Capacity-Building Syllabus for Medical Device Stakeholders

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Program Background & Objectives

Program Background

- The **MDA** is mandated under the Medical Device Act 2012 (Act 737) to regulate and enforce the safety, quality, and effectiveness of medical devices in Malaysia. As the medical device landscape evolves with rapid technological advancements and increasing market demands, **regulatory capacity building** has become critical to ensure effective oversight, industry compliance, and alignment with global best practices.
- This curriculum is designed to strengthen the capabilities of **regulatory officers**, **industry stakeholders**, and **global regulatory partners** through targeted training programs, knowledge-sharing sessions, and process improvement initiatives.

Program Objectives

- **Enhance Regulatory Competence -** Equip new evaluation officers with the knowledge and skills to perform consistent, transparent, and effective regulatory assessments.
- **Strengthen Industry Compliance -** Provide participants with the latest regulatory updates, process improvements, and compliance guidance to ensure adherence to Malaysian laws and standards.
- **Promote Global Regulatory Collaboration -** Facilitate best practice sharing and foster harmonization with other regulatory authorities through the *Centre of Excellence (CoE)* platform.
- **Support MDA's Strategic Vision -** Advance MDA's goal of becoming a globally recognized medical device regulatory authority.

Target Group

- **Global Regulators** through the *Centre of Excellence (CoE)* – facilitating best practice exchange and regulatory alignment
- **Industry Stakeholders** through the *MDA-Core Program* – ensuring up-to-date compliance with current laws, regulations, and streamlined processes
- **Other interested Stakeholders**

Overview of Designed Syllabus

Syllabus tailored to participants' knowledge levels: ***beginner*** ★ ***intermediate*** ★★***, and advanced*** ★★★ *to maximize learning effectiveness and practical application.*

Module 1

Fundamental Understanding of Medical Devices & IVDs

Introduction to the definition of medical devices, product classification systems, and combination products within the Malaysian regulatory framework

Module 2

Risk Classification System & Grouping for General Medical Devices (GMD)

Overview of risk-based classification for General Medical Devices (GMD), including grouping criteria

Module 3

Risk Classification System & Grouping for In Vitro Diagnostic Medical Devices (IVD)

Overview of risk-based classification for IVD Medical Devices (IVD), including grouping criteria

Module 4

Common Submission Dossier Template (CSDT) for General Medical Devices (GMD)

- Detailed explanation of CSDT structure, content requirements, and best practices for preparing compliant submissions
- Guidance on demonstrating conformity to EPSP for medical devices

Module 5

Common Submission Dossier Template (CSDT) for In Vitro Diagnostic Medical Devices (IVD)

- Detailed explanation of CSDT structure, content requirements, and best practices for preparing compliant submissions
- Guidance on demonstrating conformity to EPSP for IVD medical devices

Module 6

Clinical Investigation of Medical Device

- Detailed explanation on Medical Device Lifecycle Development: From Prototype to Regulatory Approval.
- Detailed explanation on Good Clinical Practice (GCP) for Medical Devices: Implementing ISO 14155:2020 & Regulatory Requirements
- Preparation on Clinical Investigational Protocol (CIP) and Investigator Brochure (IB)

Other modules
under development

- Code of Advertisement
- Special Access/ Custom Made
- Change Management
- Product Specific - Medical Gas Systems or Software or AI/ML-based devices
- Clinical Evidence for Medical Devices
- Conformity Assessment for Medical Devices

Module 1: Fundamental Understanding of Medical Devices & IVDs

This module introduces the definition of medical devices, product classification systems, and combination products within the Malaysian regulatory framework. Emphasis is placed on the manufacturer's intended use as the primary determinant in defining and classifying medical devices, ensuring consistent regulatory interpretation and alignment with international practices.

Expected Outcomes

- Understand the definition of a medical device under Act 737 based on the manufacturer's intended use and in line with global definitions & terminology
- Differentiate medical devices, non-medical devices, and combination products using Malaysian regulatory criteria
- Apply regulatory guidance to classify device types, including borderline and combination products
- Utilize ASEAN harmonized and Malaysian-specific references for consistent classification decisions
- Understand the classification of Rehabilitation, Physiotherapy, and Speech Therapy devices
- Demonstrate classification competency through hands-on exercises, case studies, and scenario-based discussions.

