BSI Training Course

Medical Devices: CE Marking Training

Course Description:

BSI's "Medical Devices CE Marking" course is designed to provide students with the knowledge to assist their companies in getting products to market more quickly. Internal and external auditors and management personnel responsible for quality systems for medical device manufacturers will benefit from this course. The students will gain knowledge of the Medical Device Directive and CE Marking approach to provide leadership for their organizations when placing medical devices on the market in the European Union.

Learning Objectives

- Understand the Structure of the Medical Devices Directive
- Understand EU Classification of Medical Devices
- Establish an Understanding of the European CE Marking Approach
- Identify Quality Assurance Requirements for Medical Devices Sold to Europe
- Recognize the Role of Standards, Essential Requirements, and Labeling
- Understand Risk Assessment
- Value Post Market Surveillance and Vigilance
- Coming changes to the MDD

Course Structure:

- Overview of CE Marking
- CE Marking and the European Regulatory Framework
- The Medical Device Directive 93/42/EEC
- Classification under the MDD: Guidelines, Active Implantable Medical Devices & Vitro Diagnostic Devices
- Devices Outside the 'Norm'
- Essential Requirements
- Clinical Evaluation
- Technical Documentation
- Risk Management
- Post Marketing Activities/Surveillance
- Other EU Issues

Who Should Attend:

- Quality managers or implementers within an organization seeking or maintaining registration to ISO 13485:2003
- Decision makers on management system strategy
- Design Engineers, Process Engineers and Manufacturing Engineers
- Internal Auditors
- Management Team

Prerequisite:

Participants should have experience with or basic knowledge of quality management systems for the medical device industry. Recommended is a basic awareness of medical devices, quality assurance, and ISO 13485:2003.

Course Duration:

3 days

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