CAB PROFICIENCY TRAININGS

(TRAININGS SANCTIONED BY MEDICAL DEVICE AUTHORITY)

PROFICIENCY TRAINING FOR *NEW PERSONNEL* ON CONFORMITY ASSESSMENT BODY REGISTRATION UNDER THE ACT 737 (MEDICAL DEVICE LEGISLATION)

PARTICIPATION ELIGIBILITY

- Mandatory for those who have never been registered under the Act 737.
- Participants who had failed the previous training's examination.
- Personnel of the establishments, certification bodies & consultant companies, etc.

TRAINING OBJECTIVES

- To comprehend the Medical Device Act 2012 (Act 737), Medical Device Regulations 2012 (MDR 2012) and Medical Device Regulations 2019 (MDR 2019).
- To comprehend the Medical Device Gazetted Orders, Circular Letters & Guidance Documents.
- To comprehend the Conformity Assessment Procedure on QMS and PMSS (ISO 13485 & GDPMD).

TENTATIVE PROGRAM

	DAY 1
08:45	Registration
08:55	Briefing
09:00	Medical Device Regulatory Framework (Gazetted Orders, Circular Letters & Guidance Documents)
10:30	Morning Break
11:00	Medical Device Act 2012 (Act 737)
12:30	Lunch Break
14:00	Medical Device Regulations 2012 (MDR 2012)
15:30	Medical Device Regulations 2019 (MDR 2019)
16:15	CAB Registration Requirements
17:00	End of Session

	DAY 2
08:45	Registration
08:55	Briefing
09:00	Product Classification
09:30	Classification of General & *In Vitro* Diagnostic Medical Devices
10:15	Morning Break
10:30	Good Distribution Practice for Medical Device (GDPMD)
12:30	Lunch Break
14:00	Conformity Assessment on PMSS
14:30	MS 2058
16:00	Examination (40 Questions)
17:00	End of Session

REGISTRATION & FEE

Training fee per participant: RM 2,000.00

Should you have inquiries, please contact the Training Secretariats at cab.training@mda.gov.my or 03-8230 0335 / 0346 / 0361

CAB PROFICIENCY TRAININGS

(TRAININGS SANCTIONED BY MEDICAL DEVICE AUTHORITY)

PROFICIENCY TRAINING FOR *NEW PERSONNEL* ON CONFORMITY ASSESSMENT PROCEDURES ON TECHNICAL DOCUMENTATION AND VERIFICATION (FOR THE PURPOSE OF MEDICAL DEVICE REGISTRATION UNDER THE ACT 737)

PARTICIPATION ELIGIBILITY

- Mandatory for those who have never been registered under the Act 737.
- Participants who had failed the previous training's examination.
- Personnel of the establishments, certification bodies & consultant companies, etc.

TRAINING OBJECTIVES

- To comprehend the Conformity Assessment Procedure in accordance to the Third Schedule of the Medical Device Regulations 2012.
- To comprehend the Conformity Assessment Procedure by Way of Verification in accordance to Circular Letter Number 2 Year 2014.

TENTATIVE PROGRAM

	DAY 3
08:45	Registration
08:55	Briefing
09:00	Conformity Assessment Procedure (Third Schedule)
10:15	Morning Break
10:45	Conformity Assessment by Way of Verification (Including Re-Registration) & DoC
12:00	Classification of *In Vitro* Diagnostic Medical Device
12:45	Lunch Break
14:00	Classification of General Medical Device
15:00	Grouping of General Medical Device
16:00	Grouping of *In Vitro* Diagnostic Medical Device
17:00	End of Session

	DAY 4
08:45	Registration
08:55	Briefing
09:00	Clinical Investigation
10:00	Morning Break
10:30	CSDT & EPSP of *In Vitro* Diagnostic Medical Device
11:30	CSDT & EPSP of General Medical Device
12:30	Lunch Break
14:00	Case Study (Group Preparation)
14:30	Case Study (Group Presentation)
16:00	Examination (40 Questions)
17:00	End of Session

REGISTRATION & FEE

Training fee per participant: RM 2,000.00

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CAB PROFICIENCY TRAININGS

(TRAININGS SANCTIONED BY MEDICAL DEVICE AUTHORITY)

PROFICIENCY TRAINING FOR *EXISTING PERSONNEL* ON RE-REGISTRATION OF CONFORMITY ASSESSMENT BODY & PERSONNEL UNDER THE ACT 737 (COMPLIANCE TO THE CONFORMITY ASSESSMENT BODY REGISTRATION REQUIREMENTS)

PARTICIPATION ELIGIBILITY

- This refresher training is only for re-registration purpose of existing CAB & Personnel.
- Mandatory for those who have the expired or expiring Proficiency Certificate.
- Participants who had failed the previous refresher training's examination.

TRAINING OBJECTIVES

- To comprehend the Medical Device Regulatory Updates (Published Documents Collectively).
- To comprehend the Conformity Assessment Elements in accordance to the Third Schedule of the Medical Device Regulations 2012 & Circular Letter Number 2 Year 2014.

TENTATIVE PROGRAM

	DAY 1
08:45	Registration
08:55	Briefing
09:00	Medical Device Regulatory Updates
10:15	Classification of General & In Vitro Diagnostic Medical Devices
11:15	Conformity Assessment Elements (Third Schedule) + Conformity Assessment by Way of Verification (Including Re-Registration) + Declaration of Conformity
13:00	Lunch Break
14:00	Grouping of In Vitro Diagnostic Medical Device
14:30	Grouping of General Medical Device
15:00	CSDT & EPSP of *In Vitro* Diagnostic Medical Device
16:00	CSDT & EPSP of General Medical Device
17:00	End of Session

	DAY 2
08:45	Registration
08:55	Briefing
09:00	Conformity Assessment on Post-Market Surveillance System
10:30	Compliance Issues on CAB & Personnel Requirements
11:30	How to Conduct GDPMD & Expected Evidences
13:00	Lunch Break
14:00	Format & Content of the GDPMD Audit Report
15:00	Self-Study
16:00	Examination (40 Questions)
17:00	End of Training

REGISTRATION & FEE

Training fee per participant: RM 2,000.00

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