Training Program

MDD to MDR Conversion

Course Description

To provide participants with the knowledge to assist their companies in preparing for a smooth transition into the new regulations in EU. Management personnel responsible for all aspects of CE marking medical devices will benefit from this course. Participants will gain in-depth knowledge of the change and new MDR requirements and on strategy to analyze impact and prepare for the transition.

Learning Objectives

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

- Understand the key changes upcoming in the new EU MDR
- Understand the essence of early start in the transition
- Understand how to prepare a transition plan

Examination or testing

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

Program overview

- Medical Device Regulation
  - Transition Planning

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

Knowledge of and experience with the current Medical Device Directive in Europe.

Duration

1 or 2 days.

Training material

Course notes are provided on a USB stick.