Hours - TBC

Definition of a Medical Device (Act 737 & Global Context)

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- Explanation of the legal definition under the Malaysian Medical Device Act 2012 (Act 737) & Medical Device Regulation 2012.
- Global references: GHTF/IMDRF definitions and alignment with ASEAN guidance
- Role of the manufacturer's intended use as the decisive factor in determining whether a product qualifies as a medical device
- Importance of consistent interpretation for regulatory compliance and market access

Medical, Non-Medical, and Combination Products

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- Criteria for distinguishing between medical vs. non-medical products
- Regulatory approach for combination products (device + drug / drug + device)
- Examples of borderline challenges (cosmetic vs. therapeutic, wellness vs. clinical function)
- Practical framework for decision-making based on Malaysian regulatory guidance

Application of Regulatory Guidance for Classification

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- Step-by-step guide to using Malaysian and ASEAN documents for classification
- ASEAN harmonized principles for borderline and combination product assessment
- Comparative insights: alignment with FDA, EU MDR, and ASEAN practices

Classification of Rehabilitation, Physiotherapy, and Speech Therapy Devices

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- Reference to MDA/GD/0061: Classification of Rehabilitation, Physiotherapy and Speech Therapy Devices
- Regulatory expectations for specific device categories (rehab aids, physio equipment, speech therapy tools)
- Case illustrations of classification decisions and borderline issues

Case Studies and Hands-On Exercises

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- Hands-on exercises on classification of real-world products (medical vs. non-medical vs. combination)
- Problem-solving session on classification of rehab, physiotherapy, and speech therapy devices
- Mock submission and regulatory decision-making simulation
- Reflection & feedback: regulator expectations, pitfalls, good practices

- Guidance Documents (TBC)

Module 2: Risk Classification System & Grouping for General Medical Devices (GMD)

This module introduces the risk classification system, including the rules and factors that determine risk class within the Malaysian regulatory framework, with emphasis on how the manufacturer's intended purpose drives classification decisions and the selection of conformity assessment procedures. The module also covers the principles of device grouping and their application to streamline registration while ensuring regulatory compliance. By mastering these principles, regulators and industry stakeholders will be able to ensure accurate classification, effective grouping, robust conformity assessment, and regulatory consistency, while achieving aligning with international frameworks.

Expected Outcomes

- Understand the risk-based classification principles for General Medical Devices under Act 737 and Medical Device Regulation 2012.
- Apply the 16 classification rules to assign devices to the correct risk classes (A–D) with appropriate justification, referencing both local and international frameworks.
- Compare Malaysia's risk classification with other regulatory jurisdictions (e.g. IMDRF, EU MDR, US FDA) to identify similarities and differences.
- Interpret the requirements of the ASEAN Medical Device Directive (AMDD) and the ASEAN harmonized classification framework, ensuring consistency with regional requirements.
- Differentiate and apply the principles of device grouping (single, family, system, set) to streamline product registration.
- Demonstrate classification and grouping competency through hands-on exercises, case studies, and scenario-based discussions.

Hours - TBC

Principles of Risk-Based Classification ★

- Overview of risk-based classification principles under Act 737 & Medical Device Regulations 2012.
- Key concepts: intended use, duration of use, degree of invasiveness, local vs. systemic impact.
- Why classification is necessary: link to conformity assessment and regulatory approval.
- Importance of accurate classification for regulatory compliance and market access

Application of the 16 Classification Rules ★

- Detailed review of the 16 rules (non-invasive, invasive, active devices, special rules including software)
- Step-by-step application methodology for applying classification rules
- Using decision trees and structured justification templates
- Role of manufacturer's intended purpose in rule application

Assigning Devices into Classes A–D ★★

- Criteria for risk class determination (A, B, C, D)
- Documentation of rationale & regulator expectations
- Comparative approaches: IMDRF, EU MDR, US FDA
- ASEAN AMDD harmonized classification framework
- Regulator's perspective: common misclassifications & preventive measures

Principles & Application of Grouping ★

- Types of grouping: single device, family, system, set
- Regulatory criteria for grouping
- Benefits of grouping for efficient registration & regulatory review
- Preparing grouping documentation for submissions

