

PERRY JOHNSON CONSULTING, INC.

The World Leader in ISO Standards

ISO 13485:2003 INTERNAL AUDITOR TRAINING

Course Outline

- I. Introduction**
- II. The International Organization for Standardization**
 - A. What is ISO 9000?
 - B. What is ISO 13485?
 - C. What is a Registrar?
- III. Internal Auditor Qualification and Certification**
 - A. What are the applicable requirements for Internal Auditors?
 - B. Introduction to ISO 19011:2011
 - C. Internal Auditor Conduct/Attributes
 - D. Audit Team Leaders
- IV. Essential Quality Vocabulary**
 - A. ISO 9000 vocabulary
 - B. ISO 13485 vocabulary
- V. Architecture of ISO 13485**
 - A. The four primary standards
 - B. Eight Quality Management Principles
- VI. What are Quality Audits?**
 - A. Examining the ISO 9000 definition of the term "Audit"
 - B. Objectives of Auditing
 - C. Types of Audits
- VII. The Process Approach**
 - A. What is a process?
 - B. Input-Output
 - C. PDCA
 - D. Turtle
- VIII. ISO 13485:2003 section by section**
 - A. Section by section analysis/discussion
 - B. Section by section critical audit points and scenario analysis
- IX. Progression of an Audit**
 - A. Audit Initiation
 - B. Document Review
 - C. Working Documents
 - D. Audit Plans
 - E. Opening and Closing Meetings
 - F. Obtaining Audit Evidence
 - G. Audit Reports
- X. Nonconformities**
 - A. Classifications of findings
 - B. The Three Pieces of a well written Nonconformity
- XI. Case Studies**
 - A. Situational analysis and discussion
- XII. Corrective Action and Follow-Up**
 - A. Correction vs Corrective Action
 - B. Systemic Cause Analysis
 - C. Assessing Corrective Action
 - D. Methods of Follow-Up
- XIII. Adding Value to an Audit**
 - A. Seeking to add value – appropriate practices
- XIV. Mock Audit or Exam**