MTBM

ISO 14971 RISK MANAGEMENT FOR MEDICAL DEVICES TRAINING

MTBM Group Sdn. Bhd. (1600656-M)

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Course Title: ISO 14971 Risk Management for Medical Devices Training

Course Validity: 2 Days

Validity: Not Applicable

HRD Corp Scheme: Claimable

INTRODUCTION

This training provides participants with a complete understanding of ISO 14971:2019, the international standard for risk management in medical devices. The course covers the full lifecycle approach to identifying hazards, estimating and evaluating risks, implementing risk controls, and ensuring ongoing monitoring throughout production and post-production activities. Participants will learn how risk management integrates with ISO 13485, regulatory requirements (EU MDR, US FDA, MDA Malaysia), and medical device file documentation. Practical workshops guide participants in developing risk management files, hazard analyses, and risk control measures.

OBJECTIVE(S):

- Understand ISO 14971:2019 structure and key concepts.
- Learn how to apply risk management throughout the medical device lifecycle.
- Identify hazards, estimate risks, evaluate acceptability & apply risk controls.
- Develop risk management plans, hazard analyses, and risk evaluation matrices.
- Understand regulatory expectations (EU MDR, FDA, MDA) for risk management.
- Prepare compliant risk management files for certification and regulatory submission.

TARGET GROUP(S):

- Medical Device Manufacturers & Designers
- QA/QC Managers & Executives
- Regulatory Affairs Personnel
- R&D and Engineering Teams
- Internal Auditors
- Anyone involved in product lifecycle and safety management

ENTRY REQUIREMENT(S):

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

TOPIC(S):

1. Introduction to ISO 14971:2019
2. Key Terms: Hazard, Harm, Risk, Risk Controls
3. Risk Management Principles & Lifecycle Model
4. Risk Management Plan Development
5. Hazard Identification (Normal Use, Foreseeable Misuse, Failure Modes)
6. Risk Analysis & Risk Evaluation
7. Risk Control Measures & Residual Risk Assessment
8. Production & Post-Production Information
9. Risk Management File Requirements
10. Relationship to ISO 13485 & Regulatory Requirements
11. Risk–Benefit Analysis & Decision-Making
12. Practical Risk Analysis Workshop

LIST OF REFERENCE BOOK(S):

- ISO 14971:2019 Standard
- ISO/TR 24971:2020 Guidance on Application of ISO 14971
- ISO 13485:2016
- EU MDR Annex I Safety & Performance Requirements

LIST OF TEACHING AID(S):

- LCD projector
- Computer
- Whiteboard with accessories

METHODOLOGY(S):

- Lecture
- Group discussions
- Case studies
- Risk analysis workshop

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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 ISO 14971:2019
9:45 am – 10:30 am	Topic 2: Key Definitions & Risk Management Concepts
10:30 am – 10:45 am	**Morning Tea Break**
10:45 am – 11:30 am	Topic 3: Risk Management Principles & Lifecycle Model
11:30 am – 12:30 pm	Topic 4: Developing a Risk Management Plan
12:30 pm – 1:30 pm	**Lunch Break**
1:30 pm – 2:30 pm	Topic 5: Hazard Identification Methodologies
2:30 pm – 3:30 pm	Topic 6: Risk Analysis & Risk Evaluation Techniques
3:30 pm – 3:45 pm	**Afternoon Tea Break**
3:45 pm – 5:00 pm	Workshop: Identifying Hazards & Failure Modes

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: Risk Control Options & Implementation
9:45 am – 10:30 am	Topic 8: Residual Risk Evaluation & Risk–Benefit Analysis
10:30 am – 10:45 am	**Morning Tea Break**
10:45 am – 11:30 am	Topic 9: Production & Post-Production Information
11:30 am – 12:30 pm	Topic 10: Risk Management File Requirements
12:30 pm – 1:30 pm	**Lunch Break**
1:30 pm – 2:30 pm	Topic 11: Regulatory Requirements (EU MDR, FDA, MDA Malaysia)
2:30 pm – 3:30 pm	Topic 12: Integrating Risk Management with ISO 13485
3:30 pm – 3:45 pm	**Afternoon Tea Break**
3:45 pm – 5:00 pm	Final Workshop: Developing a Complete Risk Management File