



## **ISO 13485 & 21CFR820 (QSR) Internal Assessor**

**Overview:** 2-day (16-hour course) designed to provide participants with auditing skills to ISO 13485 & 21CFR820. Class typically taught in two consecutive days.

**Audience:** Quality professionals, supervisors/managers, engineers, senior technicians. Participants will utilize both analytical and communication skills.

### **Course Outline:**

- Overview of ISO 13485 & 21CFR820 and Quality Management System Standards
  - Class objectives
  - History of Quality Management Standards
  - Quality Management System Terms and Vocabulary
- Understanding ISO 13485 & 21CFR820
  - Customer Perspective of ISO 13485 & 21CFR820
  - Benefits internally of ISO 13485 & 21CFR820 Certification
  - History of the ISO 13485 & 21CFR820 Standard
- Interpreting ISO 13485 & 21CFR820
  - Overview of the QMS Model
  - Element Analysis Exercise
  - Element by Element Review including
    - Element key points
    - What to look for during an audit
    - Who is audited
    - Role plays
- Audit Process
  - Audit Preparation Activities, Including:
    - Documentation Review
    - Reviewing Previous Audit History
    - Creation of Element Application Matrix
    - Creating the Audit Checklist
  - Audit Performance Activities, Including:
    - Providing Introductions
    - Framing Questions
    - Recording Objective Evidence
  - Audit Report Writing Activities, Including:
    - Creating the Audit Report
    - Presenting Findings
    - Follow-up Activities
- Auditor Skills
  - Audit Responsibilities
  - Communication Skills
  - Do's and Don'ts During the Audit
  - Audit Role Plays
- Presentation of Final Exam