

ISO 13485:2003 Internal Auditor Training for Medical Devices (Plexus Curriculum) – SC-326

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This course provides either new or current internal auditors an understanding of ISO 13485:2003 and a process approach methodology. Participants will acquire the necessary skills to become a leader in preparing and conducting audits through interactive methods and avoiding lecture based learning.

CEU's: 1.4 RUs: 1.4 Prerequisite: Understanding ISO 13485:2003, SC 325

WHAT YOU WILL LEARN

- ISO 19011:2002 Standard on performing audits
- Complying to the ISO 13485:2003 Standard by applying the Process Approach to your quality management system
- Forming an audit team
 - Who needs to be on it
 - Determine rolls and responsibilities of each individual
- Conducting 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 ISO 19011:2002 Standard
- Nonconformities
 - How to classify and record
 - How to implement preventative measures to avoid future nonconformities

A copy of the ISO 13485:2003 Standard will be provided.

WHO SHOULD ATTEND

- Any member of an ISO 13485:2003 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

SCHEDULE

- 2-Day session, 8:30AM-4:30PM, - Course Fee: \$ 700.00.
- Lunch and refreshments included.