



ISO 15189 Medical Laboratories Lead Auditor Training

Course Introduction:

The ISO 15189 standard specifies the requirements for quality and competence in medical laboratories, focusing on the specific needs of these environments. As the global healthcare landscape evolves, the need for consistent, accurate, and reliable laboratory results becomes ever more critical. This comprehensive 5-day training course provides professionals with the skills and knowledge necessary to lead audits of medical laboratories, ensuring compliance with ISO 15189 standards. The course offers both theoretical knowledge and practical insights into the auditing process, helping participants understand the essential principles of quality management, laboratory safety, and technical competency.

Through this training, participants will gain the ability to conduct internal and external audits of medical laboratories, assess the effectiveness of the laboratory's quality management system (QMS), and ensure that it adheres to regulatory and accreditation standards. By the end of the course, attendees will have a solid understanding of the auditing process, from preparation to reporting, with a focus on continual improvement within medical laboratory operations. The course also provides insights into the role of a Lead Auditor in fostering a culture of quality and excellence in laboratory services.

Course Objectives:

By the end of this course, participants will be able to:

- Understand the key principles and requirements of ISO 15189 and its application in medical laboratories.
- Gain the skills to plan, conduct, and report on audits of medical laboratories based on ISO 15189 standards.
- Develop competency in evaluating laboratory processes, documentation, and overall quality management systems.
- Learn to identify and categorize non-conformities and recommend corrective actions to improve laboratory quality.
- Master techniques for leading audit teams, conducting interviews, and observing laboratory practices effectively.
- Gain experience through exercises to strengthen auditing capabilities.
- Understand the process of medical laboratory accreditation and the role of Lead Auditors in maintaining compliance.

Who Should Attend?

This course is suitable for Quality managers and professionals working in medical laboratories, Internal and external auditors involved in the auditing of medical laboratories, Laboratory directors and managers looking to improve their understanding of quality management and auditing processes, Healthcare professionals involved in laboratory accreditation and regulatory compliance, Individuals seeking to become certified Lead Auditors for ISO 15189, and Consultants providing advisory services on laboratory quality systems and compliance.

Course Outline:

Day 1: Introduction to ISO 15189 and Quality Management Systems (QMS) in Medical Laboratories

- **Overview of ISO 15189:** History, structure, and key elements of the standard.
- **Quality Management System (QMS) Basics:** Introduction to quality principles and systems in the laboratory setting.
- **ISO 15189 Requirements:** Exploring the main requirements of ISO 15189 and their application in medical laboratories.
- **Key Concepts in Laboratory Competence:** Understanding the importance of accuracy, reliability, and proficiency in laboratory results.
- **Roles and Responsibilities of Auditors:** Overview of the responsibilities and expectations for Lead Auditors.

Day 2: Audit Planning and Preparation

- **Audit Process Overview:** Understanding the steps involved in an audit, from planning to reporting.
- **Audit Scope and Objectives:** Defining audit goals, scope, and critical areas for review in a medical laboratory.
- **Audit Plan Development:** Creating a comprehensive audit plan, including scheduling, resources, and team roles.
- **Document Review and Preparation:** Reviewing ISO 15189 documentation and preparing for the audit process.
- **Audit Tools and Checklists:** Introduction to tools, templates, and audit checklists tailored for medical laboratories.

Day 3: Conducting the Audit – Techniques and Methodology

- **Opening Meeting:** How to lead the opening meeting, set expectations, and outline the audit process.
- **Interviewing Techniques:** Best practices for conducting interviews with laboratory staff and management.
- **On-Site Observation:** Approaches for observing laboratory operations and assessing compliance.
- **Sampling Methods:** Techniques for sampling laboratory processes, records, and equipment.
- **Audit Evidence Collection:** Identifying and collecting evidence to support audit findings.
- **Non-Conformities and Findings:** Identifying, documenting, and categorizing non-conformities during the audit.

Day 4: Reporting and Follow-up

- **Audit Report Structure:** How to write clear, concise, and objective audit reports.
- **Categorizing Findings:** Identifying major and minor non-conformities and their potential impact on laboratory operations.
- **Corrective and Preventive Actions:** Recommending corrective actions, preventive measures, and strategies for continual improvement.
- **Closing Meeting:** Leading the closing meeting, presenting audit findings, and fostering a collaborative approach to improvements.
- **Follow-up Audits:** Planning and conducting follow-up audits to ensure corrective actions are implemented.

Day 5: Competency Assessment

- **Lead Auditor Competencies:** Essential skills and knowledge for a successful Lead Auditor.
- **Exercises:** Exercises to apply the audit process, including mock audits and report writing.
- **Evaluating Audit Effectiveness:** Measuring the effectiveness of the audit and identifying areas for improvement.
- **ISO 15189 Accreditation Process:** Understanding the accreditation process for medical laboratories and the role of the auditor in maintaining accreditation.

Course Methodology:

A variety of methodologies will be used during the course that including:

- (30%) Based on Case Studies
- (30%) Techniques
- (30%) Role Play
- (10%) Concepts

- Pre-test and Post-test
- Variety of Learning Methods
- Lectures
- Case Studies and Self Questionnaires
- Group Work
- Discussion
- Presentation

Course Certificate:

International Center for Training & Development (ICTD) will award an internationally recognized certificate(s) for each delegate on completion of training.

Course Fees:

To be advised as per course location. This rate includes participant's manual, Hand-Outs, buffet lunch, coffee/tea on arrival, morning & afternoon of each day.

Course Timings:

Daily Course Timings:

08:00 - 08:20	Morning Coffee / Tea
08:20 - 10:00	First Session
10:00 - 10:20	Coffee / Tea / Snacks
10:20 - 12:20	Second Session
12:20 - 13:30	Lunch Break & Prayer Break
13:30 - 15:00	Last Session