BLACKBIRD FOR TRAINING

ISO 14971: Risk Management of Medical Devices

Geneva (Switzerland)

30 June - 4 July 2025

ISO 14971: Risk Management of Medical Devices

Code: QM28 From: 30 June - 4 July 2025 City: Geneva (Switzerland) Fees: 4700 Pound

Course Introduction

On completion of this course, the participant will learn why the risk management process is important, the general requirements of a risk management system and how to perform a risk analysis and control risk in an organization. ISO 14971 specifies a process for a manufacturer to identify the hazards associated with medical devices, estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls. The requirements of ISO 14971 are applicable to all stages of the lifecycle of a medical device. This course helps medical device professionals understand how ISO14971 can improve their business and risk management efforts. The student will gain an understanding of the impact that ISO14971 has on the decision-making process when manufacturing medical devices. After finishing the course, the student will gain the ability to work with risk management for medical devices according to the ISO 14971 standard.

Course Objectives of ISO 14971: Risk Management of Medical Devices

- Identifying the links between ISO 13485 QMS and ISO 14971 RM.
- Explaining how risk management relates to the product lifecycle.
- Defining risk management terminology.
- Outlining the stages of the risk management process.
- Defining the key deliverables of the risk management process.

ISO 14971: Risk Management of Medical Devices Course Outlines

Day 1

Introduction to risk management in medical devices

- Links of risk management to regulatory requirements.
- The relationship of ISO14971 to other standards.
- ISO13485 and Risk Management.
- Understanding ISO13485.

Day 2

The development of ISO14971

- Why do we risk managing medical devices using ISO14971?
- The Lifecycle approach.
- ISO14971 - Overview of the standard.
- Terms and definitions.
- General requirements of the standard.

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Day 3

The risk management process

- The risk management plan.
- Risk analysis.
- Risk evaluation.
- Risk Control.

Day 4

Residual risk acceptability

- Report/documentation.
- The Risk Management File Postproduction.
- IEC 606011:2005: Medical Electrical Equipment, General requirements for basic safety and essential performance.

Day 5

Tools for Risk Management

- Failure modes and effect analysis.
- Fault tree analysis.
- Hazard analysis and critical control point.
- Summary and conclusions.

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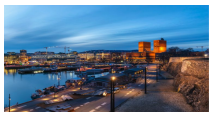
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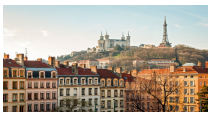
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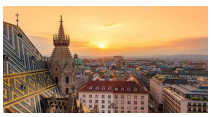
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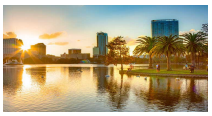
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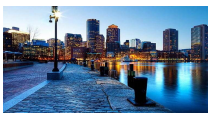
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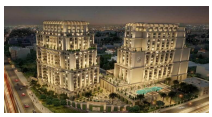
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International House 185 Tower Bridge Road London SE1 2UF United Kingdom

+44 7401 1773 35
+44 7480 775526

Sales@blackbird-training.com

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