BRC Training Course

Understanding & Implementing ISO 13485:2016

Course Description

This introductory 2 day course provides a broad understanding of the requirements of ISO 13485:2016 - Medical devices - Quality management systems - Requirements for regulatory purposes. Through immersive, hands-on exercises and discussion, participants will review the standard's requirements in detail and review approaches and techniques for implementing its requirements.

Who Should Take It

Individuals with responsibility for management, operation, implementation or maintenance of an ISO 13485:2016 QMS. This includes, but is not limited to:

- Those responsible for implementing (or transitioning) their organization's QMS to meet the ISO 13485:2016 requirements.
- Senior Management
- ISO Coordinators, Quality Managers & Management Representatives
- Members of the Quality Team and/or Internal Audit Team
- ISO 13485 Auditors, Quality Professionals and Consultants

Learning Objectives

- Become familiar with the standard's requirements (review of each section and its requirements).
- Understand the timeline for transition (from ISO 13485:2003) and how it will affect your quality program (documentation, training, registration, etc.).
- Appreciate the different factors that should be considered when implementing, or working within, an ISO 13485:2016 Quality Management System.
- Identify the general approach to implementing the requirements of ISO 13485:2016.
- Learn how to use the Gap Analysis as a tool to create an action plan for implementation.
- Build the confidence of QMS team members as you prepare your implementation project.

Prerequisites

This is an introductory course. However, participants will benefit from previous experience working with, or within, an ISO 13485 quality management system.

Location

Public Venue or On-Site

Duration

2 Days