Post-market Surveillance and Vigilance

Course Description

Post-market surveillance including clinical follow-up, complaint and vigilance handling, impacts on all aspects of the quality management system.

Proactive and reactive sources of information are a regulatory requirement to be incorporated in your post-market surveillance procedures applicable to all products.

By developing a post-market surveillance plan you can target sources of information enabling a cost effective product launch. Obtaining the right post-market information will ensure continued compliance with the directives and identify consumer needs enabling continued product development.

BSI's "Post-market Surveillance and Vigilance" 1 day course is designed to help you identify the requirements of the European medical device directives (90/385/EEC, 93/42/EEC, 98/79/EC), standards and guidance documents to enable effective implementation of a post market surveillance system.

Learning Objectives

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

- Confirm the PMS regulatory requirements of the directives required for the particular class of product
- Create a procedure that includes both proactive and reactive sources of information
- Implement cost effective and targeted post-market clinical follow-up using various tools and techniques
- Recognise when a complaint needs to be reported as an incident.

Intended Audience

- Regulatory professionals
- Quality managers
- Clinical affairs specialists
- Complaint handling specialists
- Design and development professionals
- Medical Device Sales & marketing.

Course Duration

One day.

Prerequisites

Participants should have experience with or basic knowledge of quality management systems for the medical device industry or experience of the manufacture, design, marketing or use of medical devices.

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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