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Webinar on

Human Factors/ Usability Studies Following ISO62366 And The New FDA Guidance

Learning Objectives

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

In This webinar you will learn the device risk analysis and design process, and validating the effectiveness of the studies will be explained.

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.

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On-Demand Webinar

Duration : 60 Minutes

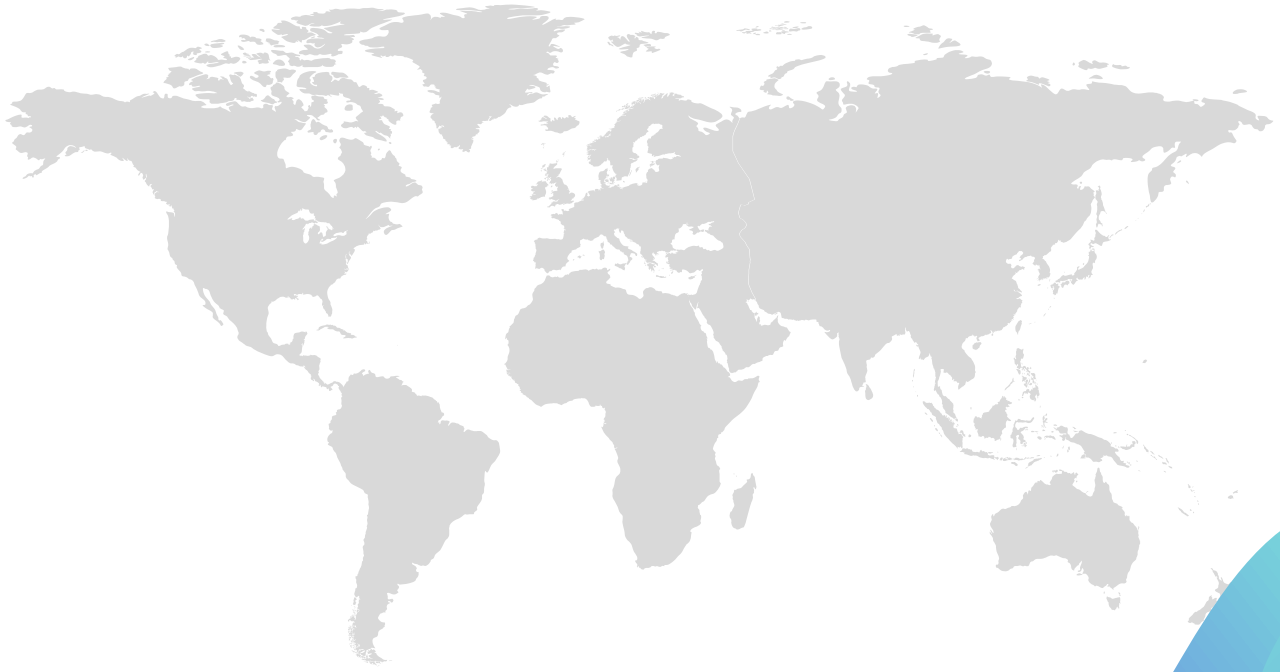
Price: $200

Webinar Description

Human Factors/Usability is the analysis of how people interact with medical devices. The process of conducting rigorous human factors studies throughout the design process, integrating it 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.

Who Should Attend ?

Engineer , Engineer management
Quality assurance , Regulatory



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Why Should Attend ?

The FDA will only approve devices which are designed so that it is practically impossible for people to accidentally harm themselves even if they use the device improperly. The FDA has replaced the term "user error" with "use error".
This means that use 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 used specification template, user interface evaluation template, and usability validation control form.

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