Introduction to Risk Management for Medical Devices

Course Description

This course is designed to provide participants with an understanding of the impact that ISO 14971:2009 has on the decision making process at medical device manufacturing firms. This one-day training course helps medical device professionals gain an understanding of how ISO 14971 can improve their business and risk management efforts. Participants will also understand how ISO 14971 applies to ISO 13485.

The training includes exercises, and participants will have the chance to ask questions about how ISO 14971 and risk management apply to their organizations.

Learning Objectives

On completion of this training, participants will be able to:

- Identify the links between ISO 13485 (QMS) and ISO 14971 (RM)
- Explain how risk management relates to the product lifecycle
- Define risk management terminology
- Outline the stages of the risk management process
- Define the key deliverables of the risk management process.

Intended Audience

- Regulatory, quality, design (including design changes), development, manufacturing, marketing managers and personnel
- Decision makers on management system strategy
- Internal auditors.

Course Duration

One day.

Prerequisites

Participants should have experience with or basic knowledge of quality management systems for the medical device industry. Recommended is a basic awareness of medical devices, quality assurance, and ISO 13485.

How will I learn?

We use accelerated learning techniques that encourage interaction and collaboration, keep the course varied and put your learning in context. Our tutors are the best in their field and will make sure your learning needs are met. Choose between public or in-company courses tailored to your business – whatever delivers the most positive and successful outcome for you.

Where will I learn?

We deliver five star learning at first class venues. Each venue has been selected to provide the best possible learning environment so you can maximize your learning experience.

Who are we?

As an EU Notified Body, our expertise is in auditing to the requirements of the Directives. Our tutors are skilled in transferring knowledge contained within each standard to help you embed excellence within your organization. With over 65,000 clients in 150 countries worldwide, you can trust BSI to help you perform better, reduce risk and grow sustainably.

Why train with us?

We've trained and audited thousands of businesses using the same standards so we can genuinely benchmark performance. And we can take you from beginner to certification quickly then support you with follow-up courses and webinars – and all this for the price of your course.

Did you know?

Our tutors are active practitioners in their subjects, ensuring the latest developments are fully understood. We are the leaders in medical devices regulatory expertise with over 200 BSI Medical Device product and regulation experts around the world.

Next step:

To book this course, call one of our dedicated training experts on +1 800 862 6752 or book online at bsigroup.ca/training

In-company Training

Discuss your product development in confidential surroundings by opting for bespoke in-company training.

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