Practical Implementation of Medical Device Maintenance , Testing & Commissioning: MS 2058 & MS 2739 in GDPMD and ISO 13485

MdDev
MedTech Consultancy

ONLINE Training : 4th of May 2026

SYNOPSIS

This training provides a practical, implementation-focused approach to managing medical devices across their lifecycle, with emphasis on maintenance management (MS 2058) and testing & commissioning processes (MS 2739). It is designed to help organisations translate requirements into effective operational practices, ensuring that maintenance and commissioning activities are carried out consistently and safely.

The programme bridges the gap between written procedures and actual implementation by providing a structured approach to:

- Implementing maintenance systems based on MS 2058
- Implementing testing and commissioning processes based on MS 2739

Participants will gain hands-on knowledge, practical tools, and structured guidance to develop relevant procedures, documentation, and records. This enables organisations to enhance device performance, operational efficiency, and compliance with applicable standards, while strengthening overall audit readiness

WHAT YOU'LL LEARN

- Implement MS 2058 maintenance systems
- Set up MS 2739 commissioning procedures
- Build practical SOPs, workflows & documentation
- Produce audit-ready SOPs and records

WHY JOIN THIS TRAINING

- Hands-on, practical approach
- Aligned with MS 2058 & MS 2739
- Step-by-step templates you can use immediately
- Real case studies from industry audits

TARGET PARTICIPANTS

- Biomedical /Clinical Engineers,
- BEM Service Provider
- Medical Device Manufacturers
- Medical Device AR,Distributors & Importers
- Quality Assurance & Regulatory Affairs Personnel

Training Fee Structure

- **Early Bird Rate: RM 800.00 per participant (available from April 24, 2026, to April 28, 2026)**
- **Standard Rate: RM 900.00 (starting April 29, 2026)**

SPEAKER

DR IR SASIKALA DEVI A/P THANGAVELU

IIr. Dr. Sasikala Devi is a senior medical device regulatory consultant, Professional Biomedical Engineer, and HRDF-certified trainer with over 28 years of experience in the medical device industry.

She previously served as the Director of Policy, Code and Standards at the Medical Device Authority (MDA), Ministry of Health Malaysia and also has been engaged as a Consultant to the World Health Organization (WHO), contributing to regulatory oversight and the development of international technical guidelines.

Dr. Sasikala is actively involved in international and national standardisation work, serving as the Convenor of ISO/TC 210/WG 7 and a member of NSC 18 / TC 10 under the Department of Standards Malaysia (DSM).

SCAN HERE TO REGISTER :

FOR FURTHER ENQUIRIES

Kindly reach us at :
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TRAINING CERTIFICATE IS AVAILABLE

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TRAINING ITINERARY

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Module 1:	**Standards & Operational Framework** • Overview of MS 2058 & MS 2739 • Overview of GDPMD requirements (focus on Clause 28) • Introduction to ISO 13485 (Clause 7 & Clause 8 – brief) • Roles and responsibilities of establishments

Module 2	**Implementing Maintenance System (MS 2058)**
	• Preventive and corrective maintenance
	• Risk-based maintenance planning
	• Developing maintenance SOPs
	• Equipment performance monitoring (KPIs)
	• Maintenance documentation:
	  ◦ Maintenance reports
	  ◦ Maintenance logs

Module 3:	**Implementing Testing & Commissioning (MS 2739)** • Installation procedure development • Acceptance testing requirements • Functional and safety verification • Commissioning documentation and sign-off • Handover requirements
Module 4:	**GDPMD Clause 28 Implementation & Traceability** • Control of installation and maintenance activities • Personnel competency requirements • Documentation and record retention • Maintenance traceability and accountability • Integration with operational processes
Module 5:	**Monitoring, CAPA & Audit Readiness** • Monitoring maintenance effectiveness (basic KPI tracking) • Complaint handling related to maintenance • CAPA implementation (root cause & corrective action) • Case studies and common audit findings

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