ISO 13485 Internal Auditor Training Course

Course Description

BSI's "Internal Auditor: ISO 13485" course is intended for medical device quality professionals aiming to build on their current knowledge of ISO 13485 and evaluate the effectiveness of the quality management system in their organization.

This intensive two-day course teaches the principles and practices of effective quality management systems process audits in accordance with the ISO 13485 and ISO 19011.

An experienced instructor guides students through the internal audit process, from planning an audit to reporting on audit results and following up on corrective actions. Participants will gain necessary auditing skills through a balance of formal classroom tutorials, practical role-playing, and group workshops.

Course Benefits

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

- Explain the structure and scope of ISO 13485 management system standard and how it applies to the organization aiming for regulatory compliance worldwide
- Identify the principles of auditing and auditor responsibilities
- Plan an internal audit
- Conduct informal opening and closing meetings
- Conduct an audit based on process identification, sampling and questioning
- Provide verbal and written feedback
- Document concise nonconformities
- Effectively report on an audit
- Follow-up on corrective actions

Intended Audience

- Medical Device Quality professionals with knowledge of quality management systems and ISO 13485
- Individuals interested in conducting first-party or second-party audits
- Management representatives
- Internal auditors
- Managers
- Consultants

Course Duration

2.0 days

Prerequisites

This course does not detail the requirements of ISO 13485.

Prior knowledge of the ISO 13485 standard, such as the overview provided in BSI's 'Introduction to ISO 13485 or previous work with ISO 13485 in an organization, is strongly recommended as a prerequisite for this course.

Agenda

Day 1

Time	Topic
9.00	Introduction
	Participants introductions
	Overview of course structure and learning objectives
	The 8 principles of Quality Management
	Fundamentals of quality management, ISO 13485 and the relationship to ISO 9000 series of standards and ISO 14971 (risk management).
	Use of ISO 13485 in relation to compliance with worldwide regulatory requirements
	Principles and concepts of quality, quality management, and quality management systems
	Define an audit
	Overview of process auditing and ISO 19011
	Managing the audit programme
	Audit activities
	Auditor responsibilities and competence
	Plan an internal audit
	Create work documents
	Conducting an (informal) opening meeting
	Collecting and verifying audit information

	Audit techniques
	Gathering and verifying information
	Introduction of audit findings and nonconformities
	Conducting the audit (Part 1)
5.00	Close

Day 2

Time	Topic
9:00	Review of day 1
	Conducting the audit (Part 2)
	Prepare audit conclusions
	Generate audit findings
	Identify and define nonconformities
	Prepare audit conclusions
	Write an audit report
	Closing meeting
	Conduct audit follow up
5.00	Evaluation and close

Two short breaks will be taken at suitably convenient times in the morning and afternoon. An hour will be given for a lunch break.