



Understanding ISO 13485

Training Program Overview

This one day program provides an in-depth look at the background and content of ISO 13485. Participants in this program will quickly and easily gain a good understanding of the requirements of this standard.

Participants in this course will

- Review the ISO 13485 standard and how ISO 13485 differs from ISO 9001 and the areas of focus for Medical Devices.
- Review changes in auditing methods and techniques needed to perform internal audits to ISO 13485 requirements
- Understand how to document business process relationships and interactions
- Understand the process management principles that are part of ISO 13485
- Interpret the AS9100C requirements from a Process Owner/Auditor's perspective
- Discuss strategies and tools that you can use now to prepare for ISO 13485 compliance

Program Duration

This program will take 8-hours to complete.

Program Prerequisites

There are no prerequisites for this program.

Program Fees

ETI Group can present this training program at your facility. Your cost, including workbooks for up to sixteen participants is \$2,750. The training program and materials can also be "tailored" to meet any requirements unique to your company. For more information please contact ETI Group.