Advanced Laboratory Quality Management and Accreditation Training Course



23 - 27 Nov 2026

Tokyo

5800 € (Per Person)

Ref: #HSM2454_106034

Course Introduction / Overview:

This course provides a comprehensive exploration of Laboratory Quality Management Systems (QMS) and the intricate process of achieving accreditation. In today's data-driven world, the accuracy and reliability of laboratory results are paramount, underpinning critical decisions in healthcare, manufacturing, and environmental safety. This program is meticulously designed to equip participants with the knowledge and skills to implement, manage, and sustain a robust QMS that complies with international standards, primarily focusing on ISO/IEC 17025. We will delve into the core principles of quality assurance and control, drawing upon the foundational concepts of quality management pioneers like Joseph M. Juran, who emphasized the "quality trilogy" of planning, control, and improvement. Participants will learn to navigate the complexities of documentation, internal audits, corrective actions, and method validation. The curriculum, inspired by authoritative texts such as "A Practical Guide to ISO/IEC 17025," ensures a practical, hands-on approach. BIG BEN Training Center has developed this course to bridge the gap between theoretical knowledge and the practical challenges faced in a modern laboratory, preparing professionals to lead their organizations toward successful accreditation and a culture of continuous improvement.

Target Audience / This training course is suitable for:

- Laboratory Managers and Supervisors.
- Quality Assurance and Quality Control Managers.
- Laboratory Technicians and Scientists.
- Internal and External Auditors.
- Regulatory Affairs Specialists.
- Research and Development Professionals.
- Compliance Officers.
- Consultants in laboratory quality systems.

Target Sectors and Industries:

- Pharmaceutical and Biotechnology Industries.
- Medical and Clinical Diagnostic Laboratories.
- Food and Beverage Testing and Safety.
- Environmental Testing and Monitoring Agencies.
- Chemical and Materials Manufacturing.
- Forensic Science Laboratories.
- Petrochemical and Energy Sector.
- Governmental regulatory bodies and public health organizations.
- Calibration and Testing Service Providers.

Target Organizations Departments:

- Quality Assurance (QA) Department.
- Quality Control (QC) Department.
- Laboratory Operations.
- Research and Development (R&D).
- Regulatory and Compliance Department.
- Health, Safety, and Environment (HSE) Department.
- Production and Manufacturing.
- Technical Support and Services.

Course Offerings:

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

- Develop and implement a comprehensive Laboratory Quality Management System (QMS).
- Interpret and apply the requirements of ISO/IEC 17025 and other relevant standards.
- Create and manage essential quality documentation, including manuals, SOPs, and records.
- Plan, conduct, and report effective internal laboratory audits.
- Master the techniques for method validation, verification, and measurement uncertainty estimation.
- Implement robust procedures for corrective and preventive actions (CAPA).
- Manage non-conforming work and conduct thorough root cause analysis.
- Prepare a laboratory for the formal accreditation process and external assessments.
- Foster a culture of continuous improvement and quality within the laboratory environment.
- Effectively manage equipment calibration, maintenance, and qualification programs.

Course Methodology:

The training methodology employed by BIG BEN Training Center is designed to be highly interactive, engaging, and practical, ensuring that participants can immediately apply their learning in their professional roles. We move beyond traditional lectures to create a dynamic learning environment that fosters deep understanding and skill development. The course incorporates a blend of expert-led presentations, detailed case studies from various industries, and interactive group discussions where participants can share experiences and solve real-world problems collaboratively. A significant portion of the training is dedicated to hands-on workshops and practical exercises, such as drafting quality documents, simulating internal audit scenarios, and performing risk assessments. Participants will work in teams to analyze non-conformities and develop effective corrective action plans. This immersive approach is supported by continuous feedback from the instructor, allowing for personalized guidance and clarification. Our goal is to empower attendees not just with knowledge of the standards, but with the confidence and competence to drive quality excellence within their own laboratories.

Course Agenda (Course Units):

Unit One: Fundamentals of Laboratory Quality Management

- Introduction to Quality Management Systems (QMS).
- The importance of quality assurance and quality control in laboratories.
- Overview of key international standards (ISO/IEC 17025, ISO 15189, GLP).
- Understanding the process approach and risk-based thinking.
- The structure and clauses of the ISO/IEC 17025:2017 standard.
- Defining the scope of the quality management system.
- Roles and responsibilities in a laboratory QMS.

Unit Two: QMS Documentation and Control

- Developing a Quality Manual.
- Writing effective Standard Operating Procedures (SOPs).
- Control of documents and records management.
- Implementing a system for managing laboratory data and information (LIMS).
- Ensuring data integrity and security.
- Configuration management and version control.
- Archiving and retention policies for laboratory records.

Unit Three: Technical Requirements and Competence

- Personnel competence, training, and authorization.
- Managing laboratory facilities and environmental conditions.
- Equipment calibration, maintenance, and verification programs.
- Metrological traceability and its importance.
- Method selection, validation, and verification processes.
- Estimating and reporting measurement uncertainty.
- Ensuring the quality of test and calibration results through proficiency testing.

Unit Four: Auditing, Review, and Improvement

- Planning and conducting internal audits.
- Audit reporting and follow-up activities.
- Management review process and inputs/outputs.
- Identifying and managing non-conforming work.
- Root cause analysis techniques.
- Implementing effective corrective and preventive actions (CAPA).
- Strategies for continuous improvement in laboratory processes.

Unit Five: The Path to Accreditation

- Understanding the accreditation process and bodies.
- Preparing the application and required documentation.
- Hosting the external assessment team.
- Responding to audit findings and non-conformities.
- Achieving and maintaining accreditation status.
- Surveillance audits and reassessment cycles.
- Leveraging accreditation for business and operational excellence.

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:

In an era of increasing automation and AI in laboratories, how does the human element in quality management evolve to ensure both compliance and innovation?

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

This course distinguishes itself by moving beyond a purely theoretical review of standards to a deeply practical and strategic implementation framework. While many programs focus on simply understanding the clauses of ISO/IEC 17025, our curriculum emphasizes the "how" and "why" behind each requirement, fostering a culture of quality rather than a mere checklist-based compliance. We integrate principles of risk-based thinking and continuous improvement into every module, empowering participants to build a QMS that is not only compliant but also resilient, efficient, and value-adding. The course is built upon a pedagogical foundation that prioritizes real-world application through extensive use of case studies drawn from diverse industries, interactive workshops on root cause analysis, and simulated internal audit exercises. This hands-on approach ensures that participants leave with tangible skills and actionable strategies they can implement immediately. Furthermore, the content is designed to address the entire accreditation lifecycle, from initial gap analysis and documentation to successfully navigating external assessments and maintaining long-term compliance, providing a truly holistic and career-enhancing learning experience.