ISO 17025 Laboratory Management System (LMS)

Introduction

All laboratories need to have sound business processes to enable them to deliver technically sound calibrations and tests to their clients. When a laboratory is seeking to have its competence recognized through accreditation by the United Kingdom Accreditation Service, these processes must also enable the laboratory to meet the requirements of ISO/IEC 17025. This course enables participants to be familiar with the basic concepts of implementation and management of a laboratory management system (LMS) as specified in ISO/IEC 17025. The participant will learn the different components of a LMS, including the quality manual, policy, required procedures, management review, internal audit and all the factors that can influence test and/or calibration results performed by a laboratory. This course enables participants to learn about the best practices for implementing and managing a laboratory management system (LMS) as specified in ISO/IEC 17025, as well as best practices for implementing quality controls. The participants will learn the different component of this standard, including the quality manual, policy, required procedures, management review, internal audit and all the factors that can influence test and/or calibration results performed by a laboratory.

Who Should Attend?

Managers, Team Leaders, Line Managers, Superintendents, OE Champions, Quality and Project Managers, Supervisors, Executives, Internal and External Auditors, Members of IT Team, Health & Safety Managers, Risk Managers, Business Process Owners, Business Finance Managers, Business Risk Managers, Regulatory Compliance Managers, Project Managers, Continuity, Risk, Quality, IT and Environmental Managers, Anyone involved in the system development, implementation and maintenance, Regulatory Affairs Managers, Consultants, Anyone who is involved in ISO standards, Laboratory professional wanting to gain a comprehensive knowledge of the main requirements of ISO/IEC 17025, Staff involved in the implementation of the ISO/IEC 17025 standard, Managers responsible for implementing a Management System

Course Objectives:

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

- Understand the fundamentals of laboratory management
- Know the key components of a laboratory management system in accordance with ISO/IEC 17025
- Introduce the concepts, approaches, methods and techniques allowing to effectively manage a LMS
- Understand the relationship between a laboratory management system, including quality management, controls and compliance with the requirements of different stakeholders of the organization
- Understand the management and technical requirements of ISO/IEC 17025
- Understand the implementation of a laboratory managements system in accordance with ISO/IEC 17025
- Understand the requirements of ISO/IEC 17025
- Know the concepts, approaches, methods and techniques allowing to effectively manage a Laboratory Management System
- Acquire the necessary knowledge to contribute in implementing a laboratory management system (LMS) as specified in ISO/IEC 17025
- Understand and Interpreting the requirements of ISO 17025 standard with clarity
- Be familiar with the principles of testing and calibration
- Be able to develop, implement and maintain management system based on ISO 17025
- Conduct initial gap analysis at respective organizations
- Learn how to plan, prepare, conduct, report and follow up an internal audit
- Understand how to apply the framework for any type of laboratory, company or culture

Course Outline:

- Introduction to ISO/IEC 17025
- Introduction to management systems and the process approach
- General requirements: presentations of the clauses 4 and 5 of ISO/IEC 17025
- Implementation phases of the ISO/IEC 17025 framework
- Continual improvement of laboratory management
- Conducting an ISO/IEC 17025 accreditation audit
- Laboratory structure to ensure integrity and competence
- Exercise: organization chart and report back
- Quality management system as a framework for the business processes and the role of ISO 17025
- Exercise: job descriptions of QM and TM and report back
- Laboratory facilities
- Services and supplies
- Ensuring competence: equipment and personnel

- Tenders, contracts and requests – the review process
- Subcontracting
- Ensuring competence – test and calibration methods
- Content of a test method and validation
- Exercise continued and report back
- Documentation and documentation control process
- Documentation control and content of a procedure and report back
- Handling of samples and items from customers for calibration and test
- Sample/item handling process and booking in of samples/items
- Performance of calibrations and tests
- Management controls
- Audit program and test - calibration method audit and report back
- Identifying potential and actual non-conforming work
- Proforma production via brainstorming
- Process of recording and storage and retrieval of records
- Reporting results to client including opinions and interpretations
- Complaints process and records and report back
- UKAS assessment and the roles of the QM and TM
- Implementing requirements from ISO/IEC 17025
- Documentation of a LMS
- Monitoring and reviewing process
- Conducting an ISO/IEC 17025 audit
- Steps towards accreditation