MTBM

ISO 13485:2016 UNDERSTANDING & IMPLEMENTING TRAINING

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: ISO 13485:2016 Understanding & Implementing Training

Course Validity: 2 Days

Validity: Not Applicable

HRD Corp Scheme: Claimable

INTRODUCTION

This course provides participants with a comprehensive understanding of ISO 13485:2016, the international standard for Quality Management Systems (QMS) for medical devices. The training covers regulatory alignment, risk-based approaches, lifecycle-based controls, documentation, production and post-production activities, and conformity with global medical device requirements. Participants will learn how to implement and maintain an ISO 13485-compliant QMS to support product quality, safety, and regulatory compliance within medical device organizations.

OBJECTIVE(S):

- Understand the structure, purpose, and regulatory alignment of ISO 13485:2016.
- Learn QMS requirements specific to medical device design, production, installation, and servicing.
- Understand risk-based processes and regulatory documentation requirements.
- Learn how to establish documentation, procedures, and controls to support compliance.
- Strengthen implementation competency for certification readiness.

TARGET GROUP(S):

- Medical Device Manufacturers
- QA/QC Managers & Executives
- Regulatory Affairs Personnel
- Production & Engineering Personnel
- Internal Auditors
- Anyone involved in medical device quality management or certification

ENTRY REQUIREMENT(S):

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

TOPIC(S):

1. Introduction to ISO 13485:2016
2. Regulatory Requirements for Medical Devices
3. QMS Framework & Documentation Requirements
4. Management Responsibility & Planning
5. Risk Management & Control of Contamination
6. Product Realization Requirements
7. Design & Development Process
8. Purchasing & Supplier Management
9. Production & Process Controls
10. Monitoring, Measurement & Data Analysis
11. Handling Complaints, Nonconformities & CAPA
12. Maintaining Certification & Continual Improvement

LIST OF REFERENCE BOOK(S):

- ISO 13485:2016 Standard
- ISO 14971:2019 (Medical Device Risk Management)
- Medical Device Regulatory Guidelines (e.g., EU MDR, FDA CFR 820)

LIST OF TEACHING AID(S):

- LCD projector
- Computer
- Whiteboard with accessories

METHODOLOGY(S):

- Lecture
- Group discussions
- Case studies
- Implementation workshop

MTBM

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 ISO 13485:2016
9:45 am – 10:30 am	Topic 2: Regulatory Requirements & Alignment
10:30 am – 10:45 am	**Morning Tea Break**
10:45 am – 11:30 am	Topic 3: QMS Framework & Documentation
11:30 am – 12:30 pm	Topic 4: Management Responsibility & Resource Planning
12:30 pm – 1:30 pm	**Lunch Break**
1:30 pm – 2:30 pm	Topic 5: Risk Management & Contamination Control
2:30 pm – 3:30 pm	Topic 6: Product Realization & Lifecycle Requirements
3:30 pm – 3:45 pm	**Afternoon Tea Break**
3:45 pm – 5:00 pm	Workshop: Mapping Medical Device QMS Processes

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: Design & Development Requirements
9:45 am – 10:30 am	Topic 8: Supplier Management & Purchasing Controls
10:30 am – 10:45 am	**Morning Tea Break**
10:45 am – 11:30 am	Topic 9: Production & Process Controls
11:30 am – 12:30 pm	Topic 10: Monitoring, Measurement & Data Analysis
12:30 pm – 1:30 pm	**Lunch Break**
1:30 pm – 2:30 pm	Topic 11: Complaints, NC, CAPA & Vigilance Requirements
2:30 pm – 3:30 pm	Topic 12: Certification, Maintenance & Continual Improvement
3:30 pm – 3:45 pm	**Afternoon Tea Break**
3:45 pm – 5:00 pm	Final Workshop: Implementation Planning & Q&A