

ISO 13485 Medical Device Management Systems Internal Auditor

Course Description:

BSI's "ISO 13485:2003 Internal Quality Systems Auditor" course, designed for those with knowledge of medical device manufacturing, starts with one full day of review of ISO 13485:2003. Students gain a broad understanding of the ISO 13485:2003 quality management system requirements. In addition, the concepts of ISO/TR 14971:2001, "Application of Risk Management to Medical Devices," are introduced. Through small group activities, audit role-plays, lively discussions, and instructor-led lectures, students gain a thorough understanding of the principles of auditing. Students also learn how to apply the guidance of ISO 19011:2002, "Guidelines for Quality and/or Environmental Management Systems Auditing," to implement effective internal audit programs for medical device manufacturing organizations.

Course Structure :

This course includes a high level of interactivity during presentations on:

- Interpret All Clauses of ISO 13485:2003
- Understand Differences between ISO 13485:1996 and ISO 13485:2003
- Apply Principles of ISO/TR 14969:2003-WD2 and ISO 14971:2001
- Understand the Quality Management Principles
- Apply Principles of ISO 19011:2002 to the Auditing Process
- Plan, Conduct, and Report Effective Internal Audits to ISO 13485:2003

Who Should Attend :

- Quality managers
- RA managers
- Auditors of medical device manufacturing firms (internal and external)
- Cross functional team members implementing the standard



Benefit to Your Business :

A trained combined system Internal Auditor with the skill set to:

- Conduct an internal audit of the ISO 13485 Management System
- Enable your business to remain compliant with the requirements of the ISO 13485
- Follow through complex audit trails and identify any possible Management Systems discrepancies
- Identify any gaps that threaten the effectiveness of your Management Systems and propose corrective action

Prerequisite for the Course:

A prior working knowledge of the Quality Management Systems, ISO 9001:2000, or ISO 13485:2003, is recommended for this course.