

COURSE OUTLINE

Course Title

Accreditation requirements & internal auditing of Medical Laboratories according to ISO 15189

Course Dates:

2nd -3rd November 2009- 2 days

Course Fees:

AED 2000 (Two Thousand Dirham per participant)

Course Venue:

Dubai Central Laboratory- Administration Building
Za'beel Street, Next to Main Post Office, Dubai
DAC Office Premises- 2nd Floor, Fazaa Hall.

Course Description:

This course has been developed for medical laboratories specifically to assist them in upgrading their management systems to ISO 15189. The course highlights the new requirements that medical laboratories must meet with accreditation and discussing the management and technical requirements of ISO 15189.

It provides the basic knowledge and skills to persons who are intended to do the internal audits for a laboratory, and the methodology of auditing the systems appropriately, and to encourage constructive development of effective assessment skills through analysis and self-criticism.

The course is designed to comply with the requirements of the ILAC G3 document. The course content is based on the requirements of the international standard ISO 15189 and ISO 19011:2002.

Course Objectives:

On successful completion of this course the participants will be able:

- To understand the philosophy of accreditation, basic Internal Auditing techniques, the role of ILAC and other relevant accreditation cooperation's;
- To comprehend the purpose and content of ISO 15189 and to interpret the requirements of this standard in the context of an assessment;

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- To identify the purpose and interaction of the management system and technical requirements;
- To assess their laboratory's current compliance to ISO 15189 and identify the gaps;
- prepare an action plan to address the gaps in their system's compliance;
- determine documentation requirements for ISO 15189;
- To plan and conduct an audit in accordance with ISO 19011, developing ability to:
 - Plan and prepare effectively for an audit,
 - Organize and manage a team during the complete auditing process,
 - Review relevant management system documents and records and determine their adequacy,
 - Gather information and objective evidence through effective interviewing, observation, sampling and recording details,
 - Analyze the information and interpret it to audit compliance with the requirements,
 - Gain sufficient knowledge and experience to identify, record and classify non-conformities and observations,
 - Reporting the audit findings and writing factual complete NCRs and ORs,
 - Conducting audit follow up activities including assessing the effectiveness of the corrective actions.

Course structure:

The course is interactive and requires class participation both as individuals and in teams. It consists of exercises, case studies, Syndicate work, presentations, practical training so that the participant gets to understand, learn and implement the skills and techniques in practical situations.

Who should attend?

This course is organized for laboratory managers, quality managers, technical managers, Pathologists, laboratory technicians, auditors and consultants or any personnel involved in the processes of assessments and accreditation of Management Systems in Medical laboratories as per ISO 15189.

Course Certificate:

Participants who attended the entire course will be awarded a Certificate of Participation approved by DAC.