaluation form and the Corrective Action Plan will be handouts.

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To register please visit:

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