Case Studies and Hands-On Exercises ★★★

- Hands-on exercises on classification of real-world devices (simple to complex)
- Problem-solving session: applying risk classification and grouping to case scenarios
- Mock submission exercise: classification & grouping dossier preparation.
- Reflection & feedback: regulator expectations, pitfalls, good practices

- Guidance Documents (TBC)

Module 3: Risk Classification System & Grouping for IVD Medical Devices (IVDs)

This module introduces the risk classification system, including the rules and factors that determine risk class within the Malaysian regulatory framework, with emphasis on how the intended purpose, public health risk, and impact of erroneous results drives classification decisions and the selection of conformity assessment procedures. The module also covers the principles of device grouping and their application to streamline registration while ensuring regulatory compliance. By mastering these principles, regulators and industry stakeholders will be able to ensure accurate classification, effective grouping, robust conformity assessment, and regulatory consistency, while achieving aligning with international frameworks.

Expected Outcomes

- Understand the risk-based classification principles for IVDs Medical Devices under Act 737 and Medical Device Regulation 2012.
- Apply the 7 classification rules to assign devices to the correct risk classes (A–D) with appropriate justification, referencing both local and international frameworks.
- Compare Malaysia's risk classification with other regulatory jurisdictions (e.g. IMDRF, EU MDR, US FDA) to identify similarities and differences.
- Interpret the requirements of the ASEAN Medical Device Directive (AMDD) and the ASEAN harmonized classification framework, ensuring consistency with regional requirements.
- Differentiate and apply the principles of device grouping (single, family, system, set, IVD cluster) to streamline product registration.
- Demonstrate classification and grouping competency through hands-on exercises, case studies, and scenario-based discussions.

Hours - TBC

Principles of Risk-Based Classification ★

- Overview of risk-based classification principles under Act 737 & Medical Device Regulations 2012.
- Key concepts: intended use, duration of use, degree of invasiveness, local vs. systemic impact.
- Why classification is necessary: link to conformity assessment and regulatory approval.
- Importance of accurate classification for regulatory compliance and market access

Application of the 16 Classification Rules ★

- Detailed review of the 7 rules
- Risk class determination factors: analyte type, intended user (professional vs. self-test), disease criticality, epidemiological impact.
- Step-by-step application methodology for applying classification rules
- Using decision trees and structured justification templates
- Role of manufacturer's intended purpose in rule application

Assigning Devices into Classes A–D ★★

- Criteria for risk class determination (A, B, C, D)
- Documentation of rationale & regulator expectations
- Comparative approaches: IMDRF, EU MDR, US FDA
- ASEAN AMDD harmonized classification framework
- Regulator's perspective: common misclassifications & preventive measures

Principles & Application of Grouping ★

- Types of grouping: single device, family, system, set, IVD cluster
- Regulatory criteria for grouping
- Benefits of grouping for efficient registration & regulatory review
- Preparing grouping documentation for submissions

Case Studies and Hands-On Exercises ★★★

- Hands-on exercises on classification of real-world devices (e.g., self-test vs. professional-use kits)
- Problem-solving session: applying risk classification and grouping to IVD case scenarios
- Mock submission exercise: classification & grouping dossier preparation.
- Reflection & feedback: regulator expectations, pitfalls, good practices

- Guidance Documents (TBC)

Module 4: Common Submission Dossier Template (CSDT) for General Medical Devices (GMD)

This module provides participants with a structured understanding of the CSDT requirements for General Medical Devices (GMD), covering documentation elements, conformity to Essential Principles of Safety and Performance (EPSP), and technical evidence expectations. Practical exercises and case studies will strengthen skills in preparing and evaluating CSDT submissions from both regulator and industry perspectives.

Expected Outcomes

- Understand the structure and content requirements of the CSDT for General Medical Devices under Act 737 and Medical Device Regulations 2012.
- Apply the principles to prepare, compile, and assess CSDT dossiers in alignment with Malaysian requirements and ASEAN AMDD provisions.
- Develop practical skills in mapping evidence to EPSP, reviewing verification & validation data, assessing clinical evidence, and evaluating risk management documentation.
- Identify compliance gaps in submissions, including labelling, QMS, and documentary requirements, from both regulator and industry perspectives
- Strengthen regulatory consistency and harmonisation by aligning practices with international frameworks (e.g. IMDRF STED, ASEAN CSDT).

