

ISO 13485:2003 Internal Auditor

Course Description:

This course is designed to provide information on how to conduct audits of an ISO 13485:2003 Medical Devices Quality Management System. Participants will acquire the required knowledge and skills that will enable them to perform and document internal audits.

Learning Objectives:

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

- Understand the specified requirements for a Quality Management System where an organization needs to demonstrate ability to provide medical devices that consistently meet customer and regulatory requirements applicable to medical devices.
- Interpret the ISO 13485:2003 requirements for their own company.
- Develop skills to participate in Internal and Supplier Audits
- Increase knowledge of planning and following up with audits.

Who Should Attend:

- Staff responsible for documenting management system processes.
- Staff who, as part of their responsibilities, carry out the audit function.
- Any individual interested in managing or participating in an internal audit.

Prerequisite:

Participants should have taken the "Understanding & Implementing ISO 13485:2003" course, or have commensurate experience working within a quality management system, preferable in a medical device environment.

Location:

- Public Course
- On-Site: An actual audit "walk-through" may be used as part of the instructional process for on-site training during day two (instead of the generic exercises used in the public course).

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.