NEW CHEM VISION

for Consulting & Supplies

UNDERSTANDING & IMPLEMENTATION OF ISO 15189:2012

Understanding & Implementation of Medical Laboratories Quality Management System (MLQMS) ISO 15189 : 2012

Description

Program #: *MSP-0008*

Learn everything you need to know about ISO 15189 medical laboratory accreditation. We'll take you through every stage of the certification journey on our ISO 15189 Implementation. Start with a detailed overview of the standard and its requirements. And discover how to meet these in your laboratory by implementing an ISO 15189 quality control system. Our experts will also explain auditing techniques so you can maintain accreditation by monitoring, assessing and improving performance.

Who Should Attend ?

- Those responsible for maintaining and achieving medical laboratory accreditation
- Those who manage medical laboratory support functions, testing and operations
- Technicians and laboratory staff who need to understand ISO 15189

Learning Objectives

- The requirements and scope of the ISO 15189 standard
- How to meet the requirements of ISO 15189
- The principles and application of quality control
- Understand the laboratory accreditation process
- How to monitor and continually improve quality control processes

Prerequisites

- None

Outcomes

- Identify documents and records required by ISO 15189 and regulations
- Design and apply a risk management system
- Recognize how and when to implement Individualized Quality Control Plan (IQCP)
- Describe the benefits of compliance with the ISO 15189 standard in conjunction with regulations requirements
- List the steps in the EGAC accreditation process.
- Describe the main elements of ISO 15189
- Understand the process based approach
- Understand how ISO 15189 fits into the day to day operation of a lab
- Recall the differences between registration, certification and accreditation
- Identify the safety requirements for medical laboratory according to ISO 15190 and regulations

Training Place

- In site training
- As NCV schedule

Duration

- 5 Days

Content

- Scientific Material (**Hardcopy**)
- Attendance Certificate from **NCV**

Language

- Arabic / English

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Agenda

Day 1: Introduction to Laboratory accreditation

- Course Introduction.
- Registration vs. Accreditation vs. Certification.
- Mutual Recognition Arrangements.
- EGAC Accreditation Process.

Day 2: ISO 15189:2012 Requirements

- Management requirements and 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 nonconformities
- Corrective and preventive action
- Continual improvement
- Control of records
- Evaluation and audits
- Management review
- Technical requirements
- Personnel
- Accommodation and environmental conditions
- Laboratory equipment, reagents, and consumables
- Pre-examination, examination and post-examination processes
- Ensuring quality of examination results
- Reporting and release of results
- Laboratory information management.

Day 3: EGAC Specific Requirements

- Advertising accreditation
- Reporting accredited results
- Traceability requirements for measurement equipment
- Participation in proficiency testing

Day 4: Medical laboratories — Requirements for safety

- Risk and risk management
- Risk estimation and evaluation
- Failure Mode and Effects Analysis (FMEA)
- Designing for safety
- Staffing, procedures, documentation, inspection and records
- Hazardous identification
- Reporting of incidents, injury, accidents and occupational illnesses
- Training
- Personnel responsibilities
- Clothing and personal protective equipment (PPE), including gloves, eye, face, foot and respiratory protection

Day 5: Medical laboratories — Requirements for safety

- Good housekeeping practices
- Safe work practices
- Aerosols
- Microbiological safety cabinets, chemical safety hoods and cabinets
- Chemical safety
- Radiation safety
- Fire precautions
- Emergency evacuations
- Electrical equipment
- Transport of samples
- Waste disposal