Hours - TBC

Structure of CSDT for GMD
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- Overview of CSDT elements and documentation expectations.
- Relationship between classification outcomes and dossier requirements.
- Importance of standardisation for regulatory efficiency.

Executive Summary
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- Introduction of device overview, intended purpose, and risk classification.
- Global regulatory status and approvals.
- Local conformity assessment route under Act 737 and MDR 2012.

Essential Principles
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- How to demonstrate conformity to EPSP
- Mapping evidence to recognised standards (ISO, IEC, ASTM)
- Common mistakes in insufficient cross-referencing.

Pre-Clinical Studies
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- Applicable design verification & validation requirements with relevant standards
- Evidence from performance testing, sterilisation validation, and packaging integrity.
- Electrical safety, EMC testing, and usability studies.
- Software lifecycle documentation and cybersecurity controls.

Clinical Evidence
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- Addressing clinical evaluation requirements for medical devices.
- Assessing sufficiency of clinical data for safety and performance claims: Types of evidence: clinical trials, literature, post-market surveillance, demonstration of equivalence
- Preparation of a Clinical Evaluation Report (CER)

Labelling Requirements
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- Overview of CSDT elements and documentation expectations.
- Relationship between classification outcomes and dossier requirements.
- Importance of standardisation for regulatory efficiency.

Risk Analysis
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- Introduction of device overview, intended purpose, and risk classification.
- Global regulatory status and approvals.
- Local conformity assessment route under Act 737 and MDR 2012.

Manufacturer Information
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- How to demonstrate conformity to EPSP
- Mapping evidence to recognised standards (ISO, IEC, ASTM)
- Common mistakes in insufficient cross-referencing.

Case Studies and Hands-On Exercises
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- Hands-on exercises using EPSP in real-device scenarios to evaluate safety and performance justification (e.g. active, implantable)
- Gap analysis from regulator and industry perspectives
- Reflection & feedback: regulator expectations, pitfalls, good practices

- Guidance Documents (TBC)

Module 5: Common Submission Dossier Template (CSDT) for IVD Medical Devices (IVD)

This module provides participants with a structured understanding of the CSDT requirements for In Vitro Diagnostic Medical Devices (IVD), covering documentation elements, conformity to Essential Principles of Safety and Performance (EPSP), and technical evidence expectations. Practical exercises and case studies will strengthen skills in preparing and evaluating CSDT submissions from both regulator and industry perspectives.

Expected Outcomes

- Understand the structure and content requirements of the CSDT for IVD Medical Devices under Act 737 and Medical Device Regulations 2012.
- Apply the principles to prepare, compile, and assess CSDT dossiers in alignment with Malaysian requirements and ASEAN AMDD provisions.
- Develop practical skills in mapping evidence to EPSP, reviewing verification & validation data, assessing clinical evidence, and evaluating risk management documentation.
- Identify compliance gaps in submissions, including labelling, QMS, and documentary requirements, from both regulator and industry perspectives
- Strengthen regulatory consistency and harmonisation by aligning practices with international frameworks (e.g. IMDRF STED, ASEAN CSDT).

Hours - TBC

Structure of CSDT for GMD ★

- Overview of CSDT elements and documentation expectations.
- Relationship between classification outcomes and dossier requirements.
- Importance of standardisation for regulatory efficiency.

Executive Summary ★

- Introduction of device overview, intended purpose, and risk classification.
- Global regulatory status and approvals.
- Local conformity assessment route under Act 737 and MDR 2012.

Essential Principles ★

- How to demonstrate conformity to EPSP
- Mapping evidence to recognised standards (ISO, IEC, ASTM)
- Common mistakes in insufficient cross-referencing.

