MTBM

GDPMD UNDERSTANDING & IMPLEMENTING TRAINING

MTBM Group Sdn. Bhd. (1600656-M)

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Course Title: GDPMD Understanding & Implementing Training

Course Validity: 2 Days

Validity: Not Applicable

HRD Corp Scheme: Claimable

INTRODUCTION

This training provides participants with a full understanding of Good Distribution Practice for Medical Devices (GDPMD) as required by the Medical Device Authority (MDA) of Malaysia. It explains the quality management, regulatory, and operational requirements needed to ensure the safe storage, handling, transportation, and distribution of medical devices. Participants will learn how to develop and implement GDPMD-compliant procedures, maintain controlled environments, ensure traceability, manage documentation, handle complaints and adverse events, and prepare for establishment licensing and compliance audits.

OBJECTIVE(S):

- Understand the GDPMD regulatory framework set by MDA Malaysia.
- Learn the quality management system requirements for distributors, importers, and authorized representatives.
- Understand storage, handling, delivery, and transportation controls for medical devices.
- Develop GDPMD documentation, SOPs, forms, and records.
- Learn requirements for product traceability, vigilance, complaint handling & recall.
- Strengthen competency to implement and maintain GDPMD compliance for establishment licensing.

TARGET GROUP(S):

- Medical Device Distributors & Importers
- Authorized Representatives (AR)
- Medical Device Establishment Personnel
- QA/QC & Regulatory Personnel
- Warehouse, Logistics & Supply Chain Personnel
- Anyone involved in GDPMD compliance or MDA licensing

ENTRY REQUIREMENT(S):

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

TOPIC(S):

1. Introduction to GDPMD & MDA Regulatory Framework
2. Overview of Medical Device Act 737 & Regulations
3. GDPMD Quality Management System Requirements
4. Documentation, SOPs & Record Control
5. Storage, Handling & Environmental Controls
6. Transportation & Delivery of Medical Devices
7. Receiving, Inspection & Inventory Controls
8. Traceability, UDI & Product Identification
9. Complaint Handling, Adverse Events & Field Safety Corrective Actions
10. Product Recall & CAPA Requirements
11. Internal Audit & Management Review under GDPMD
12. Establishment Licensing & Compliance Audit Preparation

LIST OF REFERENCE BOOK(S):

- GDPMD Requirements by MDA Malaysia
- Medical Device Act 737
- Medical Device Regulations 2012
- ISO 13485:2016 (as supporting reference)

LIST OF TEACHING AID(S):

- LCD projector
- Computer
- Whiteboard with accessories

METHODOLOGY(S):

- Lecture
- Group discussions
- Case studies
- Practical implementation 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: Introduction to GDPMD & Regulatory Framework
9:45 am – 10:30 am	Topic 2: Medical Device Act 737 & Key Requirements
10:30 am – 10:45 am	**Morning Tea Break**
10:45 am – 11:30 am	Topic 3: GDPMD Quality Management System
11:30 am – 12:30 pm	Topic 4: Documentation, SOPs & Record Control
12:30 pm – 1:30 pm	**Lunch Break**
1:30 pm – 2:30 pm	Topic 5: Storage, Handling & Environmental Controls
2:30 pm – 3:30 pm	Topic 6: Transportation & Delivery of Medical Devices
3:30 pm – 3:45 pm	**Afternoon Tea Break**
3:45 pm – 5:00 pm	Workshop: Developing GDPMD SOPs

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: Receiving, Inspection & Inventory Controls
9:45 am – 10:30 am	Topic 8: Traceability, UDI & Device Identification
10:30 am – 10:45 am	**Morning Tea Break**
10:45 am – 11:30 am	Topic 9: Complaint Handling & Adverse Event Reporting
11:30 am – 12:30 pm	Topic 10: Product Recall, CAPA & Field Safety Corrective Actions
12:30 pm – 1:30 pm	**Lunch Break**
1:30 pm – 2:30 pm	Topic 11: Internal Audit & Management Review Requirements
2:30 pm – 3:30 pm	Topic 12: Establishment Licensing & Compliance Audit Preparation
3:30 pm – 3:45 pm	**Afternoon Tea Break**
3:45 pm – 5:00 pm	Final Workshop: GDPMD Implementation Plan