OMNEX

DRIVING WORLDWIDE BUSINESS EXCELLENCE

ISO/IEC 17025:2017
Lead Auditor Training for Laboratory Management Systems

Course Duration: 5 Days - 8 Hours/day

CQI | IRCA

CERTIFIED COURSE

CONSULTING • TRAINING • SOFTWARE

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Seminar Content

This is an IRCA certified training course under certificate 17082 and meets the training requirements for the Lead QMS Auditor grade or lower. This seminar covers the requirements of ISO 17025:2017 by quickly reviewing the standard as part of the discussions during the exercises only. Other topics include audit systems, the auditing process and audit instruments; the documentation process, conducting an audit, writing the audit report, and taking corrective action. Auditing case studies to develop skills for identifying nonconformities will be used. Techniques for leading audit teams will also be discussed.

Attendees who successfully pass the final exam and continual assessments will receive an IRCA certificate of successful completion. Certificates are only valid for three years from the last day of the course for the purposes of auditor certification by IRCA.

Learning Objectives

- Understand the application of Quality Management Principles in the context of ISO 17025
- Relate the quality management system to the lab services, and operational processes including the context of the lab, risk assessment, and risk-based thinking specific to the lab.
- Understand the application of the principles, procedures, and techniques of auditing.
- Understand the conduct of an effective audit in the context of the auditee's organizational situation.
- Understand the application of the regulations, and other considerations that are relevant to the management system, and the conduct of the audit.
- Practice personal attributes necessary for the effective and efficient conduct of a management system audit.
- Establish, plan and task the activities of an audit team.
- Communicate effectively with the auditee and audit client.
- Organize and direct audit team members.
- Prevent and resolve conflict with the auditee and/or within the audit team.
- Prepare and complete the audit report.

Seminar Outline

Day 1

- Introduction and Welcome
- Chapter 1: Changes in ISO/ IEC 17025: 2017
- Chapter 2: Introduction to ISO/IEC 17025:2017
- Team Breakout Exercise 1: Definition of a Laboratory
- Graded Exercise 1: Understanding ISO/IEC 17025:2017
- Chapter 3: ISO/IEC 17025:2017 Requirements
- Team Breakout Exercise 2: Key Processes
- Graded Exercise 2: Audit Scenarios (Clauses 4-6)

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Day 2

- Chapter 3: ISO/IEC 17025:2017 Requirements (continued)
- Graded Exercise 3: Audit Scenarios (Clause 7)
- Graded Exercise 4: Management Responsibility (clause 8)
- Chapter 4: Process Approach to Auditing, Turtle Diagrams, and Audit Trails
- Chapter 5: Audit Guidance, Definitions, and Principles
- Chapter 6: The Audit Program
- Chapter 7: Audit Planning and Preparation
- Team Breakout Exercise 3: Writing Scope and Objective Statements

Day 3

- Chapter 7: Audit Planning and Preparation (continued)
- Team Breakout Exercise 4: Laboratory Document Review
- Team Breakout Exercise 5: Creating an Audit Plan
- Chapter 8: Conducting the Audit
- Team Breakout Exercise 6: Conducting the Audit
- Chapter 9: Writing Nonconformity Statements
- Team Breakout Exercise 7: Writing Nonconformity Statements

Day 4

- Chapter 10: Closing Meeting
- Chapter 11: Completing the Audit Report
- Chapter 12: Corrective Action and Closeout
- Team Breakout Exercise 8: Verification and Closeout
- Chapter 13: Leading Audit Teams

Day 5

- Mock Audit Exercise
- ISO/IEC 170125:2017 Final Exam

Who Should Attend

This seminar is designed for Management Representatives, ISO 17025 Implementation Teams, Internal Auditors, and others who would like to develop judgment and decision-making in ISO 17025 and learn the auditing process for first, second, and third party auditors.

Seminar Materials

Each participant will receive a seminar manual and a breakout workbook that includes auditing case studies.

Pre-Requisite

An understanding of the ISO 17025 requirements and/or work experience in applying ISO 17025 is recommended. Students are expected to have the following prior knowledge:

- Knowledge of the following quality management principles and concepts:
- The Plan, Do, Check Act (PDCA) cycle
- The relationship between quality management and customer satisfaction
  Commonly used Lab quality management terms and definitions and the Quality Principles as given in ISO 17025

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- The process approach used in quality management
- The Model of the requirements of ISO 17025, which may be gained by completing an IRCA certified Foundation Training course or equivalent.
- Knowledge of the requirements of ISO 17025, which may be gained by completing an IRCA certified QMS Foundation training course for ISO 17025 or equivalent.

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