BRC Training Course

ISO 13485:2016 Internal Auditor

Course Description

Building on knowledge acquired through previous training in the requirements of ISO 13485:2016, this course delivers the practical knowledge required to conduct internal audits of an ISO 13485:2016 Quality Management System.

A review of ISO 13485:2016 to ensure thorough and common understanding of the new requirements is followed by information on how to conduct audits in accordance with the ISO 9000 series of standards:

- ISO 19011:2011 - "Guidelines for Auditing Management Systems", and
- "Guidance on the Concept and Use of the Process Approach for Management Systems".

Through a balance of formal presentations, case studies, simulation of audit activities and group activities, participants will learn the necessary elements to perform a quality audit.

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).
- Appreciate the roles and responsibilities of the Auditor.
- Understand the basic skills and principles of auditing.
- Apply the concepts and guidelines detailed in ISO 19011:2011 when performing an audit.
- Learn the different methods of gathering evidence.
- Practice all phases of an internal audit (using checklists, recording evidence, writing reports, etc.).
- Develop the communication skills, leadership skills and attitudes required to perform internal audits.

Prerequisites

Attendees should already be familiar with the ISO 13485:2016 standard and its requirements for medical device quality management systems. "Understanding & Implementing ISO 13485:2016" or equivalent training is strongly recommended as a prerequisite.

Location

Public Venue or On-Site

Duration

2 Days