ISO 17025 Laboratory Competence and Accreditation Training Course

Ref: #ISO6016

Course Introduction / Overview:

This comprehensive training course provides a deep dive into the requirements of ISO/IEC 17025:2017, the international standard for the competence of testing and calibration laboratories. In today's global market, demonstrating technical competence and the ability to generate valid results is paramount for credibility and market access. This course is meticulously designed to guide participants through every clause of the standard, from management system requirements to technical specifications. We will explore the core principles of impartiality, confidentiality, and the process-oriented approach that underpins the standard. Drawing on the quality management philosophies of pioneers like Dr. W. Edwards Deming, who emphasized continuous improvement, the course connects theoretical knowledge with practical application. Participants will learn not just what the standard requires, but how to effectively implement a robust laboratory quality management system (QMS) that fosters a culture of quality and ensures data integrity. BIG BEN Training Center has developed this program to empower laboratory professionals with the skills to navigate the complexities of accreditation, manage risks effectively, and drive operational excellence, ensuring their organization's services meet the highest international benchmarks for quality and competence.

Target Audience / This training course is suitable for:

- Laboratory Managers and Supervisors.
- Quality Assurance and Quality Control Managers.
- Technical Staff, Chemists, and Analysts.
- Internal Auditors for Laboratories.
- Laboratory Accreditation Assessors.
- Research and Development Scientists.
- Calibration Engineers and Technicians.
- Consultants in Laboratory Management Systems.
- Regulatory and Compliance Personnel.

Target Sectors and Industries:

- Pharmaceutical and Biotechnology Industries.
- Environmental Testing and Monitoring Services.
- Food and Beverage Safety and Quality Control.
- Forensic Science and Crime Laboratories.
- Manufacturing and Materials Testing.
- Petrochemical and Chemical Industries.
- Clinical and Medical Testing Laboratories.
- Governmental regulatory bodies and public health agencies.
- Calibration and Metrology Services.
- Construction and Civil Engineering.

Target Organizations Departments:

- Quality Assurance and Quality Control (QA/QC).
- Research and Development (R&D).
- Calibration and Metrology Laboratories.
- Production and Operations.
- Regulatory Affairs and Compliance.
- Technical Services and Support.
- Internal Audit Departments.
- Health, Safety, and Environment (HSE).

Course Offerings:

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

- Interpret the requirements of each clause of the ISO/IEC 17025:2017 standard.
- Develop and implement a compliant laboratory quality management system (QMS).
- Establish procedures for ensuring impartiality and confidentiality in laboratory operations.
- Apply risk-based thinking to laboratory processes and controls.
- Manage and document the competence of laboratory personnel effectively.
- Implement robust procedures for equipment calibration, maintenance, and verification.
- Master the principles of method selection, verification, and validation.
- Calculate and report measurement uncertainty for test and calibration results.
- Develop a framework for ensuring the validity of results through quality control.
- Plan, conduct, and report effective internal audits of the laboratory QMS.
- Manage nonconforming work and implement effective corrective actions.
- Prepare a laboratory for a successful third-party accreditation assessment.

Course Methodology:

The training methodology at BIG BEN Training Center is designed to be highly interactive and participant-centered, moving beyond traditional lecture formats to ensure deep comprehension and practical skill acquisition. This course utilizes a blended learning approach that combines expert-led presentations with dynamic group discussions, allowing participants to share experiences and solve common challenges. A significant portion of the training is dedicated to practical workshops and hands-on exercises, such as developing sections of a quality manual, performing a risk assessment on a laboratory process, and analyzing case studies of nonconformities. Participants will work in teams to tackle real-world scenarios related to method validation, calculating measurement uncertainty, and planning an internal audit. This collaborative environment fosters critical thinking and problem-solving skills. Our experienced instructors facilitate these sessions, providing continuous feedback and personalized guidance to ensure that every participant can confidently apply the ISO 17025 principles within their own operational context upon returning to their workplace. The focus is on building competence, not just transferring information.

