BRC Training Course

Transitioning to ISO 13485:2016

Course Description

This 1-day course provides n in-depth study of the new ISO 13485:2016 - Medical devices - Quality management systems - Requirements for regulatory purposes.

Learn the new requirements through hands-on exercises and class discussion, and review in detail the changes from the ISO 13485:2003 standard to this new ISO 13485:2016 edition. This course provides critical knowledge for leadership, management and team members who need to understand the new requirements of ISO 13485:2016 as they prepare to transition the organization's QMS.

Who Should Take It

Individuals with responsibility for management, operation, implementation or maintenance of an ISO 13485 QMS. This includes, but is not limited to:

- Those responsible for transitioning their organization's QMS to meet the new requirements
- Senior Management
- ISO Coordinators & Quality Managers
- Members of the Quality Team and/or Internal Audit Team
- ISO 13485 Auditors, Quality Specialists and Consultants

Learning Objectives

- Become familiar with the new standard's requirements (review of each section and its requirements).
- Recognize the changes relative to the previous ISO 13485:2003 standard.
- Understand the timeline for transition and how it will affect your quality program (documentation, training, registration, etc.).
- Identify the general approach to implementing the new requirements of ISO 13485:2016.
- Build the confidence of quality team members as you prepare your transition project.

Prerequisites

For maximum benefit, attendees should already be familiar with the ISO 13485:2003 standard and its requirements for medical device quality management systems.

Location

Public Venue or On-Site

Duration

1 Day