

# Course Description

## ISO 13485: Quality Management Systems – Medical Devices System Requirements for Regulatory Purposes AMS318



### Overview

ISO 13485 is a new requirement for medical device companies. In this course, the reason for complying with ISO 13485 will be defined. An overview of the 1996 and new version (2003) will be performed. ISO 13485 will be compared to other regulatory requirements for medical device companies. Information on implementation of ISO 13485 will be provided.

### Learning Objectives

- Understand what ISO 13485 is and who has to comply with it
- Understand why ISO 13485 is required for Medical Device companies
- Explore how ISO 13485 relates to other regulatory requirements
- Understand the differences between the 1996 and 2003 versions of ISO 13485
- Identify when and how to implement ISO 13485

### Format

This course is highly interactive and how-to oriented. Discussion of concepts and principles is followed by hands-on exercises. The emphasis is on the practical application and adaptation of selected tools and processes.

### Delivery Options

### Duration

One day

### Who Should Attend

Professionals involved with ISO 13485 would benefit by taking this course.