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 (1ST SESSION)

	DAY 1
08:45	Registration
08:55	Briefing
09:00	Medical Device Regulatory Framework (Gazetted Orders, Circular Letters & Guidance Documents)
10:15	Morning Break
10:30	Medical Device Act & Regulations 2012 (Act 737 & MDR 2012)
11:30	Medical Device Regulations 2019 (MDR 2019) & Related Legislations
13:00	Lunch Break
14:00	CAB Registration Requirements
15:15	Compliance Issues on CAB & Personnel Requirements
16:00	Examination
17:15	End of Session

	DAY 2
08:45	Registration
09:00	Briefing
09:15	Conformity Assessment on PMSS
09:45	Overview Requirement of GDPMD Part 1 & Part 2 GDPMD Documentation Requirement and Evidence Expected
10:45	Morning Break
11:00	Part 3 & Part 4 GDPMD Documentation Requirement and Evidence Expected
12:15	Part 5 GDPMD Documentation Requirement and Evidence Expected
12:45	Lunch Break
14:00	Part 5 GDPMD Documentation Requirement and Evidence Expected (Continue)
15:00	Part 6 GDPMD Documentation Requirement and Evidence Expected
16:00	Examination (40 Questions)
17:15	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 0352 / 0374 / 0394 / 0238

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 (2ND SESSION)

	DAY 3
08:45	Registration
08:55	Briefing
09:00	Conformity Assessment Procedure (Third Schedule)
	Conformity Assessment by Way of Verification (Including Re-Registration) & DoC
10:30	Morning Break
10:45	Product & Medical Device Classification of General & IVD Medical Devices
11:30	Risk Classification & Grouping of General Medical Devices
	Illustrative Examples of Risk Classification & Grouping of General Medical Devices
13:00	Lunch Break
14:00	Risk Classification & Grouping of IVD Medical Devices
	Illustrative Examples of Risk Classification & Grouping of IVD Medical Devices
15:30	CSDT & EPSP of IVD Medical Device
17:00	End of Session

	DAY 4
08:45	Registration
08:55	Briefing
09:00	Clinical Evidence in General Medical Devices
10:00	Morning Break
10:15	Clinical Evidence in IVD Medical Devices
11:15	Case Study (Group Preparation)
12:45	Lunch Break
14:00	Case Study (Group Presentation)
15:45	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 CAB 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	Classification of General Medical Devices
09:15	Classification of IVD Medical Devices
09:30	Grouping of General Medical Devices
09:45	Grouping of IVD Medical Devices
10:00	Morning Break
10:15	EPSP of General Medical Device
10:45	EPSP of IVD Medical Device
11:15	Conformity Assessment Elements (Third Schedule)
	Conformity Assessment by Way of Verification (Including Re-Registration)
	Declaration of Conformity
12:00	Case Study (Group Preparation)
13:00	Lunch Break
14:00	Case Study (Group Presentation)
16:30	End of Session

	DAY 2
08:45	Registration
08:55	Briefing
09:00	Medical Device Regulatory Updates
10:15	Morning Break
10:30	Conformity Assessment on Post-Market Surveillance System
11:15	Compliance Issues on CAB & Personnel Requirements
12:15	Format & Content of the GDPMD Audit Report
13:00	Lunch Break
14:00	Format & Content of the GDPMD Audit Report (Continue)
15:45	Tea break
16:00	Examination (40 Questions)
17:00	End of Training

REGISTRATION & FEE

Training fee per participant: RM 2,000.00

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