

Understanding & Implementing ISO 13485:2003

Course Description:

This introductory course will give students a broad understanding of the ISO 13485:2003 Quality Management System requirements for implementation of the 2003 standard. In addition, the concepts of ISO 14971 (the Medical Device Risk Management Standard) will be introduced. This course is highly interactive with lively debate and in-class discussion, real life examples and exercises.

Learning Objectives:

Through a balance of formal presentations, case studies, simulation of audit activities and group activities, participants will:

- Interpret all clauses of ISO 13485:2003.
- Understand the essential requirements of ISO 13485:2003.
- Understand the proper use of ISO 14969 (guidance for implementation of an ISO 13485 quality management system).
- Understand the methodology of implementing such a system.
- Understand the essentials of ISO 14971 (The Medical Device Risk Management Standard).
- Recognize the role of management in implementing and maintaining ISO 13485.

Who Should Attend:

- Quality Managers/Auditors of Medical Device manufacturing firms (internal and external).
- Executives and Senior Executives.
- Cross-functional team members of implementation projects.

Prerequisite:

This is an introductory course. No prior training or experience is required. A basic knowledge of quality management, or of the ISO 9001:2008 standard, is helpful but not necessary.

Location:

- Public Course
- On-Site - can include the use of your organization during exercises, thereby assisting with some of the planning and initial steps of implementation.

Duration:

Two (2) Days

Cancellation Policy

An administration fee will be charged for cancellations less than 14 days prior to the course date. Substitutions will be permitted at any time. Course transfers may be made without penalty. The BRC reserves the right to cancel any seminar and will, in such event, fully refund all registration fees. No liability is assumed by the organizers for changes in seminar dates, content, speakers or venue.