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Webinar on

Medical Device Risk Management Following ISO 14971:2019

Learning Objectives

- *Explanation of Hazard Analysis terms: hazard, hazardous situation, harm, risk, acceptability criteria, benefit/ risk ratio*
- *Explanation of the hazard analysis process using a template*
- *Examples of terms will be given*
- *Hazard analysis examples will be covered step by step*
- *Risk management plan*
- *Risk management file*

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In this webinar, we will explain in detail the process of conducting a hazard analysis.

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

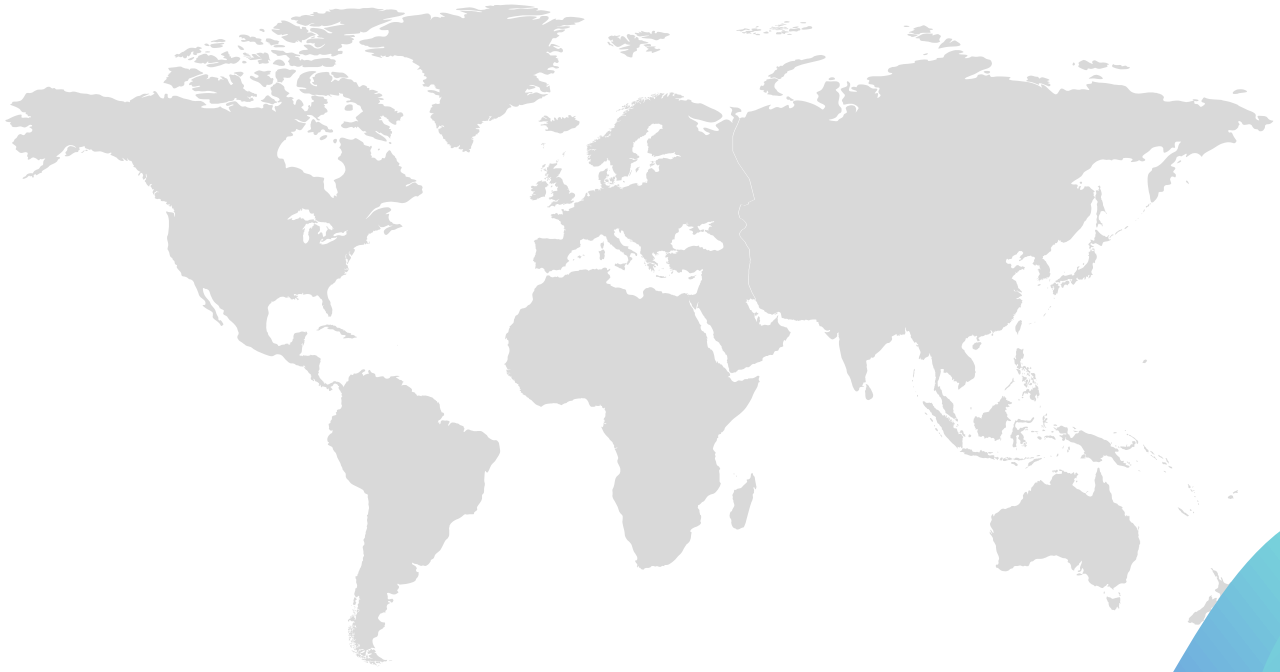
The US FDA expects that as part of a product development Design Control Program risk management will be conducted. FDA also expects that a post-production risk management program is implemented. FDA recommends using ISO 14971 as a guide and has accepted it as a recognized standard. Hazard Analysis is described in ISO 14971. 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 as reliability tools than as product safety tools.

In this webinar, we will explain in detail the process of conducting a hazard analysis. The confusing terms “hazard”, hazardous situation”, “harm”, “causative event”, “ALARP”, “risk index”, “benefit/ risk ratio”, and “residual risk” will be explained. We will go step by step through a template for risk 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 explain how to integrate Human Factors studies into the Hazard Analysis and how to integrate Hazard Analysis into the design program. Risk level can determine the extent of CAPA investigations, validations effort, etc. Application of ISO 14971 principles to software risk management will be explained. Requirements for each step of the risk management process, including the risk management plan, development of risk acceptability criteria, risk analysis, risk evaluation, risk control, risk/ benefit analysis, postproduction analysis will be explained.

Who Should Attend ?

