

ISO 15189:2012 – MEDICAL LABORATORIES – REQUIREMENTS FOR QUALITY AND COMPETENCE & INTERNAL AUDITING



Objectives

- To equip the participants with the basic knowledge and skills to interpret and to apply the requirements for enhancing Quality & Competence in Medical Laboratories.
- To enable the participants to conduct their internal audit based on ISO 15189:2012 in accordance with ISO 19011:2018 Guidelines.

Duration

2 days | 9am – 5pm | 14 hours

Who should attend

This program is designed for Top and Middle level management and any other personnel who are being engaged in managing Medical Laboratories activities. The appointed auditors and auditees are also recommended to attend the above program with a view to equip them with the necessary audit know-how and audit checklists in preparing for their internal and external audits exercise effectively.

Course Fees

Member: S\$668.75
Non-Member: S\$695.50
Registration Fee of S\$17.12 apply
All fees stated are inclusive of 7% GST

Award of Certificate

Certificate of Completion will be issued to participants who have attended at least 75% of the course.



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Course Contents

DAY ONE: Interpretation and Application of ISO 15189:2012 Requirements

- Scope / Normative References / Terms and Definitions
- Management Requirements
 - Organization & Management Responsibility
 - Quality Management System
 - Document Control
 - Service Agreements
 - Examination By Referral
 - Laboratories
 - External Services and Supplies
 - Advisory Services
 - Resolution of Complaints
 - Identification and Control of Non-conformities
 - Corrective Action
 - Preventive Action
 - Control of Records
 - Evaluation and Audits
 - Management Review
- Technical Requirements
 - Personnel
 - Accommodation and Environmental Conditions
 - Laboratory Equipment, Reagents and Consumables
 - Pre-examination Processes
 - Examination Processes
 - Post-examination Processes
 - Reporting of Results
 - Release of Results
 - Laboratory Information Management
- Class-room Exercises, Assignments & Discussion

DAY TWO: ISO 19011:2018 Guidelines For Auditing

- Terms & Definition: Audit, Audit Objective, Audit Scope, Audit Criteria, Audit Evidence, Audit Findings & Audit Conclusion
- Seven Principles of Auditing
- Audit Plan vs Audit Programme
- Management of An Audit Programme
- Six Steps In Performing An Audit
- Prepare Audit Plan and Audit Check Sheet
- Execution of Audit By Applying 6A Auditing Approach
- Documenting Non-conformity / Non-compliance, Corrective Action & Follow up Verification Audit
- Brief Outlines Of Internal Quality Audit Procedure
- Human Aspect of Auditing
- Preparatory Work for External Audit
- Group Assignment & Presentation
- Question & Answer / General Discussion



Please refer to this URL
<https://www.sqi.org.sg/courses/>
or QR Code for soft copy
and updated training schedule

Membership Application

Register membership online at www.sqi.org.sg/membership-join/ or contact us to get the membership application form.

Membership Categories:

- ~ Organisation membership
- ~ Individual membership

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