



## **ISO 13485:2003**

### Quality Management Systems – Medical Devices System Requirements for Regulatory Purposes

#### **Course Overview**

The Quality Management System standard for Medical Device companies is ISO 13485:2003. ISO 13485:2003 is replacing other medical device standards and will likely need to be complied with for most medical device companies. In this course, the ISO 13485 standard will be reviewed in great detail to ensure there is understanding of each requirement and to provide guidance on how to comply with the standard. The ISO 13485 standard will be compared to the ISO 9001:2000 to ensure the differences are understood for those companies that choose to meet both standards or only one. Information will be provided on the effect of ISO 13485:2003 on other medical device standards, and how to manage the process of implementing ISO 13485 within your company.

#### **Course Objectives**

**After attending this course, you will be able to:**

- Understand why medical companies would want to comply with ISO 13485
- Describe the philosophy and principles associated with the new standards
- Understand the relationship between ISO 13485 and other regulatory standards
- List some of the key modifications to the ISO 13485: 2003 standard
- Envision the impact the changes will have on the organization
- Define implementation strategies associated with the standard

#### **Course Outline**

Overview of ISO 13485 Quality Management System Standard

- Class Objectives
- History of Quality Management Standards
- Quality Management System Terms and Vocabulary

Understanding ISO 13485

- Customer Perspective of ISO 13485
- Benefits internally of ISO 13485 Certification
- History of the ISO 13485 Standards

Interpreting ISO 13485 and QSR

- Overview of the QMS Model
- Element Analysis Exercise
- Element by Element Review including
  - Element key points
  - What to look for during an audit
  - Who is audited
  - Role plays

Presentation of Final Exam