MTBM

ISO 13485:2016 DOCUMENTING 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 Documenting Training

Course Validity: 2 Days

Validity: Not Applicable

HRD Corp Scheme: Claimable

INTRODUCTION

This course provides participants with a comprehensive understanding of how to develop, control and maintain documentation required by ISO 13485:2016 for medical device organizations. The training focuses on documentation architecture, mandatory procedures, controlled forms, records, risk-based documentation, technical file requirements, design and development documentation, production documentation, and device-specific regulatory expectations. Participants will learn how to structure a compliant documentation system, write effective procedures, manage revisions, and ensure traceability throughout the medical device lifecycle.

OBJECTIVE(S):

- Understand the documentation and record requirements of ISO 13485:2016.
- Learn how to structure a complete documentation hierarchy (manual → procedures → work instructions → forms).
- Develop process-based documentation aligned with medical device regulatory requirements.
- Learn documentation for design control, risk management, production, validation, and post-market activities.
- Gain competency in document control, record retention, review, approval & revision processes.
- Strengthen readiness for certification and global medical device regulatory compliance.

TARGET GROUP(S):

- QA/QC Managers & Executives
- Regulatory Affairs Personnel
- Medical Device Documentation Controllers
- Production & Engineering Personnel
- Internal Auditors
- Anyone involved in QMS documentation and maintenance

ENTRY REQUIREMENT(S):

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

TOPIC(S):

1. Introduction to ISO 13485:2016 Documentation
2. Documentation Hierarchy (Manual, Procedures, WI, Forms, Records)
3. Regulatory Documentation Requirements (EU MDR, FDA, MDA Malaysia)
4. Documented Information & Process Mapping
5. Document Control Requirements (Approval, Versioning, Access)
6. Design & Development Documentation (Design History File, DMR, DHR)
7. Production Documentation (Validation, Process Control, Work Instructions)
8. Risk Management Documentation (ISO 14971 Integration)
9. Technical File & Regulatory Submissions Documentation
10. Record Management, Traceability & Retention Requirements
11. Writing Effective Procedures (Medical Device Context)
12. Documentation Workshops & Case Studies

LIST OF REFERENCE BOOK(S):

- ISO 13485:2016 Standard
- ISO 14971:2019 Risk Management
- EU MDR Annex II & III (Technical Documentation)
- FDA 21 CFR Part 820 (Quality System Regulation)

LIST OF TEACHING AID(S):

- LCD projector
- Computer
- Whiteboard with accessories

METHODOLOGY(S):

- Lecture
- Group discussions
- Case studies
- Documentation development 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 ISO 13485 Documentation Requirements
9:45 am – 10:30 am	Topic 2: Documentation Hierarchy & Structure
10:30 am – 10:45 am	**Morning Tea Break**
10:45 am – 11:30 am	Topic 3: Process Mapping & Documented Information
11:30 am – 12:30 pm	Topic 4: Document Control (Approval, Revision, Issuance)
12:30 pm – 1:30 pm	**Lunch Break**
1:30 pm – 2:30 pm	Topic 5: Regulatory Documentation Requirements (MDR, FDA, MDA)
2:30 pm – 3:30 pm	Topic 6: Design & Development Documentation (DHF, DMR, DHR)
3:30 pm – 3:45 pm	**Afternoon Tea Break**
3:45 pm – 5:00 pm	Workshop: Creating a Process-Based Procedure

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: Production & Process Control Documentation
9:45 am – 10:30 am	Topic 8: Risk Management Documentation (ISO 14971)
10:30 am – 10:45 am	**Morning Tea Break**
10:45 am – 11:30 am	Topic 9: Technical File & Regulatory Submission Documentation
11:30 am – 12:30 pm	Topic 10: Record Control, Retention & Traceability
12:30 pm – 1:30 pm	**Lunch Break**
1:30 pm – 2:30 pm	Topic 11: Writing Effective SOPs, WIs & Forms
2:30 pm – 3:30 pm	Topic 12: Maintaining Documented Information for Certification
3:30 pm – 3:45 pm	**Afternoon Tea Break**
3:45 pm – 5:00 pm	Final Workshop: Developing a Complete Document Set