ISO 13485

Overview

Course Length: 16 hours *(can be taken via flexible schedule in-center or remotely)*

Description: This course gives an overview of all important aspects for managers of an organization in order to implement and maintain an ISO 13485:2016 compliant management system.

This course material is recognized by all registrars, notified bodies and hiring companies as objective evidence of effective training on the particular standard and regulation. Since 1999, they have been the most popular and most widely used training courses in English, with over 25,000 trainees in the US and worldwide. The standards and regulations are provided online under licensing agreements.

Course Objectives/Topics

Training Structure:

- The Standard
- The Process Approach
- Scope
- Quality Management System

- Management Responsibility
- Resource Management
- Product Realization
- Measurement, Analysis and Improvement

Certificate requirements

The course uses a continuous evaluation method with on-going quizzes to facilitate the information retention. If your final average is equal or greater to 70% you will be issued a training certificate. If your final average evaluation is less than 70%, you will have to take a final exam and score above 70% to be issued the training certificate

Prerequisites

To ensure your success in this course, you should have basic project management knowledge and skills. The course has been designed so that it is easily understood by beginners and people new to Kaizen, apart from those having the basic knowledge.

Audience

This course is for those who want to quickly and efficiently understand what ISO 13485:2016 is about or upgrade their knowledge and expertise from ISO 13485:2003 or ISO 9001:2008 to ISO 13485:2016.