MiChem Dynamics
LEADING CHANGE

ISO 15189:2022 – MEDICAL LABORATORIES QUALITY MANAGEMENT SYSTEM TRAINING

This comprehensive training course on ISO 15189:2022 is designed to provide participants with a thorough understanding of the requirements and implementation of a Quality Management System (QMS) for medical laboratories. The course aligns with the latest version of the ISO 15189 standard, ensuring participants are equipped with up-to-date knowledge and skills to enhance the quality and reliability of laboratory services.

Upon completion of the course, participants will have the necessary tools and insights to implement and maintain a robust QMS in compliance with ISO 15189:2022, fostering a culture of continuous improvement within their medical laboratories.

THE COURSE WILL RUN OVER A PERIOD OF 3 DAYS

CERTIFICATION STATUS:

SMLTSA ACCREDITED (HPCSA APPOINTED ACCREDITOR): LABORATORY TRAINING: CPD EVENTS 2024			
TITLE	SP Certificate No	Level	CEU's
ISO 15189:2022 Medical Laboratory Quality Management System (LQMS)	MTS25/013	1	18

WHO SHOULD ATTEND THIS COURSE:

- Laboratory directors
- Laboratory / Quality managers
- Anyone involved in the implementation, maintenance, or improvement of a QMS in medical laboratories

MINIMUM ENTRY REQUIREMENTS:

- Fluency in English writing and reading skills

TUITION:

- Training material included (English)
- Certificate of attendance or competence (based on outcome of assessment) will be issued on successful completion of training.

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LEARNING OUTCOMES:

- Understand the underlying structure of ISO 15189:2022 and all elements of a Laboratory Quality Management System.
- Write their own Quality manual policies and procedures in compliance with ISO 15189:2022.
- Develop laboratory competency and prepare for external assessments through internal audits.
- Identify relevant performance monitoring approaches.
- Continually improve data quality and laboratory effectiveness.
- Understand the importance of internal auditing, corrective actions and risk assessments.

COURSE OVERVIEW:

DAY 1

- Introduction to ISO 15189:2022
- ISO 15189:2022 CLAUSE 4 General requirements
  - Impartiality
  - Confidentiality
  - Requirements regarding patients
- ISO 15189:2022 CLAUSE 5 Structural and Governance requirements
  - Legal entity
  - Laboratory director
  - Laboratory activities
  - Structure and authority
  - Objectives and policies
  - Risk management

DAY 2

- ISO 15189:2022 CLAUSE 6 Resource requirements
  - General
  - Personnel
  - Facilities and environmental conditions
  - Equipment
  - Equipment calibration and metrological traceability
  - Reagents and consumables
  - Service agreements
  - Externally provided products and services
- ISO 15189:2022 CLAUSE 7 Process requirements
  - Pre-examination processes
  - Examination processes
  - Post-examination processes
  - Nonconforming work
  - Control of data and information management
  - Continuity and emergency preparedness planning

DAY 3

- ISO 15189:2022 CLAUSE 8 Management system requirements
  - General requirements and options
  - Management system documentation
  - Control of management system documents
  - Control of records
  - Actions to address risks and opportunities
  - Improvement
  - Corrective action
  - Evaluations
  - Management reviews
- Test (Assessment)

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