MTBM

GDPMD INTERNAL AUDITING TRAINING

REGISTERED HRD CORP TRAINING PROVIDER

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Course Title: GDPMD Internal Auditing Training

Course Validity: 2 Days

Validity: Not Applicable

HRD Corp Scheme: Claimable

INTRODUCTION

This training equips participants with the essential competencies to perform internal audits in accordance with the GDPMD (Good Distribution Practice for Medical Devices) requirements as mandated by MDA Malaysia. The program covers auditing principles, GDPMD quality management requirements, storage and distribution controls, regulatory obligations under the Medical Device Act 737 and Regulations 2012, and key operational processes within medical device distribution. Participants will learn how to prepare audit plans, evaluate compliance, identify nonconformities, gather evidence, assess risk, and report audit findings to support continuous improvement and establishment licensing.

OBJECTIVE(S):

- Understand GDPMD requirements from an internal auditor's perspective.
- Learn auditing principles and competencies based on ISO 19011.
- Strengthen skills in planning, conducting, reporting, and closing audits.
- Audit operational controls including handling, storage, transportation, and documentation.
- Identify nonconformities and evaluate corrective actions effectively.
- Support GDPMD-maintained establishments in meeting MDA licensing requirements.

TARGET GROUP(S):

- Internal Auditors
- QA/QC Personnel
- Regulatory Affairs & Compliance Officers
- Warehouse, Logistics & Supply Chain Personnel
- GDPMD Documentation Controllers
- Establishment Licensing Personnel

ENTRY REQUIREMENT(S):

- Able to read, write, and communicate in Malay/English

TOPIC(S):

1. Overview of GDPMD Requirements
2. Medical Device Act 737 & Medical Device Regulations 2012
3. ISO 19011:2018 Auditing Principles
4. Audit Programme, Planning & Risk-Based Auditing
5. GDPMD Documentation & Controlled Records
6. Auditing Storage, Environmental & Handling Controls
7. Auditing Distribution, Transportation & Delivery
8. Auditing Receiving, Inspection & Inventory Controls
9. Auditing Traceability, UDI & Product Identification
10. Auditing Complaints, Adverse Events & FSCA
11. Writing Audit Findings & Objective Evidence
12. Corrective Actions, Root Cause Analysis & Audit Follow-up

LIST OF REFERENCE BOOK(S):

- GDPMD Requirements (MDA Malaysia)
- Medical Device Act 737
- Medical Device Regulations 2012
- ISO 19011:2018 Auditing Guidelines

LIST OF TEACHING AID(S):

- LCD projector
- Computer
- Whiteboard with accessories

METHODOLOGY(S):

- Lecture
- Group discussions
- Case studies
- Practical audit simulation

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 GDPMD Requirements
9:45 am – 10:30 am	Topic 2: Medical Device Act 737 & Regulations 2012
10:30 am – 10:45 am	**Morning Tea Break**
10:45 am – 11:30 am	Topic 3: ISO 19011 Auditing Principles & Auditor Competence
11:30 am – 12:30 pm	Topic 4: Audit Programme & Planning
12:30 pm – 1:30 pm	**Lunch Break**
1:30 pm – 2:30 pm	Topic 5: Auditing GDPMD Documentation & Records
2:30 pm – 3:30 pm	Topic 6: Auditing Storage, Handling & Environmental Controls
3:30 pm – 3:45 pm	**Afternoon Tea Break**
3:45 pm – 5:00 pm	Workshop: Developing GDPMD Internal Audit Checklists

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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 Distribution, Transportation & Delivery Processes
9:45 am – 10:30 am	Topic 8: Auditing Receiving, Inspection & Inventory Controls
10:30 am – 10:45 am	**Morning Tea Break**
10:45 am – 11:30 am	Topic 9: Auditing Traceability, UDI & Product Identification
11:30 am – 12:30 pm	Topic 10: Auditing Complaints, Adverse Events & FSCA
12:30 pm – 1:30 pm	**Lunch Break**
1:30 pm – 2:30 pm	Topic 11: Writing Nonconformities & Audit Findings
2:30 pm – 3:30 pm	Topic 12: Corrective Actions, RCA & Audit Follow-Up
3:30 pm – 3:45 pm	**Afternoon Tea Break**
3:45 pm – 5:00 pm	Final Simulation: GDPMD Internal Audit & Closing Meeting