Understanding ISO 14971:2007 & FDA Title 21 CFR Part 820

Course Description:

This course is designed to provide participants with an understanding of ISO 14971:2007 - Risk Management for Medical Devices, and the impact that the FDA's CFR 820 has on their decision-making process at medical device manufacturing firms. This one-day training course helps medical device professionals gain an understanding of how CFR 820 will affect their processes and procedures to ensure compliance to the US FDA. Participants will also understand how CFR 820 applies to ISO 13485:2003.

Learning Objectives:

Through a combination of presentations, group exercises and workshops, participants will:

- Understand the Role of Risk Management in the Medical Device Industry
- Practice the Basics of Risk Management
- Interpret the Clauses of the ISO 14971:2007 standard
- 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
- Understand the Role of CFR 820 in the Medical Device Industry
- Recognize the Application of CFR 820 to ISO 13485:2003
- Understand the Importance of Management Involvement with CFR 820 principles

Who Should Attend:

- Quality managers or quality system implementers within medical device organizations.
- Decision makers on management system strategy.
- Design Engineers, Process Engineers and Manufacturing Engineers.
- Internal Auditors
- Management Team

Prerequisites:

Participants should have experience with or basic 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:

On-Site

Duration:

One (1) Day

Cancellation Policy

An administration fee will be charged for cancellations less than 14 days prior to the course date. Substitutions will be permitted at any time. Course transfers may be made without penalty. The BRC reserves the right to cancel any seminar and will, in such event, fully refund all registration fees. No liability is assumed by the organizers for changes in seminar dates, content, speakers or venue.