

Good Distribution Practice For Medical Devices (GDPMD) Awareness And Internal Audit Training

100% HRDC
CLAIMABLE

HYBRID TRAINING

29 & 30 Oct 2026 (Thu & Fri)

Remote Online Training (Zoom) &
Dorsett Grand Subang Hotel,
Selangor (Physical)

**** Choose either Zoom OR Physical Session**

OUR SOLUTIONS

- This course can be run in-company around the world
- We can tailor the content to focus on your requirements.
- This approach makes perfect sense for groups of 4+ delegates, enhancing cost effectiveness as well as team bonding.
- Classroom accompanied by Lectures, Experience Sharing, Role-plays, Interactive Group Activities, Experiences, Simulation Activities and Feedback
- Delegate manuals and certificates of Attendance will be provided

**14 hours ZOOM & PHYSICAL
Program**

OBJECTIVES

Malaysia imposes the Medical Device Regulation 2012 for medical devices industry and thus the related organisations are required to set up and comply with the regulation.

- In this training, the participants will be guided with the explanation and discussion on each requirements of GDPMD so that they are able to understand and implement the regulation effectively. This training is to guide the participants with the knowledge and skill to establish the GDPMD regulatory system in their organization.

FOR WHOM

This course is designed for individuals in the medical device local authorized representative, distributor and importer who are involved in the development and maintenance of a quality management system based on GDPMD
No prerequisites are necessary for this course.

How you will be benefit

- Champion GDPMD benefits
- Fulfill GDPMD standard / regulatory requirements.
- Give participants an awareness of GDPMD and its alignment to respective Quality System Regulation
- Assist participants in the relationship between QMS and registration
- Identify what GDPMD and also what is regulatory expectation

Register 3 Pax, Free 1 Seat

COURSE CONTENT

Day 1

- **Session 1: Introduction of Medical Device and GDPMD (Good Distribution Practices for Medical Device)**
 - As a start, participants will be presented with the fundamentals, brief concepts, purposes, set up, certification and audit flow as well as the application of the regulation in Medical Device industry nationally and internationally.
- **Session 2: GDPMD: Part 1 and 2**
 - Participants will be guided with the explanation of the requirements in the Part 1 (Preliminary) and Part 2 (Regulatory Compliance System).
- **Session 3: GDPMD: Part 3 and 4**
 - Participants will be guided with the explanation of the requirements in the Part 3 (Establishment Responsibilities) and Part 4 (Resource Management).
- **Session 4: GDPMD: Part 5 and Part 6**
 - Participants will be guided with the explanation of the requirements in the Part 5 (Supply Chain and Device Specific) and Part 6 (Surveillance and Vigilance).
- **Q&A**
- **End of the Day 1 session**

Day 2

- **Session 5: Internal Audit Based on GDPMD**
 - Initiating an audit
 - Document Review
 - Audit Plan
 - Audit Work Documents
 - Opening Meeting
 - Execute the audit
 - Documenting Non-conformities
 - Closing Meeting
 - Audit Report
 - Audit Follow-up

OUR CONSULTANT

MS. KHAIRUN

Qualified auditor for:

- ISO 9001:2015
- ISO 13485:2016
- GDPMD
- MDSAP
- Registered auditor with Malaysia Medical Device Authority (MDA)
- Registered audit for social audit (SEDEX) and RBA
- HRDF Certified Trainer

Her latest career: **Management System Auditor** with a German largest certification body.

Audited the following type of **medical industries** like:
manufacturing of rubber:

11	1	1	1	1
Glove companies	Dental dam	Rehabilitation accessories company	breathing bag company	protective equipment company

- 1 manufacturing of suture company,
- 1 manufacturing of **cardiovascular graph** company
- 3 assembly company
- 4 injection moulding company
- distributors
- 10 authorized representative company
- 1 brand owner of the medical device.]

Besides that, she also audited for non medical industries like

- 1 roofing company
- 1 vinyl coated floor company
- 1 construction company
- 1 project management company
- 3 assembly electronic companies in Japan, Singapore and Thailand.
- 1 distribution company

Audited manday for QMS: 400 manday and counting

On top of the QMS audit, she is also auditing for social auditing against SMETA requirement.

- 2 gloves company in Malaysia (member of SEDEX)
- 1 shoe lace company in Indonesia (member of SEDEX)
- 1 pallet company in Malaysia (gap analysis)
- 1 Polyolefin (PO) foams in Malaysia (gap analysis)