



ISO 13485:2003 Internal Quality Auditing

This course is designed for both new auditors and those looking to sharpen their current auditing skills. Participants will acquire the necessary skills to become a leader in preparing and conducting 1st and 2nd party audits through interactive methods and avoiding lecture based learning. This course includes a simulated audit, based on documentation from an actual organization, so participants can develop and refine their newly acquired knowledge and skills.

Length: 2 days

CEUs: 1.4

Prerequisites: *Understanding 13485:2005*

WHAT YOU WILL LEARN

- ISO 19011:2002 Standard on performing audits
- Comply to the ISO 13485:2005 Standard by applying the Process Approach to your quality management system
- Form an audit team
 - Who needs to be on it
 - Determine roles & responsibilities of each individual
- Conduct an audit meeting
 - Who needs to be there from the audit team
 - Who needs to be there from the organization receiving the audit
 - Agenda
 - What reports are needed and how to form them
- Documentation
 - What is needed
 - How to organize according to the ISO 19011:2002 Standard
- Nonconformities
 - How to classify, record and resolve
 - How to implement preventative measures to avoid future nonconformities

PLEXUS LEARNING MODEL

Learning is maximized through participation. That is why Plexus training avoids lecture-based teaching and focuses on group activities, case studies and hands-on applications. *Learn by doing.*

WHO SHOULD ATTEND

- Any member of an ISO 13485:2005 implementation team
- Risk managers
- Quality managers
- New internal auditors and experienced auditors that have not attended training in over three years
- Representatives from key functional groups involved in an organization's quality management system

ISO 13485:2005

ISO 13485:2005

INSTRUCTORS

Plexus Master Trainers. Plexus Master Trainers train and evaluate:

- ISO 9001:2008, ISO/TS 16949:2009, AS9100, ISO 14001:2004 Environmental Management Systems, ISO 22000:2005 Food Safety, ISO 9001:2008 for Healthcare and ISO 13485:2003 for Medical Devices.
- Plexus trains 3rd party auditors and wrote the materials used to certify all of them
- Supplier Auditors

AGENDA

Day 1

- ❖ A brief review of ISO 13485
- ❖ Understand the relationship with ISO 14969
- ❖ Understand essentials of ISO 14971
- ❖ Quality System Terminology
- ❖ What is an Audit? Types, objectives and relation to a standard
- ❖ Internal Auditors: attributes, roles and responsibilities
- ❖ Communication Skills: verbal, nonverbal and conflict situations

Day 2

- ❖ Plan For The Audit
- ❖ Prepare For The Audit
- ❖ Perform the Audit
- ❖ After The Audit