Course Agenda (Course Units):

Unit One: Foundations of ISO 17025 and Management System Requirements

- Introduction to laboratory accreditation and the ISO/IEC 17025:2017 standard.
- Understanding the structure, scope, and key terminology of the standard.
- Clause 4: General Requirements - Impartiality and Confidentiality.
- Clause 5: Structural Requirements for a compliant laboratory.
- Clause 8: Management System Requirements (Option A and Option B).
- Implementing a document control system for the laboratory QMS.
- Applying risk-based thinking to laboratory activities and opportunities.

Unit Two: Mastering Resource Requirements for Laboratory Competence

- Clause 6.2: Personnel - Competence, training, and authorization.
- Clause 6.3: Facilities and Environmental Conditions.
- Clause 6.4: Equipment - Calibration, maintenance, and performance verification.
- Establishing metrological traceability for measurements.
- Clause 6.5: Metrological Traceability and its importance.
- Clause 6.6: Externally Provided Products and Services.
- Developing procedures for supplier evaluation and performance monitoring.

Unit Three: Implementing Core Process Requirements

- Clause 7.1: Review of Requests, Tenders, and Contracts.
- Clause 7.2: Selection, Verification, and Validation of Methods.
- Detailed workshop on method validation protocols and documentation.
- Clause 7.3: Sampling - Developing a robust sampling plan.
- Clause 7.4: Handling of Test and Calibration Items.
- Clause 7.5: Managing and maintaining Technical Records.
- Ensuring data integrity and security for all laboratory records.

Unit Four: Measurement Uncertainty and Ensuring Result Validity

- Clause 7.6: Evaluating Measurement Uncertainty (MU).
- Practical steps for identifying sources and calculating MU.
- Reporting measurement uncertainty on certificates and reports.
- Clause 7.7: Ensuring the Validity of Results.
- Implementing internal quality control measures (e.g., control charts).
- Participation in proficiency testing and interlaboratory comparisons.
- Monitoring performance and analyzing quality control data.

Unit Five: Auditing, Improvement, and the Path to Accreditation

- Clause 7.8: Reporting of Results - Common requirements and specific statements.
- Clause 8.5: Actions to Address Risks and Opportunities.
- Clause 8.6: Improvement - Proactive enhancement of the QMS.
- Clause 8.7: Corrective Actions and root cause analysis.
- Clause 8.8: Internal Audits - Planning, conducting, and reporting.
- Clause 8.9: Management Reviews - Inputs, outputs, and effective execution.
- Preparing for the external accreditation audit and closing the loop.

FAQ:

Qualifications required for registering to this course?

There are no requirements.

How long is each daily session, and what is the total number of training hours for the course?

This training course spans five days, with daily sessions ranging between 4 to 5 hours, including breaks and interactive activities, bringing the total duration to 20 - 25 training hours.

Something to think about:

Beyond compliance, how can the principles of impartiality and risk-based thinking embedded in ISO 17025 fundamentally transform a laboratory's scientific culture and its contribution to the wider organization?

What unique qualities does this course offer compared to other courses?

This course distinguishes itself by moving beyond a simple clause-by-clause explanation of the standard to a holistic, implementation-focused experience. While other courses may focus on the theoretical "what," our program is built around the practical "how." We emphasize the integration of the ISO 17025 framework into the daily workflow of a modern laboratory, treating it not as a bureaucratic burden but as a powerful tool for operational excellence and risk mitigation. The curriculum is enriched with a diverse range of case studies drawn from various industries, from pharmaceutical to environmental testing, ensuring the content is relevant and applicable regardless of the participant's specific field. Our expert instructors are seasoned practitioners who bring real-world insights into managing audits, validating complex methods, and fostering a robust quality culture. The core uniqueness lies in our hands-on workshops, where participants actively engage in tasks like developing a measurement uncertainty budget or conducting a mock root cause analysis, thereby building tangible skills and the confidence to lead implementation and improvement initiatives within their own organizations.