PIHAK BERKUASA PERANTI PERUBATAN
Medical Device Authority
KEMENTERIAN KESIHATAN MALAYSIA
Ministry of Health Malaysia
Aras 5, Menara Prisma,
Jalan Persiaran Perdana, Presint 3,
62675 Putrajaya, Malaysia

MEDICAL DEVICE AUTHORITY TRAINING 2017

OBJECTIVE

To provide industrial support through competent regulatory training to industry, user and other authority for achieving requirements of Medical Device Act (Act 737) and Medical Device Regulation 2012 (MDR 2012).

TARGET GROUP

Medical Device Industry (Manufacturer, Authorized Representative, Distributor, Importer, Service Provider), Higher Education Institute, Competent Authority, Training Provider, Medical Device Consultant, Individual who are interested with Medical Device Industry.

TRAINING MODULE & FEE

We provide 12 Packages for Local and Overseas target group that can give the benefit to medical device Industry players. The fee applied differently based on the packages that you select. Please refer every package that we provide.

CONTACT

If you interested please email to trainingpackage@mdb.gov.my. We here to help you.

TRAINING PACKAGE

PACKAGE 1, **Development of Good Distribution Practice For Medical Devices (GDPMD)** **1.5 Day**	**Choose your module** RM 848 for each module per participant RM 1590 for this package per participant **(A)**	**Be spoke** RM 4452 for this package **(B)**
What will you get? (Module 1) Explanation of clauses in GDPMD & What a procedures need to developed in GDPMD (Module 2) Internal Auditor training in GDPMD &Explanation every Guidance document relevant with GDPMD (Module 3) Explanation and training on MS 2058	☐ ☐ ☐	☐
PACKAGE 2 **Application and renewal Of Establishment Licence** **1 Day**	**Choose your module** RM 371 for each module per participant RM 848 for this package per participant **(A)**	**Be spoke** RM 2968 for this package **(B)**
What will you get? (Module 1) Requirement of Establishment license & Knowing the Medc@st system (Module 2) Document needs to be submitted for application and for renewal & Hand on application of Establishment license (Module 3) Change ownership	☐ ☐ ☐	☐
PACKAGE 3 **Product Registration (Medc@st)**	**Choose your module** RM 371 for each module and participant	**Be spoke** RM 2968 for this package **(B)**

1 Day	RM 530 for this package per participant **(A)**	
What will you get? (Module 1) Requirement for product registration (Module 2) hands-on Product registration	 ☐ ☐	☐
PACKAGE 4 **Notification (Order:- Exemption from registration of medical device)** **3 Days**	**Choose your module** RM 848 for each module per participant RM2544 for this package per participant **(A)**	**Be spoke** RM 4452 for this package **(B)**
(Module 1) Explanation of clinical investigation or performance evaluation of medical device and documentations. (Module 2) Explanation of custom-made medical device and documentations. (Module 3) Explanation of demonstration medical device for marketing purpose and Explanation medical device for education and it documents. (Module 4) Explanation of special access medical device and documentations.	☐ ☐ ☐ ☐	☒
PACKAGE 5 **Full package of Medical Device Registration** **Be Spoke only**		**Be spoke** RM 5300 for this package **(B)**
What will you get? 1. Learning how to classify of medical device		☐

2. How to determine and checking your Medical Device Class (Class A, B, C, D) 3. General Medical Device Grouping 4. IVD Grouping 5. CSDT preparation and its elements in CSDT & Declaration of Conformity (DoC) 6. Explanation of Circular No. 2/2014 Conformity Assessment procedure for medical device approved by recognised countries (GHTF), and requirement for verification process 7. Checking of verification document (QMS, PMS, Technical Documentation (CSDT), DoC) 8. Requirement for Conformity Assessment process		
PACKAGE 6 **Change Notification For Registered Medical Device** **1.5 Days**	**Choose your module** RM 848 for each module per participant RM1590 for this package per participant **(A)**	**Be spoke** RM 3392 for this package **(B)**
(Module1) Explanation Guidance document for change notification and documentation (Module 2) Checking on change notification of medical device documentation	☐ ☐	☒
PACKAGE 7 **COA & Labelling** **1.5 Days**	**Choose your module** RM 848 for each module and participant RM1908 for this package per participant	**Be spoke** RM 2968 for this package

(Module 1) Explanation of Code of Advertisement (Module 2) Checking of advertisement documentation	☐ ☐	☐
Module 1) Explanation of Guidance document on requirement for labelling of Medical Devices (Module 2) Checking on Labelling document and requirement	☐ ☐	☐ ☐
PACKAGE 8 **Post-Market Activity** **2 Days**	**Choose your module** RM 848 for each module and participant RM 1590 for this package per participant **(A)**	**Be spoke** RM 4982 for this package **(B)**
What Will you Get? (Module 1) Post-Market Surveillance and Vigilance requirement (Module 2) Medical Device complaint Handling with documentation (Module 3) Mandatory problem reporting with documentation (Module 4) Field Corrective Action with documentation (Module 5) Recall activity with documentation	☐ ☐ ☐ ☐ ☐	☐
PACKAGE 9 **CAB Registration** **1.5 Days**	**Choose your module** RM 1272 for each module and participant	**Be spoke** RM 4452 for this package **(B)**

	RM 2120 for this package per participant **(A)**	
(Module 1) Requirement on Registration of CAB including documentation requirements (Module 2) Explanation of Fourth Schedule of MDR 2012	☐ ☐	☐
PACKAGE 10 **1 Day** **Private Healthcare Institutions**	RM 2120 **For This Package**	
(Module 1) Requirement on Regulatory Requirement for Private Healthcare Institutions Under MDA 2012 (Act 737) (Module 2) Requirement on Technical Competency for Technical Personnel		
PACKAGE 11 **1 Day** **Higher Education Institutions only**	**RM212 each module**	
(Module 1) Medical Device Act 2012 (Act 737) and Medical Device Authority Act 2012 (Act 738) (Module 2) Medical Device Regulation 2012 and other medical device regulation (GHTF Country) (Module 3) Medical Device class, grouping and Medical device life cycle	☐ ☐ ☐	
PACKAGE 12 (OVERSEAS) INDUSTRY TRAINING	**Choose your package**	**Number of Officers**

Package 1 & 3 Package 2 Package 3 & 4 Package 5 Package 6 & 7 Package 8 Package 10 Package 11	RM31,800.00☐ RM16,960.00☐ RM31,800.00☐ RM21,200.00☐ RM 31,800.00☐ RM21,200.00☐ RM21,200.00☐ RM31,800.00☐	**3 officers** **3 officers** **3 officers** **3 officers** **3 officers** **3 officers** **3 officers** **3 officers**
CAB TRAINING (MIN 3 DAYS) **Package A CONFORMITY ASSESSMENT PROCEDURES [8 HRS -1 DAY]** • Medical Device Classification • Medical Device Grouping • EPSP • CSDT • DoC • Verification • Conformity Assessment for the Purpose of Medical Device Registration **Package B: QMS [4 HRS]** • GDPMD • PMSS • MS 2058 • Conformity Assessment for QMS **Package C:** Act & Regulation 4 HRS • Act 737 • MDR 2012 • Order • Circular Letters • Guidance documents • CAB Registration Process	RM42,400.00☐ RM10,600.00 ☐ RM31,800.00 ☐	**3 officers**

Package D: Refreshments Training • Act 737 • MDR 2012 • Updates (Regulation, order, circular, guidance documents) • Case Studies (MDA expectation – report, audit finding, evaluation)	RM21,200.00 ☐	