Pre-Clinical Studies ★★

- Evaluation of analytical performance: accuracy, precision, specificity, sensitivity, linearity, detection limit.
- Performance testing against claimed intended use.
- Stability studies, reagent shelf-life, and packaging integrity

Performance Evaluation ★★

- Analytical performance assessment: repeatability, trueness, interference/cross-reactivity evaluation.
- Clinical performance assessment: clinical sensitivity, specificity, predictive values, concordance with reference methods.
- Scientific validity: ensuring analyte relevance to intended clinical use.
- Sources of evidence: published literature, laboratory and comparative studies, clinical data from intended populations.
- Preparation of a Performance Evaluation Report (PER)

Labelling Requirements ★

- Overview of CSDT elements and documentation expectations.
- Relationship between classification outcomes and dossier requirements.
- Importance of standardisation for regulatory efficiency.

Risk Analysis ★★

- Introduction of device overview, intended purpose, and risk classification.
- Global regulatory status and approvals.
- Local conformity assessment route under Act 737 and MDR 2012.

Manufacturer Information ★

- How to demonstrate conformity to EPSP
- Mapping evidence to recognised standards (ISO, IEC, ASTM)
- Common mistakes in insufficient cross-referencing.

Case Studies and Hands-On Exercises ★★★

- Hands-on exercises using EPSP in real-device scenarios to evaluate safety and performance justification (e.g. reagent kits, analyzers)
- Gap analysis from regulator and industry perspectives
- Reflection & feedback: regulator expectations, pitfalls, good practices

- Guidance Documents (TBC)

Module 6: Clinical Investigation of Medical Device

This module introduces the regulatory and practical aspects of clinical investigations for medical devices under the Medical Device (Exemption) Order 2024 and focusing on Good Clinical Practice (GCP), documentation and ethical requirements. Participants will gain insight into planning, assessing and aligning clinical studies with Malaysian regulatory requirement and ISO 14155

Expected Outcomes

- Understand the regulatory framework and requirements on clinical investigations of medical devices under the Medical Device (Exemption) Order 2024 including relevant MDA guidance documents.
- Apply the principles of Good Clinical Practice (GCP) and ethical considerations in the planning, conduct, monitoring and reporting of medical device clinical investigations.
- Develop competency in preparing and assessing clinical investigation documentation including Clinical Investigation Plan (CIP) and Investigator's Brochure (IB).
- Strengthen regulatory by aligning practices with ISO 14155:2020 and international standards for medical device clinical investigations.

Hours - TBC

Exemption Order 2024

- Understand the scope, intent and key provisions under the Medical Device (Exemption) Order 2024.
- Identify categories of medical devices and research activities that qualify for exemption from registration.

Product Classification

- Learn how to determine whether a product falls under the definition of a medical device in Act 737.
- Strengthen decision-making through case-based discussions and regulatory reference tools.

Medical Device Lifecycle Development

- Gain an overview of the medical device development journey from concept, prototype to market approval.
- Understand the importance of preclinical, verification and validation stages before clinical investigation.
- Recognize regulatory checkpoints and documentation required throughout the device lifecycle.

Good Clinical Practice (GCP) for Medical Devices: Implementing ISO 14155:2020 & Regulatory Requirements

- Understand the fundamental principles and structure of ISO 14155:2020 for clinical investigations.
- Identify roles and responsibilities of sponsors, investigators and ethics committees.
- Learn documentation, monitoring and reporting requirements specific to device studies.
- Strengthen compliance through real-world applications of GCP principles in Malaysia.

Regulatory Framework for Clinical Research Use of Medical Devices

- Explore the national regulatory framework and understand key principles for exemption, notification and approval of device-based studies.
- Identify practical compliance pathways for institutions conducting device-related research.

Type of Cilinical Investigation Application

- Understand different types of studies under Device Studies (DS) notification and types of Clinical Research Use (CRU) studies.
- Define CRU and differentiate it from DS categories.
- Explore real examples of clinical investigations (CI), performance evaluations (PE) and Post Market Clinical Follow-Up (PMCF) studies.
- Learn notification requirements, supporting documents and compliance expectations (documentation and ethical oversight required before study initiation).

Case Studies and Hands-On Exercises

- Step-by-step guidance on accessing the MDA Portal to reach the MeDC@St online system, including account creation, user roles, and security features.
- Learn how to complete each section of the notification form and identify common mistakes and how to avoid them.
- Review required supporting documents (e.g. CIP,IB, ethics approval) and apply for submitting the notification.

- Guidance Documents (TBC)