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AL171:
Laboratory Quality Management System (LQMS)

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Training Description:

Laboratory Quality Management Systems (LQMS) are vital to ensuring that laboratories operate in an efficient, effective, and compliant manner. The objective of this training is to equip participants with the knowledge and skills required to understand and implement LQMS in their respective laboratories, with a special focus on managing quality documents and internal auditing procedures.

This intensive training course will cover key aspects of the LQMS framework, including its structure, regulatory requirements, quality control mechanisms, documentation management, and audit processes. The focus will be on compliance with ISO 17025 (the international standard for laboratory competence) and other relevant regulations.

Training Objectives:

By the end of the training, participants will be able to:

- ✓ **Understand the key principles of LQMS** and its application within laboratories
- ✓ **Understand the requirements of ISO 17025** and other regulatory standards
- ✓ **Manage laboratory quality documents** effectively (document control, document review, and document retention)
- ✓ **Conduct internal audits** with a focus on identifying non-conformities and improving quality processes
- ✓ **Implement corrective and preventive actions (CAPA)** based on audit findings
- ✓ **Understand the roles and responsibilities of internal auditors** in the laboratory environment
- ✓ **Identify and mitigate risks** related to laboratory processes and quality systems

Training Designed for:

This course is intended for Laboratory managers and supervisors, Quality managers and quality assurance personnel, Laboratory technicians involved in quality management and auditing, Internal auditors and those responsible for conducting audits in the laboratory, Regulatory compliance officers and personnel and Anyone involved in the development, maintenance, or improvement of LQMS.

Training Requirement:

"Hand's on practical sessions, equipment and software will be applied during the course if required and as per the client's request."

Contents can be adapted to your specific wishes. It is therefore possible to focus on specific modules of the training course as per client's learning needs and objectives. Further, it should be forwarded to us a month prior to the course dates.

Training Program:

DAY ONE:

- ❖ **Introduction to Laboratory Quality Management Systems (LQMS)**
- ❖ Overview of LQMS
  - Definition and purpose of Quality Management Systems (QMS) in laboratories
  - Importance of quality in laboratory operations
  - Introduction to ISO 17025 and its significance in laboratory accreditation

- Key Concepts in Laboratory Quality
  - Quality assurance vs. quality control
  - Continuous improvement and risk management
  - Management review process
- Core Components of LQMS
  - Organizational structure and responsibilities
  - Laboratory procedures and methods
  - Competence of personnel and training requirements
  - Equipment calibration and maintenance
- Documentation Requirements
  - Types of documents required in LQMS (policies, procedures, work instructions, etc.)
  - Overview of document control processes
- Activity:
  - Discussion on the importance of quality systems in the laboratory
  - Case study on the impact of non-compliance in laboratory operations

DAY TWO:

- Laboratory Documentation Management and Control
- Document Control in LQMS
  - What is document control and why it is critical
  - Document lifecycle (creation, review, approval, revision, distribution, archiving, and disposal)
  - Key principles of document management: accessibility, accuracy, and security
- Types of Quality Documents in Laboratories
  - Quality Manual and Procedures
  - Work Instructions and SOPs
  - Forms and Records (e.g., calibration records, test results, etc.)
- Document Control Procedures
  - Document numbering and version control
  - Document approval and authorization
  - Document revision and update processes
  - Retention and disposal of quality documents
  - Digital document management systems vs. paper-based systems
- Record Management
  - Importance of maintaining accurate and up-to-date records
  - Legal and regulatory requirements for record keeping
  - Best practices in archiving and retrieval of laboratory records
- Activity:
  - Practical exercise: Develop a sample document control procedure for a laboratory
  - Interactive session: Review a case study on document mismanagement and its consequences

DAY THREE:

- Internal Auditing Principles & Practices
- Introduction to Internal Auditing
  - Definition and purpose of internal audits in a laboratory setting

- Difference between external audits, internal audits, and third-party audits
- Key principles and requirements for internal auditing in ISO 17025

