

ISO 14971: Risk Management of Medical Devices

Amsterdam (Netherlands)

9 - 13 June 2025

UK Training

PARTNER



ISO 14971: Risk Management of Medical Devices

Code: QM28 From: 9 - 13 June 2025 City: Amsterdam (Netherlands) Fees: 4200 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.

UK Training

PARTNER



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.

Blackbird Training Cities

Europe



Malaga (Spain)



Sarajevo (Bosnia and Herzegovina)



Oporto (Portugal)



Glasgow (Scotland)



Edinburgh (UK)



Oslo (Norway)



Annecy (France)



Bordeaux (France)



Copenhagen (Denmark)



Birmingham (UK)



Lyon (France)



Moscow (Russia)



Stockholm (Sweden)
(Netherlands)



Podgorica (Montenegro)



Batumi (Georgia)



London (UK)



Istanbul (Turkey)



Amsterdam



Düsseldorf (Germany)



Paris (France)



Barcelona (Spain)



Munich (Germany)



Geneva (Switzerland)



Prague (Czech)



Vienna (Austria)



Rome (Italy)



Brussels (Belgium)



Madrid (Spain)



Berlin (Germany)



Lisbon (Portugal)



Zurich (Switzerland)



Manchester (UK)



Milan (Italy)



Blackbird Training Cities

USA & Canada



Los Angeles (USA)



Orlando, Florida (USA)



Online



Phoenix, Arizona (USA)



Houston, Texas (USA)



Boston, MA (USA)



Washington (USA)



Miami, Florida (USA)



New York City (USA)



Seattle, Washington (USA)



Washington DC (USA)



In House



Jersey, New Jersey (USA)



Toronto (Canada)

Africa



Baku (Azerbaijan)
(Thailand)



Maldives (Maldives)



Doha (Qatar)



Manila (Philippines)



Bali (Indonesia)



Bangkok



Beijing (China)



Singapore (Singapore)



Sydney (Australia)



Tokyo (Japan)



Jeddah (KSA)



Riyadh (KSA)



Dubai (UAE)



Kuala Lumpur (Malaysia)



Kuwait City (Kuwait)



Pulau Ujong (Singapore)



Jakarta (Indonesia)



Amman (Jordan)



Beirut (Lebanon)

UK Training
PARTNER

Blackbird Training Cities

Asia



Kigali (Rwanda)



Cape Town (South Africa)



Accra (Ghana)



Lagos (Nigeria)



Marrakesh (Morocco)



Nairobi (Kenya)



Zanzibar (Tanzania)



Tangier (Morocco)



Cairo (Egypt)



Sharm El-Sheikh (Egypt)



Casablanca (Morocco)



Tunis (Tunisia)



Blackbird Training Clients



UK Training
PARTNER

Blackbird Training Categories

Management & Admin

Professional Skills
Finance, Accounting, Budgeting
Media & Public Relations
Project Management
Human Resources
Audit & Quality Assurance
Marketing, Sales, Customer Service
Secretary & Admin
Supply Chain & Logistics
Management & Leadership
Agile and Elevation

Technical Courses

Hospital Management
Public Sector
Special Workshops
Oil & Gas Engineering
Telecom Engineering
IT & IT Engineering
Health & Safety
Law and Contract Management
Customs & Safety
Aviation
C-Suite Training



BLACKBIRD
FOR TRAINING

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

 +44 7401 1773 35
+44 7480 775526

 Sales@blackbird-training.com

 www.blackbird-training.com

UK Training
PARTNER

