ISO 13485 Medical Device QMS Lead Auditor Training (IRCA)

Course Description

BSI's "Medical Devices – Quality Management Systems Auditor/Lead Auditor Course (ISO 13485 & EN ISO 13485)" course teaches the principles and practices of effective quality management system audits in accordance with ISO 13485 and ISO 19011, "Guidelines for auditing management systems". Experienced BSI tutors will guide delegates through the entire audit process, from initiating the audit through to conducting audit follow-up.

By attending this course delegates will gain necessary auditing skills developed through a balance of formal classroom tutorials, practical role-playing, group workshops, and open forum discussions.

Course Benefits

Successful completion of this IRCA certified training course by passing the relevant IRCA examination and skills assessment, will demonstrate knowledge and basic skills to undertake and lead a management systems audit.

Learning Objectives

Upon completion of this training, delegates will be able to:

- Describe the purpose of a quality management system, of quality management systems standards, of management system audit and of third-party certification
- Explain the role of an auditor to plan, conduct, report and follow up a quality management system audit in accordance with ISO 19011 (and ISO 17021 where appropriate)
- Plan, conduct, report and follow up an audit of a quality management system to establish conformity (or otherwise) with ISO 13485 and in accordance with ISO 19011 (and ISO 17021 where appropriate)

Intended Audience

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

Course Duration

5 Days.

Written exam is conducted on Day 5

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.

Prerequisites

Before attending this course, delegates are expected to have:

- Knowledge of the following quality management principles and concepts:
  - The Plan, Do, Check, Act (PDCA) cycle
  - The relationship between quality management and customer satisfaction
  - Commonly used quality management terms and definitions and the 8 Quality Principles as given in ISO 9000
  - The process approach used in quality management
  - The Model of a Process Based Quality Management System, the structure and content of ISO 13485
- Knowledge of the requirements of ISO 13485

It is advisable that delegates have either attended an internal auditors course, or had experience with conducting internal or supplier audits

Agenda

Day 1

Time	Topic
08.30	Benefits to you, Welcome and Introductions
	Course Aims, Objectives and Structure
	KNOWLEDGE
	First, Second & Third Party Audits
	Audit Process
	Audit Objectives, Scopes & Criteria's
	Audit Resources
	Roles & Responsibilities & Confidentiality
	Audit Methods
	Stage 1 Audit
	Stage 2 Audit
	Audit Plan
	Work Documents
	Opening Meeting
	Audit Evidence
	Effective Communication
	Audit Findings

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	Audit Meetings
	Closing Meeting
	Audit Reports
	Audit Follow-Up
17.30	Close Day 1

Day 2

Time	Topic
08.30	Day 1 review
	KNOWLEDGE continued
	Purpose & Business Benefits of a QMS
	Terminology
	Plan-Do-Check-Act
	QMS Processes & Context
	Role of the Auditor
	QMS Documentation
	SKILLS
	Initiating the Audit
	Document Review
	Audit Plan
	Work Documents
	Opening Meeting
	Observations
	Auditing Top Management
18.00	Close Day 2

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Day 3

Time	Topic
08.30	Specimen Exam: Sections 1 & 2 Review
	SKILLS
	Auditing 'Planning to meet Requirements'
	Auditing 'Design & Development'
	Tutorial on body language
	Questions & Evidence
	Auditing 'Purchasing'
	Auditing 'Monitoring & Measurement'
18.00	Close Day 3

Day 4

Time	Topic
08.30	Specimen Exam: Section 3 Review
	SKILLS
	Auditing 'Improvement'
	Nonconformities
	Closing Meeting
	Audit Report
	Audit Follow-Up
	Specimen Exam: Section 4
18.00	Close Day 3

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Day 5

Time	Topic
08.00	Hand in homework – audit report
	The certification and accreditation process, the role of IRCA, the IRCA QMS auditor certification requirements and code of conduct
	Final questions/final revision
	Evaluation
	Introduction/readiness to the exam
10.15	Exam
12.15	End of Course

Two short breaks will be taken at suitably convenient times in the morning and afternoon. Forty five minutes will be given for a lunch break. Additional breaks may be taken as long as agreed by delegates and tutor, and all learning objectives are met.

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