Introduction to ISO 13485 Medical Device Quality Management System

Course Description

BSI's "Introduction to: ISO 13485" one day course has been designed to provide an insight in to the use of ISO 13485:2003 as the basis for a quality management system implemented by medical device manufacturers.

Time will be spent during the course reviewing requirements of ISO 13485 and making comparisons to ISO 9001:2008 and the FDA's Quality System Regulation.

In addition to this, participants will also gain an awareness of the relationship between ISO 13485 and ISO 14971:2007, "Application of Risk Management to Medical Devices".

Course Benefits

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

- Compare the requirements between ISO 13485 and ISO 9001
- Interpret the clauses of ISO 13485 using ISO 14969:2005
- Recognize the role and responsibilities of management in ISO 13485
- Recognize the relationship between ISO 13485 and ISO 14971
- Compare the requirements between ISO 13485 and FDA's Quality System Regulation
- Appreciate the use of ISO 13485 as the basis of Medical Device Regulations worldwide

Intended Audience

- Senior Management
- Quality Managers
- Regulatory Affairs Managers
- Internal and external Auditors
- Anyone involved with the implementation of the standard

Course Duration 1.0 day

Prerequisites There is no prerequisite from this course but participants will benefit from a basic knowledge of the quality management systems, ISO 9001:2008 or ISO 13485:2003.

Agenda

Time	Topic
9.00	Welcome and introductions
	Overview of course structure and learning objectives
	Introduction to ISO 9001 – the process approach
	Definition of a medical device within the industry
	Introduction to ISO 13485 and guidance document ISO/TR 14969
	ISO 13485 Clause 4 - General requirements
	ISO 13485 Clause 5 - Roles and responsibilities of management
	ISO 13485 Clause 6 – Resource management - health, hygiene and environment
	ISO 14971 Medical devices - Risk management principles
	ISO 13485 Clause 7 - Product realization
	ISO 13485 Clause 8 – Monitoring and measurement
	ISO 13485 and the U.S. Food and Drug Administration Quality System Regulation – comparisons
	ISO 13485 as the basis of worldwide regulations
5.00	Evaluation and close