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Webinar on

Medical Device Hazard Analysis Following ISO 14971

Learning Objectives

- *Explanation of Hazard Analysis terms*
- *Hazard Analysis Process Explanation using a Template*
- *Examples of Terms will be given*
- *Hazard Analysis Examples will be Covered Step by Step*

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In this webinar you will learn how to integrate Human Factors studies into the Hazard Analysis and how to integrate Hazard Analysis into the design program

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 9 years.

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On-Demand Webinar

Duration : 60 Minutes

Price: $200

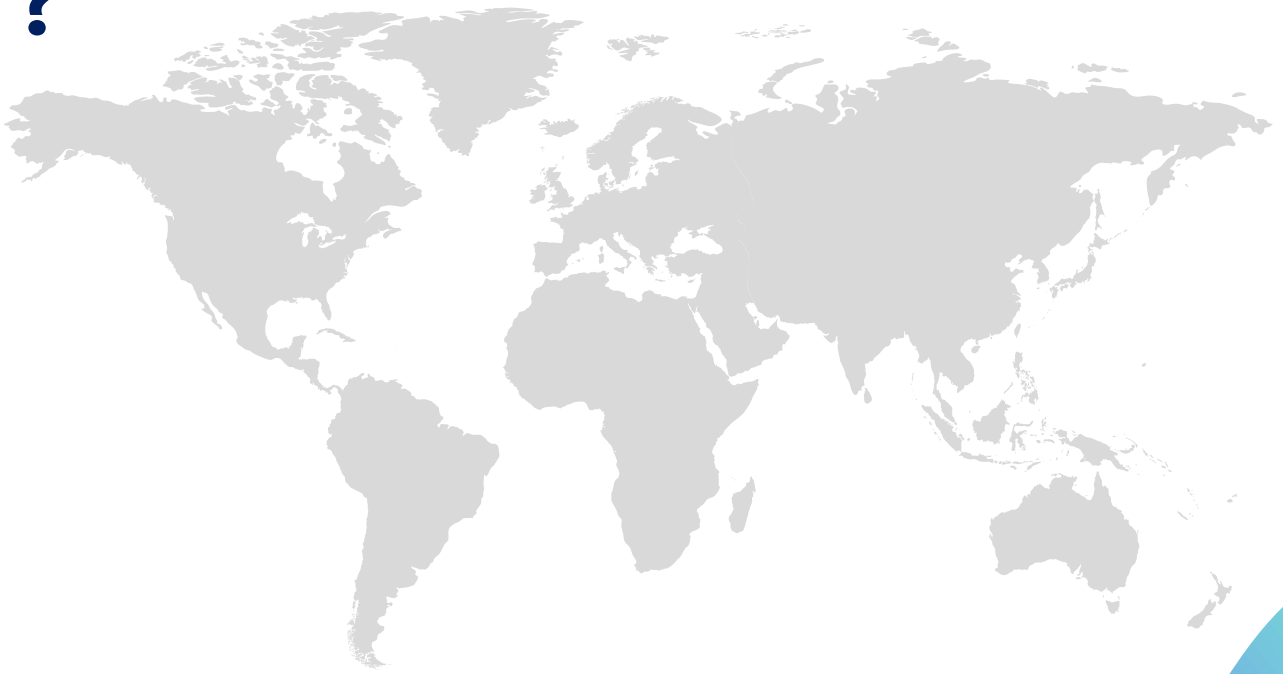
Webinar Description

The US FDA expects that as part of a product development Design Control Program risk management will be conducted. FDA recommends using ISO 14971 as a guide and has accepted it as a recognized standard. One of the techniques described in ISO 14971 is Hazard Analysis. This is the most powerful of the risk management techniques because it considers risks in normal operation as well as fault conditions. FMEA and FTA consider only fault conditions and are more suited to reliability tools than as product safety tools.

In this seminar, we will explain in detail the process of conducting a hazard analysis. The confusing terms “hazard”, hazardous situation”, “harm”, “causative event”, “ALARP”, “risk index”, “residual risk” will be explained. We will go step by step through a template for hazard analysis so that the process is clear. Examples of hazards and hazardous situations will be discussed. How to deal with residual risk will be discussed. We will go step by step through a typical hazard analysis.

We will explain how to integrate Human Factors studies into the Hazard Analysis and how to integrate Hazard Analysis into the design program.

Who Should Attend ?



Engineer

Engineering Manager

Regulatory Personnel

QA

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Why Should Attend ?

FDA expects that as part of a product development program risk management will be conducted. FDA recommends using ISO 14971 as a guide and has accepted it as a recognized standard. Hazard Analysis is the most powerful of the risk management tools described in ISO 14971 but it is very confusing. Many new concepts are introduced. We will explain these concepts and provide examples so that the process is clear.

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