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Medical devices CE marking

Course Description

This three day course is designed to provide participants with the knowledge to assist their companies in getting products to market more quickly.
Management personnel responsible for all aspects of CE marking medical devices as well as internal and external auditors will benefit from this course. Participants will gain knowledge of the requirements of the Medical Device Directive and the CE Marking approach. Participants will be able to provide leadership for their organizations when placing medical devices on the market in the European Union.

Course Benefits

- Benefit from CE Marking expertise within your organization
- Work without uncertainty when placing products on the EU market
- Gain recognition as a producer of products with CE Marking
- Improve the quality and safety of your medical devices
- Increase EU market access and boost customer confidence

Learning Objectives

Upon completion of this training, delegates will be able to:

- Explain the European CE marking approach
- Explain the structure and purpose of the medical devices directive
- Implement the EU risk classification criteria for medical devices
- Identify the conformity assessment routes and quality assurance requirements for the various risk classes
- Describe the role of the essential requirements as the basis for CE Marking, including the use of standards
- Explain the importance and role of clinical data
- List labeling requirements
- Identify the regulatory significance of risk management and process validation
- Identify the necessary steps required for post market surveillance for different risk classes
- Interpret the criteria for reporting adverse incidents under the vigilance system
- Define the manufacture's regulatory responsibilities, including reporting of changes to products and QMS system to the notified Body
- Identify the relevance of recent changes to the medical devices directives
- Conduct internal and external audits for compliance with the directives

Intended Audience	• Regulatory, quality, design, development, manufacturing, marketing managers and personnel • Organizations preparing “own branding” or “private labeling” of devices • Potential internal auditors and others who need an in-depth knowledge of the requirements of the medical devices directives
Course Duration	3 Days.
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.

