BRC Training Course

ISO 13485:2016 Management Overview

Course Description

This flexible 1/2 Day (3.5 hour) course provides top management with a high-level overview of the ISO 13485:2016 standard, as well as the specific roles and responsibilities that are placed upon the organization's leadership.

Participants will review the standard's requirements, discuss key concepts relating to management activities, and discuss the ways in which an ISO 13485:2016 quality management system is aligned and integrated with the organization's strategic goals and objectives.

Who Should Take It

Senior and executive managers who need a general understanding of their leadership role in an ISO 13485:2016 quality management system. This course is ideal for those who do not need a detailed understanding of the specific requirements, but who will be involved in high-level, strategic decision making and leadership roles.

Learning Objectives

Through presentation, discussion and several exercises, participants will:

- Receive an introduction to the concepts of "Quality Management" and "Quality Management Systems".
- Review the 7 Quality Management Principles.
- Understand the structure of the ISO 13485:2016 standard at how it relates to the planning, production/service, and improvement activities of an organization.
- Receive a general overview of the standard's requirements.
- Understand the ISO certification process.
- Understand the concept of Risk as it relates to medical devices, as well as different tools and processes available to address the topic.
- Receive a general overview of the Medical Device Single Audit Program (MDSAP).
- Gain an appreciation for the value that an effectively implemented ISO 13485:2016 QMS can bring to an organization.

Prerequisites

None. This is an introductory course for senior and executive management.

Location

On-Site

Duration

½ Day (3.5 hours)