Engineer
Engineering Manager
Manufacturing manager
Regulatory Personnel
QA



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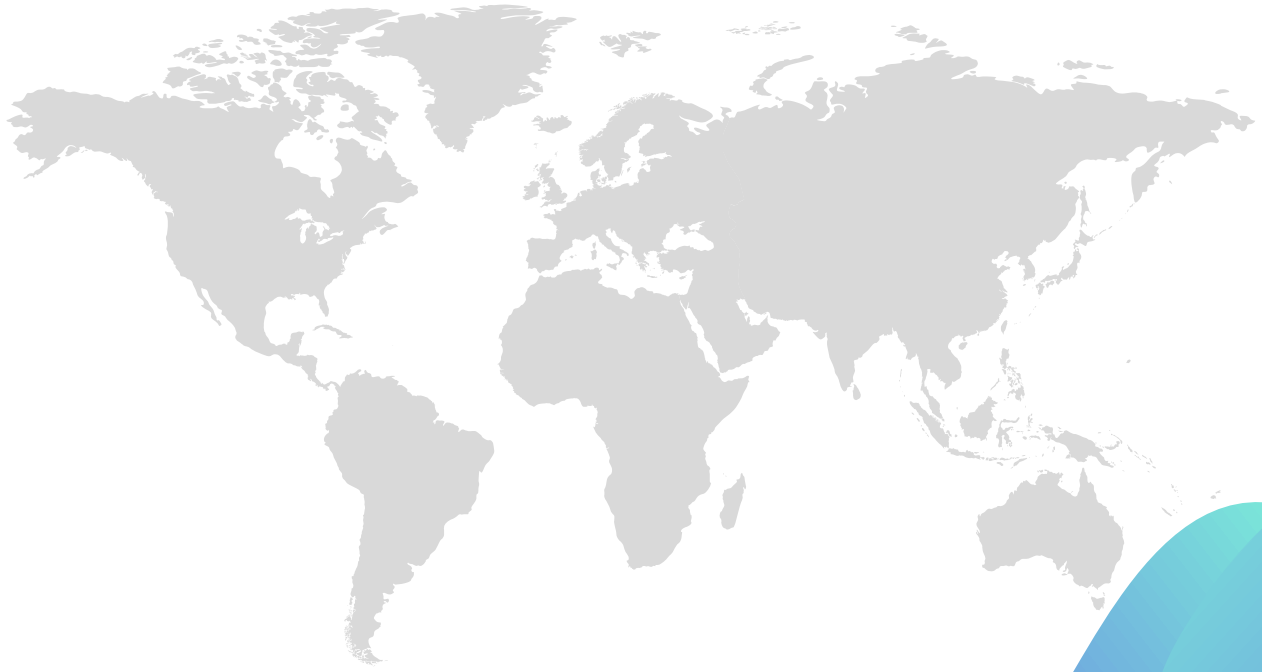
Why Should You Attend ?

FDA expects that as part of a product development program risk management will be conducted and risks will be mitigated as far as practical. Risk Analysis is required in a FDA product submission. FDA recommends using ISO 14971 as a guide and has accepted it as a recognized standard. Hazard Analysis, described in ISO 14971, is the most powerful of the risk management tools, but it is very confusing. Many new concepts are introduced. We will explain these concepts and provide examples so that you can expertly perform the process. Templates will be provided.
Handouts are hazard analysis forms and HA report template.



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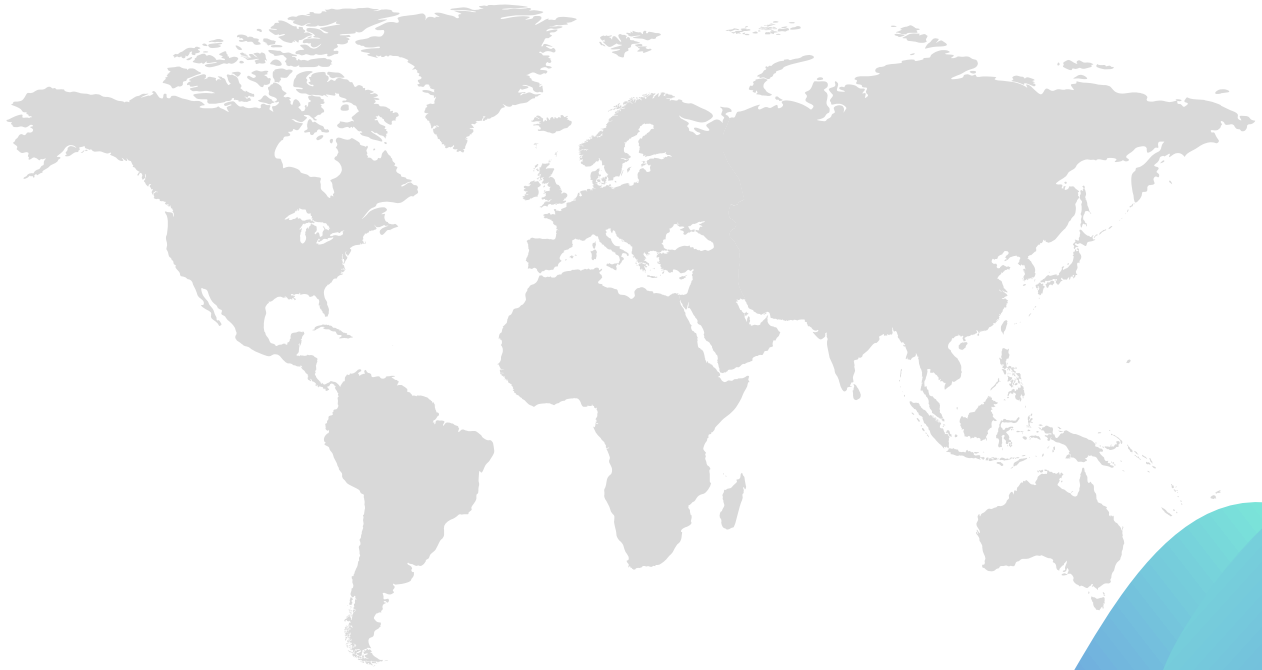
Topic Background

A new version of ISO14971 has been issued containing many important changes to risk management. US FDA accepts this document and expects companies to conform to it's requirements.



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