ISO 13485 Medical Device Management Systems Lead Auditor - IRCA Certified (A17579)

Course Description:

BSI's "Lead Auditor: ISO 13485" course teaches the principles and practices of effective quality management systems and process audits in accordance with ISO 13485 and ISO 19011, "Guidelines for Quality and/or Environmental Management Systems Auditing." Experienced instructors guide students through the entire audit process, from managing an audit programme to reporting on audit results. Participants will gain necessary auditing skills through a balance of formal classroom tutorials, practical role-playing, group workshops, and open forum discussions.

Learning Objectives:

Upon completion of the training, participants will be able to:

- Interpret the requirements of ISO 13485 in the context of an audit
- Explain the relationship with ISO/TR 14969 and the ISO 9000 series
- Describe the purpose of a quality management system and explain the 8 principles of quality management
- Explain the role of an auditor to plan, conduct, report and follow up a quality management system audit in accordance with ISO 19011
- Plan, conduct, report and follow-up on a QMS audit in accordance with ISO 19011 and by interpreting ISO 13485
- Manage the duties of a lead auditor in their organization or for a third-party

Who Should Attend :

- Medical Device quality professionals interested in conducting first-party, second-party, and/or third-party audits
- Management Representatives
- Quality Directors
- Managers
- Engineers
- Consultants

Duration of Course:

5.0 days. There is a written exam on Day 5.

Prerequisite for the Course:

This course teaches auditing principles using ISO 13485, therefore a basic knowledge of ISO 13485 and its application within a Medical Device organization is strongly recommended together with internal audit experience.

IRCA Certified Course (A17579)

This course is certified by the International Register of Certificated Auditors (IRCA) and meets the training requirements for IRCA QMS 2008 auditor certification.

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