MTBM

MS ISO 15189:2022 INTERNAL AUDITING TRAINING

REGISTERED HRD CORP TRAINING PROVIDER

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MTBM Group Sdn. Bhd. (1600656-M)
Level 8, MCT Tower, Sky Park, One City, Jalan USJ 25/1, 47650 Subang Jaya, Selangor
+603 8022 8330 +603 8022 8201 info@mtbmgroup.com mtbmgroup.com

Course Title: MS ISO 15189:2022 Internal Auditing Training

Course Validity: 2 Days

Validity: Not Applicable

HRD Corp Scheme: Claimable

INTRODUCTION

This training equips participants with the competencies required to conduct internal audits in accordance with MS ISO 15189:2022 for medical laboratories. It covers quality management requirements, technical competence requirements, pre-analytical, analytical, and post-analytical processes, as well as auditing methods aligned with ISO 19011. Participants will learn to prepare audit plans, perform effective audit interviews, identify nonconformities, evaluate corrective actions, and support laboratories in maintaining accreditation-level compliance.

OBJECTIVE(S):

- Understand MS ISO 15189:2022 requirements from an internal auditor's perspective.
- Learn how to plan, conduct, report, and close internal audits effectively.
- Strengthen skills in evidence gathering, interviewing, observation, and audit sampling.
- Learn how to audit critical medical laboratory processes (pre-analytical, analytical, post-analytical).
- Identify nonconformities and evaluate corrective actions using root-cause methodologies.
- Strengthen readiness for accreditation and continual improvement.

TARGET GROUP(S):

- Medical Laboratory Technologists
- Medical Laboratory Managers & Supervisors
- Pathologists & Clinical Scientists
- QA/QC & Compliance Personnel
- Internal Auditors
- Anyone involved in quality or accreditation activities in medical laboratories

ENTRY REQUIREMENT(S):

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

TOPIC(S):

1. Overview of MS ISO 15189:2022 Requirements
2. Introduction to ISO 19011 Auditing Principles
3. Audit Planning, Programme & Checklist Development
4. Auditing Management System Requirements
5. Auditing Personnel Competence & Training
6. Auditing Equipment, Reagents & Metrological Traceability
7. Auditing Pre-Analytical Processes
8. Auditing Analytical Processes
9. Auditing Post-Analytical Processes
10. Identifying Nonconformities & Writing Audit Findings
11. Corrective Actions & Root Cause Analysis
12. Internal Audit Simulation & Reporting

LIST OF REFERENCE BOOK(S):

- MS ISO 15189:2022 Standard
- ISO 19011:2018 Guidelines for Auditing
- CLSI Guidelines (as supporting references)

LIST OF TEACHING AID(S):

- LCD projector
- Computer
- Whiteboard with accessories

METHODOLOGY(S):

- Lecture
- Group discussions
- Case studies
- Audit simulation workshop

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 Requirements
9:45 am – 10:30 am	Topic 2: ISO 19011 Auditing Principles & Auditor Competence
10:30 am – 10:45 am	**Morning Tea Break**
10:45 am – 11:30 am	Topic 3: Understanding Requirements for Audit Purposes
11:30 am – 12:30 pm	Topic 4: Audit Planning, Programme & Checklists
12:30 pm – 1:30 pm	**Lunch Break**
1:30 pm – 2:30 pm	Topic 5: Auditing Management System Requirements
2:30 pm – 3:30 pm	Topic 6: Auditing Personnel & Equipment Requirements
3:30 pm – 3:45 pm	**Afternoon Tea Break**
3:45 pm – 5:00 pm	Workshop: Developing Internal Audit Checklists

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: Auditing Pre-Analytical Processes
9:45 am – 10:30 am	Topic 8: Auditing Analytical Processes
10:30 am – 10:45 am	**Morning Tea Break**
10:45 am – 11:30 am	Topic 9: Auditing Post-Analytical Processes
11:30 am – 12:30 pm	Topic 10: Identifying Nonconformities & Audit Report Writing
12:30 pm – 1:30 pm	**Lunch Break**
1:30 pm – 2:30 pm	Topic 11: Corrective Action, Root Cause Analysis & Effectiveness
2:30 pm – 3:30 pm	Topic 12: Internal Audit Simulation & Evidence Gathering
3:30 pm – 3:45 pm	**Afternoon Tea Break**
3:45 pm – 5:00 pm	Final Audit Simulation, Reporting & Feedback