MEDICAL DEVICE TRAINING 2017

APPLICATION FORM

Personal Information						
Title						
First Name						
Last Name						
Email						
Phone Number						
	1-2 year	5 year	>10 year	Other		
Experiences (Please tick)						
Designation						
Citizen						
Company Information						
Company Name						
Address						
Phone Number						
Email						
	Manufacturer	**AR, Distributor, Importer**	**Consultant**	**University/Higher Education**	**Private Hospital**	**Government**
Type of business						

Select your package or module

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	**Be spoke** RM 2968 for this package

	participant **(A)**	**(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)** **1 Day**	**Choose your module** RM 371 for each module and participant RM 530 for this package per participant **(A)**	**Be spoke** RM 2968 for this package **(B)**
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** RM 5300

Be Spoke only		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 MD** **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 RM 2120 for this package per participant **(A)**	**Be spoke** RM 4452 for this package **(B)**
(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**	
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☐	
CAB TRAINING (MIN 3 DAYS) (Overseas) **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	RM42,400.00☐ RM10,600.00 ☐ RM31,800.00 ☐	

Package C: Act & Regulation 4 HRS • Act 737 • MDR 2012 • Order • Circular Letters • Guidance documents • CAB Registration Process **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 ☐	

All Price inclusive of 6% GST