



ISO 14971 - Risk Analysis for Medical Devices

Learn about the steps of the risk assessment process and its application specifically to medical devices on this ISO 14971 Risk Analysis for Medical Devices training course.

On this practical 1-day course you will examine all steps of the risk management process, from risk analysis and risk evaluation through risk control to post-production information gathering.

The course employs interactive workshops to allow you to practise what you are learning, as well as group discussions on topics such as risk control, hazard identification and techniques for risk analysis.

COURSE DURATION

1 day

CPD

Equivalent to 7 hours

COURSE PRICE

From £645 + VAT

DATES & VENUES

[View dates & venues](#)

CERTIFICATES

All delegates will receive a certificate on completion.

Who should attend?

This course is suitable for designers, production professionals and managers who need to work together to measure risk and promote safety. These include:

- R&D managers/engineers
- RA/QA managers/engineers
- management representatives
- members of multi-discipline design teams
- members of design review teams
- sales and marketing management
- product, project, and programme managers
- internal auditors

If you wish to explore more deeply into Failure Mode and Effects Analysis (FMEA) at the same time as learning about risk analysis, we recommend you look at our 2-day [Risk Analysis and FMEA for Medical Devices](#) training course.

Key topics

Topics covered on the course include:

- expectations of the FDA and the EU in applying risk analysis to medical devices
- risk management requirements and the purpose of ISO 14971
- the application of ISO 14971 to medical devices
- the principles of risk management planning in developing procedures and practices to analyse, evaluate and control risks
- sources of information and further development

Skills gained

By the end of this training course on risk analysis for medical devices, delegates will be able to:

- apply the process to conduct risk analysis to identify hazards, their severity and the probability that they might occur
- apply risk evaluation and risk control principles to their devices, including regulatory requirements, technical costs, accident costs, liability costs and insurance costs, which affect decision-making on the acceptability of risks in bringing a device to market



An ISO 14971 Risk Analysis for Medical Devices Training Course certificate will be awarded to delegates who complete all elements of the course.

Course agenda

Our training courses are designed to optimise the learning experience for delegates both in face-to-face settings and in our Virtual Classroom.

Under the guidance of our expert tutors, attendees will follow an agenda which is briefly outlined below:

- Welcome and Introductions
- Module 1 Introduction to Risk
- Module 2 Risk Policy
- Module 3 Scope & Definitions
- Module 4 Risk Process, Plan, File
- Module 5 Risk Analysis
- Module 6 Risk Analysis Continued: Usability
- Module 7 Risk Estimation
- Module 8 Risk Analysis – Techniques
- Module 9 Risk Evaluation
- Module 10 Risk Control
- Module 11 Residual Risk Evaluation
- Module 12 Benefit-risk Analysis
- Module 13 Evaluation of Overall Residual Risk
- Module 14 Risk Management Review
- Module 15 Production and Post-production Activities
- Course Review and Evaluation

In-company training

Ideal for groups, you can receive this course exclusively for your organisation at your premises or online in our user-friendly Virtual Classroom.

Enjoy cost-effective flexibility and personalised learning with tailored messaging designed to address your unique business challenges.

[Contact us for a quote.](#)

Tutor's interaction with the class and the way he explained things were brilliant.

Huntleigh Healthcare

The tutor was brilliant, adapted the course to each individuals job titles so we could get the most out of the training. Felt comfortable asking her any questions and kept us all engaged throughout the day.

Vernacare

The practical parts of the course were useful and easy to see where these apply to my day to day and running Risk assessments on projects going forward. The presentation approach was good and the tutor was easy to understand and guided the learning well.

Centre For Process Innovation Limited

[Read our Medical Devices course reviews](#)

Why train with Bywater?

Bywater is the leading independent provider of professional management systems training in the UK.

Our expert training offers practical understanding of how to realise the benefits and assess the success of implementing and operating successful management systems.

Bywater delegates know they can rely on proven training delivered by experts at times and locations to suit their needs.

40 years established

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15 UK locations

1000+ courses annually



Global Virtual Classroom

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