Training Program

Fundaments of the NEW European Medical Device Regulation (MDR)

Course Description

You need to know more than the basics of the NEW MDR? Take the 2-day course as there are a lot of changes! Build a solid foundation to ensure compliance. Your fresh knowledge can be used directly during practical cases, based on your company's situation. Essential Principles, Technical Documentation requirements, Risk Management, Clinical Evaluation and Post Market Surveillance.

Learning Objectives

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

- Understand the Medical Device Regulations approach in Europe
- Understand the structure and purpose of the Medical Device Directives
- Explain the use of Essential requirements, including the use of (harmonized) Standards
- Apply the Classification Criteria and Implementation rules)
- Identify the conformity assessment routes
- Identify Technical Documentation requirements
- Importance and Role of Clinical Data
- Identify the importance and contents of Post Market Surveillance

Examination or testing

During the course cases are used to verify the gained knowledge.

Program overview

- Medical Device Directives and the New Approach
- Legal and operational structure
- Structure and purpose of MDD 93/42/EC
- General contents of MDD 93/42/EC
- Guidance Documentation (MEDDEV, GHFT, NB-MED, etc)
- Article 11: conformity Assessment routes (including Annex II to Annex VII)
- Annex I: Essential Requirements
- Role and importance of Risk Management
- Post Market Surveillance
- Vigilance and reporting to the Competent Authority
- Annex 10: Clinical Evaluation
- Questions & Answers
- Evaluation of the course and Closing

Who should attend

- Senior Management, Regulatory Affairs Managers and Quality Managers
- Design, Development, Manufacturing and Marketing Managers
- Internal and external Auditors

The number of participants is maximized to twelve to provide a stimulating and practical working environment.

Level

There is no prerequisite for this course but participants will benefit from a basic knowledge of the Medical Device Regulations in Europe.

Duration

2 days.

Training material

Course notes are provided on a USB stick.