Risk Analysis and FMEA for Medical Devices

Understand the steps involved in the risk management process of bringing medical devices to market, and the value of Failure Mode and Effects Analysis (FMEA), on this Risk Analysis and FMEA for Medical Devices training course.

On the first day of this 2-day interactive and practical course you will learn about the requirements of ISO 14971 and how to carry out risk analysis from start to finish. The second day will explore in greater depth the role of FMEA and how to apply it in your risk management process.

As well as workshops and discussions around topics such as hazard Identification and risk control and reduction, delegates will have the opportunity to talk as a group about the stages of FMEA.

COURSE DURATION
2 days

CPD
Equivalent to 14 hours

COURSE PRICE
From £3995 + VAT

IN-COMPANY TRAINING
Check availability

CERTIFICATES
All delegates will receive a certificate on completion.

Course details >

Who should attend?

This course is suitable for those who participate in the risk analysis and control process. This can 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 would like to understand risk analysis and control in bringing medical devices to market without further detail around FMEA, you may like to look at our 1-day ISO 14971 Risk Analysis 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 application of risk analysis methodologies such as FMEA 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 Risk Analysis and FMEA training course for medical devices, delegates will be able to:

- apply the process to conduct risk analysis to identify hazards, their severity and the probability they might occur
- apply risk analysis methodologies to medical devices
- apply risk evaluation and risk control principles to their devices – including regulatory requirements, technical costs, accident costs, liability costs and insurance costs – all of which feed into decision-making around acceptability of risks when bringing a device to market

Delegates who complete all elements of the course will receive a certificate in recognition of their new understanding of risk analysis and FMEA for medical devices.

Course agenda >

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 Background to Risk Management
- Module 2 Review of the ISO 14971 Standard
- Module 3 Risk Analysis in ISO 14971
- Module 4 Workshop 1: Identify Intended Use, Misuse and Characteristics of a Device
- Module 5 Workshop 2: Hazard Identification, Risk Estimation and Evaluation
- Module 6 Risk Control in ISO 14971
- Module 7 Workshop 3: Risk Control and Reduction
- Module 8 Overall Residual Risk and the Risk Management Report in ISO 14971
- Module 9 Techniques for Risk Analysis
- Module 10 ISO 60812 Analysis Techniques for System Analysis – FMEA
- Module 11 FMEA in Practice
- Module 12 Workshop 4: First Stage of FMEA
- Module 13 Failure Mode Analysis – Identifying the Causes and Prevention or Detection
- Module 14 Workshop 5: Second Stage of FMEA
- Module 15 Ranking and Reducing the Risk – Calculating the RPN
- Module 16 Workshop 6: Third Stage of FMEA
- Module 17 Process FMEA
- Course Review and Evaluation

In-company training

Receive this course exclusively for your organisation, either in-person at your chosen venue 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

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