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Lead Auditor ISO 13485
Medical Device Quality

Course Description	This 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 training course by passing the relevant 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

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