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Webinar on

Human Factors/ Usability Following ISO 62366 And New FDA Guidance

Learning Objectives

- *User error versus use error*
- *Use related hazards and risk analysis*
- *User profiles*
- *Use scenarios*
- *Step by step human factors program development*
  Validation

This webinar explains the process of conducting rigorous human factors studies throughout the design process, integrating results with the device risk analysis and design process, and validating the effectiveness of the studies will be explained.

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

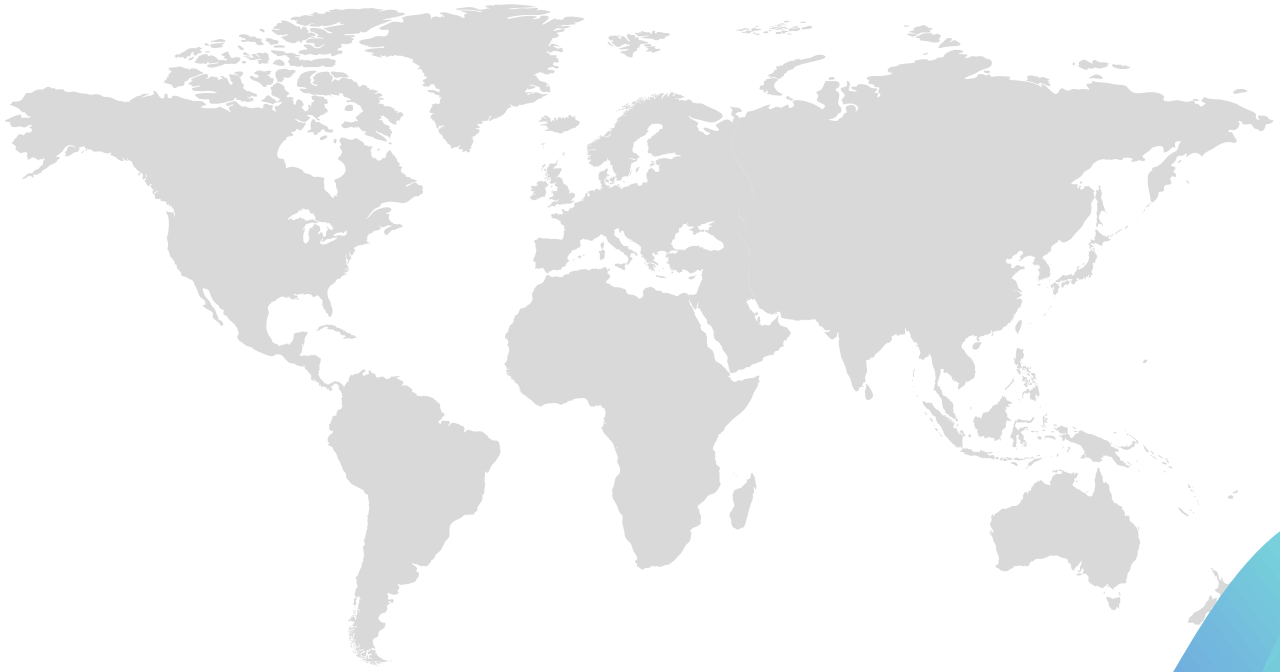
Price: $200

Webinar Description

Human Factors/ Usability is an analysis of how people interact with medical devices. The process of conducting rigorous human factors studies throughout the design process, integrating results with the device risk analysis and design process, and validating the effectiveness of the studies will be explained. The various types and methods of human factors analysis will be explained. This process conforms to the new ISO 62366 standard and the new FDA Guidance document.

Many medical devices cause harm to the user or others not because the device fails but because the user makes an error when using the device. The FDA, by requiring Human Factors studies, wants to minimize user errors.

Who Should Attend ?



Engineer

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Company Management

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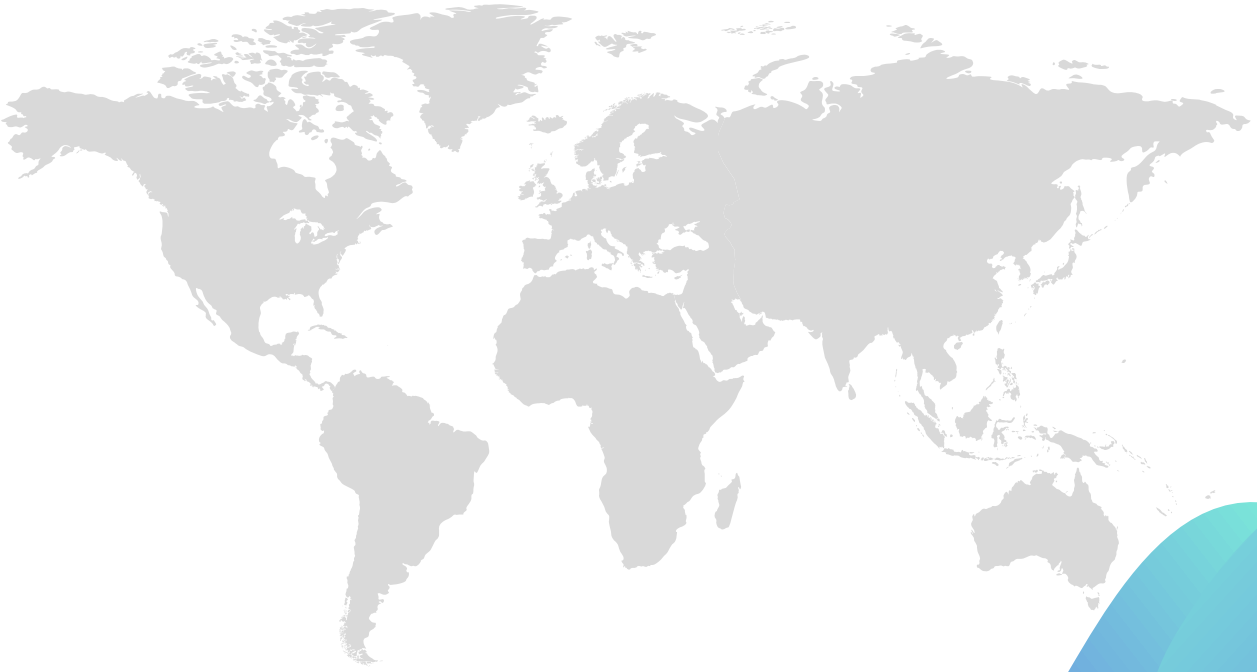
Why Should You Attend ?

The FDA will only approve devices that are designed so that it is practically impossible for people to accidentally harm themselves or others even if they use the device improperly. The FDA has replaced the term “user error” with “use error”. This means that user error is considered by the FDA to be a device nonconformity because human factors should be considered in the design process. The burden is on the device designer to create an “idiot-proof” product.

Handouts are use specification template, user interface evaluation template, and usability validation control form.



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