

ISO 13485:2003 Internal Quality System Auditing

January 18-20, 2010

Course Description: “ISO 13485 Internal Quality System Auditing” is designed to help medical device manufacturers implement and maintain an effective internal audit program. The course starts with a full day study of ISO 13485 requirements. Students gain an understanding of the requirements, applicability, and the intent and interpretation of all clauses. Through small group activities and instructor-led discussions and examples, students learn auditing methodology and experience the principles of auditing by practice and audit role-plays (based on guidance of ISO-19011). The course draws on proven learning methods that prepare quality auditors to use effective audit methodology to conduct and report internal audits for the organization. The course is modular and may be taken for one day (“Understanding ISO 13485”) or three days.

Learning Objectives:

- Understand and interpret the entire requirements of the ISO 13485:2003 Standard
- Learn how to plan, conduct and report effective internal audits to 13485
- How to determine scope of the audit
- Discover internal auditing techniques
- Participate in audit scenarios, exercises and team role-plays
- Apply principles of the ISO-19011 Guidance on Quality System Audits
- Learn to write nonconformity statements
- Understand requirements of an effective audit corrective action process

Course Materials: **Students receive comprehensive course manuals with reference materials, case study, and training copies of relevant quality system and auditing standards.**

Who Should Attend:

- Management responsible for the internal quality audits
- Personnel assigned to do internal quality audits of medical device manufacturing firms
- Department managers of operational areas responsible for QMS conformance
- Personnel who may be called on as new auditors in training
- Quality Assurance and Regulatory Affairs Managers

Duration: **Course times and dates:**

January 18-20, 2010 (3) Days, each day 8:00 am – 4:30 pm

Note: Students taking the one-day “Understanding ISO 13485” course will attend January 18, 2010

Price: **One-Day “Understanding ISO 13485” - \$349/ \$299 Chamber Member price**

Three – Day “ISO 13485:2003 Internal Quality System Auditing” – \$995/ \$895 Chamber Member price; \$845 – 3 or more from same company

Prerequisite: Participants should have experience with or basic knowledge of quality systems and medical device manufacturing practices. A basic awareness of quality assurance (ISO-9000) and recognized standards, such as FDA/GMP or ISO-9001 is desirable but not mandatory.

Course Logistics: Class to be conducted at 50 N. Front, Suite 200, Memphis, TN – student class size: 6 - 20
Certificates of completion are provided to students fulfilling all course criteria.

Call Teresa at 901.543.3530 or email tfranks@memphischamber.com

Instructor: Gary Scalise, MSQPC Consulting Associate, provides expert consulting in ISO-9000, ISO-13485, QS 9000, TS 16949, FDA-QSR, Medical Device Directives, CE Marking, CMDR, Quality Engineering and process optimization. He conducts training in CQE, CMI, APQP, SPC, FMEA, MSA, PPAP, Taguchi Methods, Risk Analysis, Internal Auditing, ISO/IEC 17025, ISO 15189, cGMP, and Problem Solving.