BSI Training Course

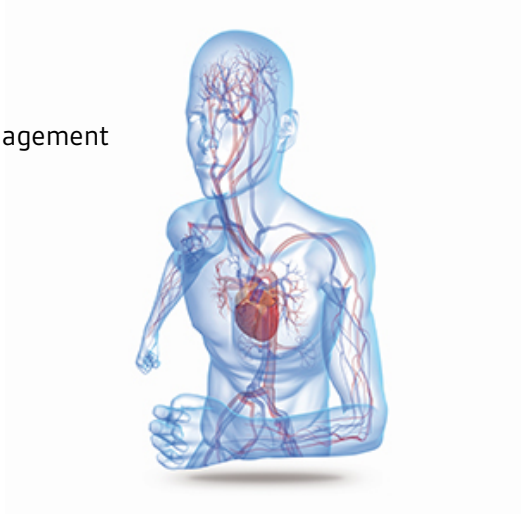
ISO 13485 Medical Device Management Systems Introduction Course

Course Description:

This one-day introductory course will give students a broad understanding of the ISO 13485:2003 Quality Management Systems requirements. In addition, the concepts of ISO 14971 – The Medical Device Risk Management Standard – will be introduced. This course is highly interactive with lively debate and in-class discussion, real life examples, and exercises.

Course Structure:

- Understanding proper use of ISO 14969.
- Understanding differences between ISO 13485:1996 and 2003 version.
- Interpret all clauses of ISO 13485:2003.
- Understanding the essentials of ISO 14971 – The Medical Device Risk Management Standard.
- Recognize the role of management in implementing and maintaining ISO 13485:2003.



Who Should Attend:

- Quality managers
- Regulatory Affairs Managers
- Auditors of medical device manufacturing firms (internal and external)
- Executives & Senior Management
- Cross functional team members of implementation project.

Course Duration:

One day.

Benefits to your Business:

Delegates are given an understanding of the relevance of various Medical Devices standards to industry in general, and to their own organization in particular.

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