MTBM

ISO 13485:2016 INTERNAL AUDITING TRAINING

MTBM Group Sdn. Bhd. (1600656-M)

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Course Title: ISO 13485:2016 Internal Auditing Training

Course Validity: 2 Days

Validity: Not Applicable

HRD Corp Scheme: Claimable

INTRODUCTION

This course equips participants with the knowledge and skills required to conduct effective internal audits on a Quality Management System (QMS) based on ISO 13485:2016. Participants will understand the audit principles from ISO 19011, learn how to evaluate conformity of medical device processes, identify nonconformities, gather objective evidence, and verify regulatory compliance. Practical workshops and simulations help participants strengthen auditing competence and prepare for certification or regulatory audits.

OBJECTIVE(S):

- Understand ISO 13485:2016 requirements from an internal auditor's perspective.
- Learn to plan, conduct, report, and follow-up internal audits effectively.
- Strengthen skills in interviewing, audit sampling, documentation review & evidence collection.
- Learn to identify nonconformities and verify corrective action effectiveness.
- Build competency aligned with ISO 19011:2018 auditing guidelines.
- Support organizations in maintaining ISO 13485 certification and regulatory compliance.

TARGET GROUP(S):

- Internal Auditors
- QA/QC Managers & Executives
- Regulatory Affairs Personnel
- Production, Engineering & Medical Device Personnel
- Anyone involved in audit activities within medical device QMS

ENTRY REQUIREMENT(S):

- Able to read, write, and communicate in Malay/English
- Basic understanding of quality management or medical device operations

TOPIC(S):

1. Introduction to ISO 13485:2016 Requirements
2. ISO 19011:2018 Auditing Principles & Competence
3. Internal Audit Programme & Planning
4. Preparing Audit Checklists
5. Conducting the Audit: Interviewing, Observing & Sampling
6. Auditing Design & Development
7. Auditing Purchasing, Production & Process Controls
8. Auditing Risk Management (ISO 14971)
9. Auditing Nonconformity, CAPA & Complaint Handling
10. Writing Audit Findings & Objective Evidence
11. Corrective Actions & Verification of Effectiveness
12. Internal Audit Simulation & Reporting

LIST OF REFERENCE BOOK(S):

- ISO 13485:2016 Standard
- ISO 19011:2018 Auditing Guidelines
- ISO 14971:2019 Risk Management Standard

LIST OF TEACHING AID(S):

- LCD projector
- Computer
- Whiteboard with accessories

METHODOLOGY(S):

- Lecture
- Group discussions
- Case studies
- Internal audit simulation workshop

TRAINING SCHEDULE

Day 1

Time	Activity / Topic
8:30 am – 9:00 am	Registration & Introduction
9:00 am – 9:45 am	Topic 1: Overview of ISO 13485:2016 Requirements
9:45 am – 10:30 am	Topic 2: ISO 19011 – Auditing Principles & Competence
10:30 am – 10:45 am	Morning Tea Break
10:45 am – 11:30 am	Topic 3: Understanding QMS Requirements for Audit Purposes
11:30 am – 12:30 pm	Topic 4: Audit Programme, Planning & Checklists
12:30 pm – 1:30 pm	**Lunch Break**
1:30 pm – 2:30 pm	Topic 5: Auditing Design & Development Processes
2:30 pm – 3:30 pm	Topic 6: Auditing Supplier, Production & Process Controls
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 Risk Management (ISO 14971)
9:45 am – 10:30 am	Topic 8: Auditing Nonconformity, CAPA & Complaint Handling
10:30 am – 10:45 am	**Morning Tea Break**
10:45 am – 11:30 am	Topic 9: Writing Audit Findings & Objective Evidence
11:30 am – 12:30 pm	Topic 10: Root Cause Analysis & Corrective Action Effectiveness
12:30 pm – 1:30 pm	**Lunch Break**
1:30 pm – 2:30 pm	Topic 11: Conducting Closing Meetings & Audit Reporting
2:30 pm – 3:30 pm	Topic 12: Full Audit Simulation & Evidence Gathering
3:30 pm – 3:45 pm	**Afternoon Tea Break**
3:45 pm – 5:00 pm	Final Internal Audit Simulation, Assessment & Feedback