



MS 2636 HALAL MEDICAL DEVICES TRAINING



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Course Title: MS 2636 Halal Medical Devices Training

Course Validity: 2 Days

Validity: Not Applicable

HRD Corp Scheme: Claimable

INTRODUCTION

This training provides participants with a complete understanding of MS 2636:2019 Halal Medical Devices, covering Halal requirements for design, materials, manufacturing, cleaning, packaging, storage, and distribution of medical devices. Participants will learn Shariah principles, Halal risk mitigation, critical material verification, contamination control, documentation, and Halal Assurance System (HAS) as required under JAKIM and Islamic authority guidelines. The training includes practical workshops to support implementation for medical device manufacturers, suppliers, distributors, and related healthcare sectors.

OBJECTIVE(S):

- Understand key requirements of MS 2636 for Halal medical devices.
- Learn Shariah, materials, and purity requirements specific to medical devices.
- Identify Halal critical points (HCPs) in the device lifecycle.
- Strengthen implementation of Halal Assurance System (HAS) in manufacturing.
- Understand contamination control, sterility, cleaning & packaging expectations.
- Learn documentation, traceability & Halal governance requirements.
- Prepare for Halal certification, audits & compliance maintenance.

TARGET GROUP(S):

- Medical Device Manufacturers
- QA/QC & Regulatory Affairs Personnel
- Production, Packaging & Engineering Teams
- Halal Committee & Halal Executives
- R&D & Material Sourcing Personnel
- Distributors, Wholesalers & Healthcare Product Suppliers

ENTRY REQUIREMENT(S):

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

TOPIC(S):

1. Introduction to MS 2636 Halal Medical Devices
2. Shariah Principles, Halal Concepts & Contamination Controls
3. Halal Certification Requirements (JAKIM, MPPHM)
4. Halal Material Classification & Material Verification
5. Design & Development Requirements under MS 2636
6. Manufacturing Controls, Equipment, Cleaning & Purity Requirements
7. Packaging, Labeling & Storage Compliance
8. Distribution, Transportation & Halal Supply Chain Requirements
9. Documentation, Traceability & Halal Assurance System (HAS)
10. Halal Risk Assessment & HCP Identification
11. Halal Internal Audit & Nonconformity Management
12. Implementation Workshop & Certification Readiness

LIST OF REFERENCE BOOK(S):

- MS 2636:2019 Halal Medical Devices
- Manual Prosedur Pensijilan Halal Malaysia (MPPHM)
- JAKIM Halal Assurance System Guidelines
- ISO 13485 & ISO 14971 (for alignment)

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 & Introduction
9:00 am – 9:45 am	Topic 1: Introduction to MS 2636 & Halal Medical Devices
9:45 am – 10:30 am	Topic 2: Shariah Principles & Halal Concepts
10:30 am – 10:45 am	Morning Tea Break
10:45 am – 11:30 am	Topic 3: Halal Certification Requirements (JAKIM/MPPHM)
11:30 am – 12:30 pm	Topic 4: Material Classification, Raw Materials & Purity Requirements
12:30 pm – 1:30 pm	Lunch Break
1:30 pm – 2:30 pm	Topic 5: Design & Development Requirements (MS 2636 Framework)
2:30 pm – 3:30 pm	Topic 6: Manufacturing Controls, Equipment & Cleaning Requirements
3:30 pm – 3:45 pm	Afternoon Tea Break
3:45 pm – 5:00 pm	Workshop 1: Identifying Halal-Critical Materials

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: Packaging, Labeling & Sterility Considerations
9:45 am – 10:30 am	Topic 8: Storage, Handling & Halal Supply Chain Requirements
10:30 am – 10:45 am	Morning Tea Break
10:45 am – 11:30 am	Topic 9: Documentation, Traceability & HAS Requirements
11:30 am – 12:30 pm	Topic 10: Halal Risk Assessment & HCP Identification
12:30 pm – 1:30 pm	Lunch Break
1:30 pm – 2:30 pm	Topic 11: Halal Internal Audit, NCs & CAPA Requirements
2:30 pm – 3:30 pm	Topic 12: Certification Planning & Audit Readiness
3:30 pm – 3:45 pm	Afternoon Tea Break
3:45 pm – 5:00 pm	Final Workshop: Developing a Halal Medical Device Implementation Plan