❖ Audit Planning and Preparation:
- Developing an audit plan (scope, objectives, criteria)
- Preparing audit checklists and audit reports
- Roles and responsibilities of an auditor
- Risk-based approach to auditing

❖ Conducting an Internal Audit
- Audit techniques: interviews, document review, and observation
- How to audit laboratory processes effectively
- Managing audit evidence and documenting findings

❖ Non-Conformities and Corrective Actions
- Identifying and documenting non-conformities
- Root cause analysis for non-conformities
- Corrective and preventive actions (CAPA)
- Follow-up procedures and verification of actions

❖ Activity:
- Practical exercise: Conduct a mock internal audit of a laboratory process
- Discussion: Common challenges in laboratory audits and solutions

DAY FOUR:

❖ Advanced Internal Auditing and CAPA

❖ Advanced Internal Auditing Techniques
- Techniques for auditing complex laboratory processes
- Managing audits for cross-functional areas (e.g., calibration, maintenance, personnel competence)
- Interviewing techniques for auditors: Effective questioning and communication

❖ Root Cause Analysis and Problem Solving
- Tools for root cause analysis (5 Whys, Fishbone diagram, etc.)
- Implementing corrective actions based on audit findings
- Preventive actions and continuous improvement

❖ Audit Reporting and Follow-up
- Writing clear and concise audit reports
- Reporting non-conformities and recommendations
- Ensuring effective follow-up and verification of actions taken
- Maintaining audit records for future reference

❖ Maintaining an Audit Trail
- Importance of traceability and transparency in auditing
- Electronic vs. manual audit trails

❖ Activity
- Case study: Develop an audit report for a laboratory non-conformity and propose corrective actions
- Interactive session: Troubleshoot audit challenges with a focus on CAPA

DAY FIVE:

- Implementing LQMS in Laboratories and Final Review
- Implementing an Effective LQMS
  - Steps for implementing LQMS in a laboratory
  - Creating a culture of quality and continuous improvement
  - Communication strategies for implementing quality systems
- ISO 17025 Accreditation Process
  - Preparing for accreditation audits
  - Role of internal auditors in supporting accreditation
  - Maintaining accreditation and continuous compliance
- Best Practices and Common Pitfalls
  - Best practices in LQMS implementation
  - Common mistakes and how to avoid them
  - The importance of leadership commitment in ensuring quality
- Final Review and Q&A
  - Recap of the entire training
  - Addressing any remaining questions or concerns
  - Discussion on how participants will implement LQMS in their own laboratories
- Activity
  - Exercise: Action plan for implementing LQMS in a lab
- Course Conclusion
- POST-ASSESSMENT and EVALUATION

Training Methodology:

This training outline is designed to ensure that participants not only gain theoretical knowledge but also practical skills they can apply directly in their laboratory settings. The emphasis on internal auditing, document management, and continuous improvement will help participants enhance their laboratory's overall quality performance and compliance.

This interactive training course includes the following training methodologies as a percentage of the total tuition hours:

- 30% Lectures, Concepts, Role Play
- 70% Workshops & Work Presentations, Techniques, Based on Case Studies & Practical Exercises, Gamification, Software & General Discussions
- Pre and Post Test

Training Certificate(s):

CMCT Internationally recognized certificate(s) will be issued to each participant who completed the course.

Training Fees:

TBA as per the course location - This rate includes participant's manual, hand-outs, buffet lunch, coffee/tea on arrival, morning & afternoon of each day.

Note: The 5% VAT (Value Added Tax), will be effective starting 01st of January 2018 as per the new regulation from the UAE Government. The VAT applies for all quotation both for local and abroad.

Training Timings:

Daily Timings:

07:45 - 08:00	Morning Coffee / Tea
08:00 - 10:00	First Session
10:00 - 10:20	Recess (Coffee/Tea/Snacks)
10:20 - 12:20	Second Session
12:20 - 13:00	Recess (Prayer Break & Lunch)
13:00 - 14:00	Last Session

For training registrations or in-house enquiries, please contact:

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