The BRC Business Resource Centre

The Business Resource Centre
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Understanding ISO 14971:2007

Course Description:

This course is designed to introduce ISO 14971:2007 - Risk Management for Medical Devices standard and provide participants with an understanding of the impact that risk management has on their decision making process. All elements of the standard will be covered, with an emphasis on the role of risk management in the medical device industry and the relationship between ISO 14971 and ISO 13485:2003 Quality Management Systems.

Learning Objectives:

Through a combination of presentation, discussion and exercises, participants will:

- Understand the Role of Risk Management in the Medical Device Industry
- Practice the Basics of Risk Management
- Interpret the Clauses of ISO 14971:2007 and outline changes from the ISO 14971:2000
- Recognize the Application of ISO 14971:2007 to ISO 13485:2003
- Understand the Importance of Management Involvement with ISO 14971 Implementation
- Understand the Impact of ISO 14971 Implementation on Medical Device Organizations

Who Should Attend:

- Quality Managers or implementers within an organization seeking or maintaining registration to ISO 13485:2003.
- Decision makers on management system strategy.
- Design Engineers, Process Engineers and Manufacturing Engineers.
- Internal Auditors
- Management Team

Prerequisites:

Participants should have experience with, or knowledge of, quality management systems for the medical device industry. A basic awareness of medical devices, quality assurance, and ISO 13485:2003 is recommended.

Location:

Public Course or On-Site

Duration:

One (1) Day