

Course: SOP, Accreditation Documentation, and Auditing Laboratory Quality Management (ISO 17025)

Course code: TEC 409

Course Overview:

This course is a comprehensive look at the latest revision of the ISO 17025 and its documentation and internal auditing requirements. You will gain critical insight on the interpretation of the requirements of this laboratory standard and you will also receive a detailed review of the accreditation process.

You will learn how to design and develop laboratory documents and quality manuals. The quality manual will be examined as to its impact on laboratory operations and what purpose it serves. You will learn what information it should contain, what writing style is most effective and how to keep your documents and quality manual up to date.

This course also gives attendees the knowledge needed to establish an internal quality audit program as required by ISO 17025, and to initiate the sequence of activities involved in scheduling, planning, conducting, reporting on and closing out internal quality audits. Participants will be able to employ effective techniques of auditing and the ability to develop the auditing procedures, scheduling and recording systems needed to sustain the program.

Attendees will receive practical instructions on the development, implementation and long-term maintenance of an effective laboratory quality system.

In addition to the updated knowledge provided to course participants during the course period, each participant will go back to his/her laboratory equipped with an outstanding manual that includes typical SOPs that can be modified and used within participant's laboratory

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Learning Objective

Upon the successful completion of this course, each participant will be able to:-

- Get certified as a "Certified ISO 17025 Auditor"
- Apply proper techniques in laboratory quality management and its standard operational procedures, accreditation, documentation and auditing (laboratory auditing) in accordance with the ISO 17025
- Recognize the requirements of an ISO 17025 accreditation and review the accreditation process
- Design and develop laboratory documents (SOP) & quality manuals and recognize the information they should contain, employ an effective writing style as well as maintain documents and quality manuals up to date
- Carryout an internal quality audit program in accordance with ISO 17025 as well as initiate the sequence of activities involved in scheduling, planning, conducting, reporting on and closing out internal quality audits
- Employ effective techniques of auditing and develop auditing procedures, scheduling and recording systems needed to sustain an auditing program
- Develop, implement and maintain a long term effective laboratory quality system in the long run in compliance with the requirements of ISO 17025

• Who Should Attend:

This course is suitable for laboratory managers, superintendents, supervisors, chemists, analysts, quality managers and quality engineers. Furthermore, the course will be of great benefit for all personnel who works in the quality assurance and/or quality control fields and would have interest in auditing.

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Training Methodology:

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

- 40% Lectures
- 20% Workshops & Work Presentations
- 20% In Class Case Studies and Videos, Software & Simulators
- 20% Lab visit

In an unlikely event, the course instructor may modify the above training methodology before or during the course for technical reasons.

Course Language:

The presentation along with the rest of the hands out will be in English while explanation of the entire course will be in Arabic / English language.

Minimum/Maximum class capacity:

The class will be held for at least 10 persons. The class to hold up to 15 persons.

Pre-requisites for attending course:

Although there are no Pre-requisites for attending course, it would be an added value to have awareness knowledge on ISO/IEC 17025:2017.

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Course Outlines

- Accreditation
- ISO/IEC 17025:2017; What the Standard Requires:
 - General requirements (2 sub)
 - Structural requirements (7 sub)
 - Resources requirements (6 sub)
 - Process Requirements (11 sub)
 - Management requirements (2 Options) – (9 sub).
- Audit principles and types of audits.
- Principles of auditing
 - Managing an audit programme
 - Establishing audit programme objectives
 - Determining and evaluating audit programme risks and opportunities
 - Establishing the audit programme
 - Implementing audit programme
 - Monitoring audit programme
 - Reviewing and improving audit programme
 - Conducting an audit
 - Initiating audit
 - Preparing audit activities

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- Conducting audit activities
- Preparing and distributing audit report
- Completing audit
- Conducting audit follow-up
- Competence and evaluation of auditors
 - Determining auditor competence
 - Establishing auditor evaluation criteria
 - Selecting appropriate auditor evaluation method
 - Conducting auditor evaluation
 - Maintaining and improving auditor competence
- Guidance for auditors planning and conducting audits:
 - Applying audit methods
 - Process approach to auditing
 - Professional judgement
 - Performance results
 - Verifying information
 - Sampling
 - Auditing compliance within a management system
 - Auditing context
 - Auditing leadership and commitment
 - Auditing risks and opportunities

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- Life cycle
 - Audit of supply chain
 - Preparing audit work documents
 - Selecting sources of information
 - Visiting the auditee's location
 - Auditing virtual activities and locations
 - Conducting interviews
 - Audit findings
- **Course Duration:**
 - 5 Days

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