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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.

This 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

Upon 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
- Complaint handling specialists
- Design and development professionals
- Medical Device Sales and marketing specialists

Course Duration

1 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.

Further Information

This course can be delivered as in-company training, customized for specific organisations and their circumstances.