Training Program

Introduction to the NEW European Medical Device Regulation (MDR)

Course Description

Be sure to know the basics of the upcoming Regulations if you want to (continue to) market products on the European market. You will learn about the structure and purpose of the NEW MDR including scope and classification changes, the new Essential Principals, identify the revised conformity assessment routes and hear about the increased importance of Risk Management, Clinical Data & 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 standards
- Identify the conformity assessment routes
- Understand the importance and role of Risk Management
- Understand the importance and role of Clinical Data
- Find Guidance Documentation on the Web

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
- Annex I: Essential Requirements
- 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 sixteen to provide adequate time for discussion and reflection.

Level

There is no prerequisite for this course.

Duration

1 day.

Training material

Course notes are provided on a USB stick.