

Medical Laboratory Internal Auditing Course Three Training Days (for 5 to 20 participants) (based on ISO 15189:2012)

Who should attend?

Medical Lab Quality System personnel responsible for QMS and Internal Auditing must participate. Medical Lab Pathologists, Microbiologists, Biochemists and Technicians should also be involved in order to understand 15189 internal audit requirements and to the lab's quality and accreditation framework.

Course Objectives

Upon successful completion of the course, participants will have gained the following:

- Knowledge on how to audit a Medical Laboratory that conforms to ISO 15189
- Identification of documents and records required by ISO 15189
- Understanding of risk management plans
- Understanding of auditing principles
- Understanding of internal auditing process including planning
- Ability and practice in the performance of an internal audit
- Writing of audit findings
- Preparation of audit report, follow-up and closing the loop
- Characteristics of an effective internal auditor

Certificates

All participants who take and qualify a written exam will receive a Certificate of Successful Completion.

Syllabus

Time	Activities
Day 1	
0830 – 0900	Registration
0900 – 0930	Introduction to the training course
0930 – 0950	Laboratory Accreditation: International Scenario
0950 – 1000	Group Photo
1000 – 1015	Tea Break
1015 – 1300	ISO 15189:2012 – Clause 4: Management Requirements
1300 – 1330	Lunch Break
1330 – 1530	ISO 15189:2012 – Clause 4: Management Requirements
1530 – 1545	Tea Break
1545 – 1700	Exercise No. 1: Clause identification (reference clause 4)
1700 – 1730	Outline of Case Study 1: Policy, Procedure, Process, Document & Record
Day 2	
0830 – 0900	Review of Day 1
0900 – 1100	ISO 15189:2012 – Clause 5: Technical Requirements
1100 – 1145	Tea Break
1145 – 1300	ISO 15189:2012 – Clause 5: Technical Requirements
1300 – 1330	Lunch Break
1330 – 1530	Exercise No. 2: Clause identification (reference clause 5)
1530 – 1545	Tea Break
1545 – 1715	Discussion on Case Study 1
1715 – 1730	Outline of Case Study 2: Evaluation of Quality Manual

Time	Activities
Day 3	
0830 – 0900	Review of Day 2
0900 – 1100	Discussion on the case study 2: Evaluation of Quality Manual
1100 – 1115	Tea Break
1115 – 1245	Audit and its associated activities (what is audit? why audit is done? How audit is done?)
1245 – 1315	Auditor's attributes
1315 – 1345	Lunch Break
1345 – 1530	Group Exercise: Conduct of mock audit
1530 – 1545	Tea Break
1545 – 1600	Written Test
1600 – 1700	Feedback & Close

Quality Management System Discussion

Management Requirements	Technical Requirements
Organisation and Management responsibility	Personnel
Quality management system	Accommodation and environmental conditions
Document control	Laboratory equipment, reagents and consumables
Service agreements	Pre-examination processes
Examination by referral laboratories	Examination processes
External services and supplies	Ensuring quality of examination results
Advisory services	Post-examination processes
Resolution of complaints	Reporting of results
Identification and control of nonconformities	Release of results
Corrective action	Laboratory information management.
Preventive action	
Continual improvement	
Control of records	
Evaluation and audits	
Management review	

Internal Audit Discussion

What is audit
Types of audits
What is Internal Audit
Process of Internal Audit including planning and execution
Internal Audit Report writing
Follow-up and Closing the loop