MTBM

MS ISO 15189:2022 UNDERSTANDING & IMPLEMENTING TRAINING

MTBM Group Sdn. Bhd. (1600656-M)

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Course Title: MS ISO 15189:2022 Understanding & Implementing Training

Course Validity: 2 Days

Validity: Not Applicable

HRD Corp Scheme: Claimable

INTRODUCTION

This course provides participants with a comprehensive understanding of MS ISO 15189:2022, the international standard that specifies quality and competence requirements for medical laboratories. It covers both management system and technical requirements, focusing on implementing processes that support reliable clinical testing, patient safety, continuous improvement, and laboratory competence. Participants will learn how to interpret the revised 2022 structure, establish documentation, manage risks, ensure metrological traceability, and comply with accreditation expectations.

OBJECTIVE(S):

- Understand the structure and intent of MS ISO 15189:2022.
- Learn the standard's quality management and technical competence requirements.
- Understand laboratory processes related to pre-analytical, analytical, and post-analytical phases.
- Learn documentation, risk management, equipment, personnel competence, and quality assurance requirements.
- Strengthen implementation competency for accreditation readiness.

TARGET GROUP(S):

- Medical Laboratory Managers & Supervisors
- Medical Laboratory Technologists & Analysts
- Pathologists, Clinical Scientists & QA Personnel
- Internal Auditors
- Anyone involved in medical laboratory quality systems

ENTRY REQUIREMENT(S):

- Able to read, write, and communicate in Malay/English
- Basic understanding of medical laboratory practices

TOPIC(S):

1. Introduction to MS ISO 15189:2022
2. Context of the Medical Laboratory & Leadership Responsibilities
3. Risk Management, Impartiality & Confidentiality
4. Documentation, Records & Management System Requirements
5. Personnel Competence, Training & Authorization
6. Laboratory Equipment, Reagents, Consumables & Metrological Traceability
7. Pre-Analytical Processes (Sample Collection, Transport, Identification)
8. Analytical Processes (Validation, Verification, Measurement Procedures)
9. Post-Analytical Processes (Reporting, Interpretation, Storage)
10. Quality Assurance, Internal Audits & Continual Improvement
11. Nonconformities, Corrective Actions & Quality Indicators
12. Accreditation Readiness & Implementation Strategies

LIST OF REFERENCE BOOK(S):

- MS ISO 15189:2022 Standard
- ISO 15190 (Safety in Laboratories)
- ISO/IEC 17025 (Reference for Metrological Concepts)
- Relevant Clinical & Laboratory Standards (e.g., CLSI)

LIST OF TEACHING AID(S):

- LCD projector
- Computer
- Whiteboard with accessories

METHODOLOGY(S):

- Lecture
- Group discussions
- Case studies
- Practical implementation workshops

TRAINING SCHEDULE

Day 1

Time	Activity / Topic
8:30 am – 9:00 am	Registration and Introduction
9:00 am – 9:45 am	Topic 1: Overview of MS ISO 15189:2022
9:45 am – 10:30 am	Topic 2: Laboratory Context, Leadership & Responsibilities
10:30 am – 10:45 am	**Morning Tea Break**
10:45 am – 11:30 am	Topic 3: Risk Management, Impartiality & Confidentiality
11:30 am – 12:30 pm	Topic 4: Documentation & Management System Requirements
12:30 pm – 1:30 pm	**Lunch Break**
1:30 pm – 2:30 pm	Topic 5: Personnel Competence & Authorization
2:30 pm – 3:30 pm	Topic 6: Equipment, Reagents & Metrological Traceability
3:30 pm – 3:45 pm	**Afternoon Tea Break**
3:45 pm – 5:00 pm	Workshop: Mapping Laboratory Processes (Pre-Analytical to Post-Analytical)

TRAINING SCHEDULE

Day 2

Time	Activity / Topic
8:30 am – 9:00 am	Recap of Day 1
9:00 am – 9:45 am	Topic 7: Pre-Analytical Requirements (Sample Handling & Management)
9:45 am – 10:30 am	Topic 8: Analytical Requirements (Method Validation/Verification)
10:30 am – 10:45 am	**Morning Tea Break**
10:45 am – 11:30 am	Topic 9: Post-Analytical Requirements (Reports & Interpretations)
11:30 am – 12:30 pm	Topic 10: Quality Assurance & Internal Quality Control
12:30 pm – 1:30 pm	**Lunch Break**
1:30 pm – 2:30 pm	Topic 11: Nonconformities, Corrective Action & Quality Indicators
2:30 pm – 3:30 pm	Topic 12: Internal Audit, Continual Improvement & Management Review
3:30 pm – 3:45 pm	**Afternoon Tea Break**
3:45 pm – 5:00 pm	Workshop: Implementation Planning & Accreditation Readiness Checklist