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Webinar on

Risk Based Design Control Requirements and Industry Best Practices for Medical Devices

Date : July 22, 2021

Areas Covered

- *Reasons for design control*
- *When design control begins*
- *Elements of a design control program*
- *How risk management fits into design control*
- *Change control*
- *Understanding validation consists of more than testing*
- *Design History File*

Learning Objectives

- *How to manage a Design Control program that will meet FDA requirements*

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This course will explain how to manage a design program that will meet FDA requirements and minimize the chances of your medical device being recalled.

PRESENTED BY:

Edwin Waldbusser - retired from the industry after 27 years in management of the development of medical device products and development of company Quality Systems. He has been a consultant for the last10 years, working with companies from startups to Fortune 100 in the US, Germany, United Kingdom, Netherlands, Canada, Poland, and Saudi Arabia.

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Date : July 22, 2021

Time : 01: 00 PM EST

Duration : 60 Minutes

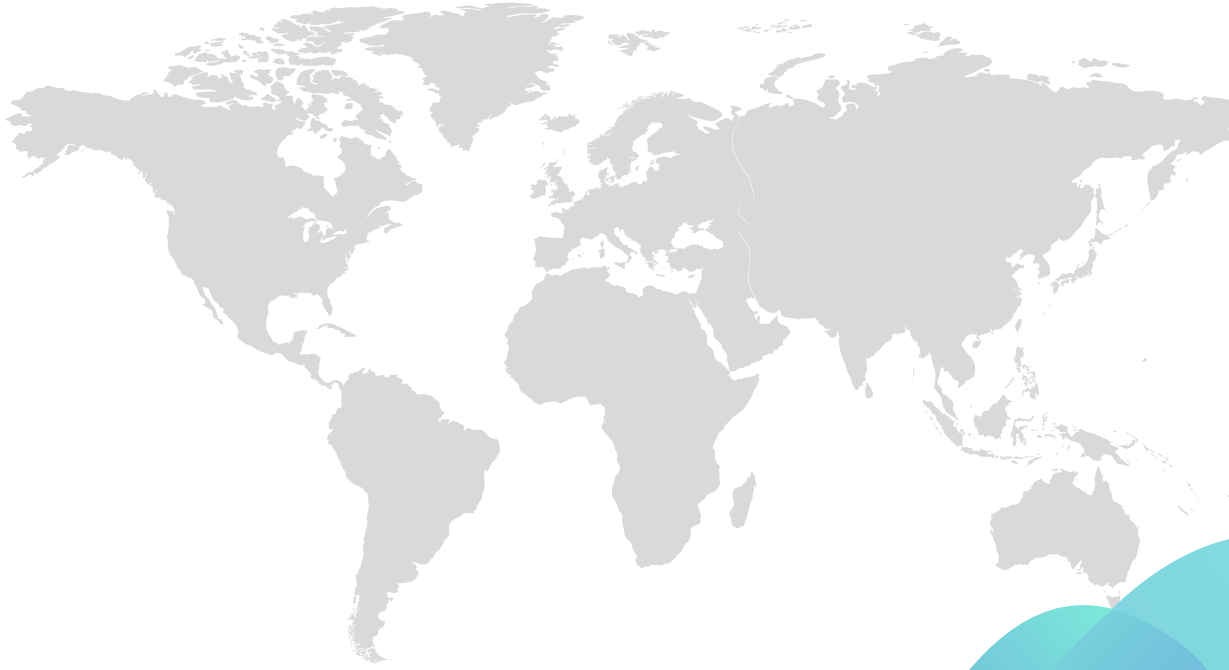
Price: $179

Webinar Description

This course will explain how to manage a design program that will meet FDA requirements and minimize the chances of your medical device being recalled. ISO 13485 has almost identical requirements. Such a program will also help to get projects completed on time and within budget.

The important and confusing question of when, in a development process, Design Control begins will be answered. The differences between pre-release and post-release change control will be explained. The Design History File will be explained and a contents checklist discussed. The interrelationship between ongoing risk analysis and the design process will be explained. The new Human Factors requirements will be discussed.

Who Should Attend ?



- *Management*
- *QA/ QC Personnel*
- *Production Management*
- *Development Engineers*
- *Software Developers*
- *Engineering Personnel*

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Why Should You Attend ?

Designing a medical device and testing it to prove it works is not sufficient in the eyes of the FDA to provide a safe product for users. The FDA has determined, through analysis of product recall data, that the majority of recalls were due to a faulty design process, not faulty manufacturing. These recalled products were tested before release and later failed in unanticipated ways that were not considered in the design and testing process. FDA also concluded that a well-controlled design process with risk analysis, change control, design reviews, hardware/ software validation, and feedback of the risk analysis results into the design process will greatly reduce the chances of an unsafe product.

Handouts are pre-release change control form, post-release change control form, user requirements template, DHF checklist.

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