Introduction to: ISO 13485

Course Description

BSI's "Introduction to: ISO 13485" one day course has been designed to provide an insight in to the use of ISO 13485 as the basis for a quality management system implemented by medical device manufacturers.

Time will be spent during the course reviewing requirements of ISO 13485 and making comparisons to ISO 9001 and the FDA's Quality System Regulation. In addition to this, participants will also gain an awareness of the relationship between ISO 13485 and ISO 14971, "Application of Risk Management to Medical Devices".

Learning Objectives

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

- Compare the requirements between ISO 13485 and ISO 9001
- Interpret the clauses of ISO 13485 using ISO 14969
- Recognize the role and responsibilities of management in ISO 13485
- Recognize the relationship between ISO 13485 and ISO 14971
- Compare the requirements between ISO 13485 and FDA's Quality System Regulation
- Appreciate the use of ISO 13485 as the basis of Medical Device Regulations worldwide.

Intended Audience

- Senior Management
- Quality Managers
- Regulatory Affairs Managers
- Internal and external Auditors
- Anyone involved with the implementation of the standard.

Course Duration

One day.

Prerequisites

There is no prerequisite for this course but participants will benefit from a basic knowledge of the quality management systems, ISO 9001 or 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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