ISO 14971 Risk Management for Medical Devices Training

Audit & Quality Assurance
Vienna (Austria)
28 Jul - 01 Aug 2025

ISO 14971 Risk Management for Medical Devices Training

Ref: 3178_130557 **Date:** 28 Jul - 01 Aug 2025 **Location:** Vienna (Austria) **Fees:** 4400 **Euro**

Course Description

This 5-day course provides comprehensive training on ISO 14971:2019 for medical device risk management. Participants will learn to apply risk management principles throughout the product lifecycle, from design to post-market surveillance. The course covers risk analysis techniques, evaluation methods, control measures, and regulatory compliance.

Learning Objectives

- Understand the principles and requirements of ISO 14971:2019
- Apply risk management techniques throughout the medical device lifecycle
- Develop effective risk analysis, evaluation, and control strategies
- Implement a compliant risk management process within a quality management system
- Integrate risk management with design controls and post-market surveillance

Course Modules

Day 1: Introduction to Risk Management

- Overview of ISO 14971:2019
- Risk management principles and terminology
- Regulatory requirements and standards
- Risk management process and lifecycle approach

Day 2: Risk Analysis Techniques

- Hazard identification methods
- Fault Tree Analysis FTA
- Failure Mode and Effects Analysis FMEA
- Preliminary Hazard Analysis PHA

Day 3: Risk Evaluation and Control

- Risk estimation and evaluation techniques
- Risk control option analysis
- Residual risk evaluation
- Benefit-risk analysis

Day 4: Risk Management Implementation

Head Office: +44 7480 775 526 | 0 7401 177 335
Email: training@blackbird-training.com
Website: www.blackbird-training.com

- Developing a risk management plan
- Integration with design controls
- Risk management file documentation
- Traceability in risk management

Day 5: Production and Post-Production

- Risk monitoring and review
- Post-market surveillance integration
- Risk management reporting
- Continuous improvement of the risk management process

Practical Wins for Participants

- Ability to implement a compliant risk management process
- Skills to perform comprehensive risk analysis and evaluation
- Knowledge to integrate risk management with other quality processes
- Confidence in addressing regulatory requirements for risk management

Head Office: +44 7480 775 526 | 0 7401 177 335
Email: training@blackbird-training.com
Website: www.blackbird-training.com

Blackbird training cities

Accra (Ghana)

Amman (Jordan)

Amsterdam (Netherlands)

Annecy (France)

Baku (Azerbaijan)

Bali (Indonesia)

Bangkok (Thailand)

Bangkok (Thailand)

Barcelona (Spain)

Batumi (Georgia)

Beijing (China)

Beirut (Lebanon)

Berlin (Germany)

Birmingham (UK)

Bordeax (France)

Boston,Massachusetts (USA)

Brussels (Belgium)

Cairo (Egypt)

Cape Town (South Africa)

Casablanca (Morocco)

Cascais (Portugal)

Copenhagen (Denmark)

Doha (Qatar)

Dubai (UAE)

Düsseldorf (Germany)

Head Office: +44 7480 775 526 | 0 7401 177 335
Email: training@blackbird-training.com
Website: www.blackbird-training.com

Blackbird Training Category

Human Resource

Audit & Quality Assurance

Finance, Accounting, Budgeting

Marketing, Sales, Customer Service

Secretary & Admin

Law and Contract Management

Project Management

IT & IT Engineering

Supply Chain & Logistics

Management & Leadership

Professional Skills

Oil & Gas Engineering

Health & Safety

Telecom Engineering

Hospital Management

Customs & Safety

Aviation

C-Suite Training

Agile and Refinement

Head Office: +44 7480 775 526 | 0 7401 177 335
Email: training@blackbird-training.com
Website: www.blackbird-training.com

Blackbird training Clients

MANNAI Trading Company WLL, **Qatar**

Alumina Corporation **Guinea**

Booking.com **Netherlands**

Oxfam GB International Organization, **Yemen**

Capital Markets Authority, **Kuwait**

Waltersmith Petroman Oil Limited **Nigeria**

Qatar National Bank (QNB), **Qatar**

Qatar Foundation, **Qatar**

AFRICAN UNION ADVISORY BOARD ON CORRUPTION, **Tanzania**

KFAS **Kuwait**

Reserve Bank of Malawi, **Malawi**

Central Bank of Nigeria **Nigeria**

Ministry of Interior, **KSA**

Mabruk Oil Company **Libya**

Saudi Electricity Company, **KSA**

BADAN PENGELOLA KEUANGAN Haji, **Indonesia**

NATO **Italy**

ENI CORPORATE UNIVERSITY, **Italy**

Gulf Bank **Kuwait**

General Organization for Social Insurance **KSA**

Defence Space Administraion **Nigeria**

National Industries Group (Holding), **Kuwait**

Hamad Medical Corporation, **Qatar**

USAID **Pakistan**

STC Solutions, **KSA**

North Oil company,

EKO Electricity

Oman Broadband

UN.

Authority for

UK Trainig
PARTNER

Head Office: +44 7480 775 526 | 0 7401 177 335
Email: training@blackbird-training.com
Website: www.blackbird-training.com

BLACKBIRD
FOR TRAINING

LONDON TRAINING PROVIDER

www.blackbird-training.com
training@blackbird-training.com
+44 7480 775526 / +44 7401 177335