GRADUATE CERTIFICATE IN MEDICAL TECHNOLOGY REGULATION

GMS5114 Post-Market for Medical Technologies

9 – 13 March 2026

WORKSHOP PROGRAMME

Learning outcomes

At the end of this workshop, participants should be able to

- Describe the post-market regulatory requirements of medical devices.
- Explain the activities involved in Adverse Events and Field Safety Corrective Action.
- Describe the benefit-risk assessment of manufacturer's Corrective Action Preventive Action (CAPA).
- Explain key regulatory considerations in product changes from safety issues.
- List harmonised guidance documents related to post-market vigilance.

Target Audience

- Medical devices, in-vitro diagnostics, or software as a medical device developers, engineers, researchers, and regulatory/quality assurance professionals.

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09 – 13 March 2026

Day 1 – 09 March 2026, Mon

Time	Topic	Speaker/ Organization
8.30am	**Registration**	
9.00am	**Welcome**	**Dr. Rathi Saravanan** Lead Education Associate Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
9.10am	**Workshop Briefing**	**Ms. Faith Tan** Education Associate I CoRE, Duke-NUS Medical School
9.20am	**Brightspace Briefing and Team Icebreaker Activity** • Brightspace familiarization • Team introductions	**CoRE Education Team**
9.55am	**Photo Taking Session**	
10.00am	**Refreshment break**	
Session 1:	**Overview of Post-Market Systems**	
10.15am	**Importance of Post-Market Surveillance** • Ensures patient safety and public trust • Covers pre-market evidence gap • Explain how benefit risks evolve over time ad how PMS bridges the gap • Stakeholders involved	**Ms. Faith Tan** Education Associate I CoRE, Duke-NUS Medical School
11.00am	**Post-Market Activities for Medical Devices (MDs) and In Vitro Diagnostic Devices (IVDs)** • Lifecycle of MDs and IVDs (feedback loop to design) • Roles/responsibilities of stakeholders: manufacturer, authorized representative, importer/distributor, etc. • Examples of post-market activities for MDs and IVDs • Importance of post-market surveillance systems	**Dr. Rama Sethuraman** Head of Quality and Regulatory, APAC Roche Diagnostics Asia Pacific
12.15pm	**Lunch**	
1.15pm	**Group Activity 1**	**CoRE Education Team**
2.15pm	**Use Errors Detected in Post-Market Settings** • Why many post-market issues stem from usability and workflow, and how to address them systematically • How to recognize common use errors across MD/IVDs and distinguish from device malfunctions	**Mr. Soma Sundaram** Global Program Management Lead, MedTech Beyonics Pte Ltd

	• What are some quick human factors tools (task analysis, heuristics, formative testing) to identify these • How to plan effective mitigations (UI tweaks, IFU changes, training, labeling) and measure impact	
3.15pm	**Triaging Post-Market Signals** • Complaints, adverse events, quality nonconformances, field feedback) and turn them into decisions	**Ms. Faith Tan** Education Associate I CoRE, Duke-NUS Medical School
4.00pm	**Refreshment Break**	
4.15pm	**Group Activity 2** Triaging Post-Market Signals	**CoRE Education Team**
5.30pm	**End**	

Day 2 – 10 March 2026, Tue

Time	Topic	Speaker/ Organization
8.30am	**Registration**	
Session 2:	**Regulatory Frameworks and Standards for Robust Post-Market Systems**	
9.00am	**ASEAN Post-Market Requirements for MDs and IVDs – AMDD** • Introduction to AMDD • Key regulatory requirements for post-market activities specific to ASEAN member states • Types of post-market reports, frequency, and content of report • Mechanisms for information exchange	**Mr. Seet Wing Gang** Director, Regulatory Affairs, APAC Cook Southeast Asia Pte Ltd
10.00am	**Refreshment break**	
10.15am	**US Post-Market Requirements for MDs and IVDs – US FDA** • FDA's role in post-market surveillance and its importance • Key regulations for post-market requirements • Post approval studies and post-market surveillance studies	**Mr. Seet Wing Gang** Director, Regulatory Affairs, APAC Cook Southeast Asia Pte Ltd
11.15am	**EU Post-Market Requirements for MDs and IVDs – MDR and IVDR** • Introduction to EU Medical Device Regulation (MDR) and In-Vitro Diagnostic Regulation (IVDR) • Responsibilities of manufacturers in maintaining PMS • Device risk classification and Periodic Safety Update Reports (PSUR) • Post-Market Performance Follow-up (PMPF)	**Ms. Irene Yap** Consultant/Medical Writer Acorn Medtech Sdn. Bhd.
12.00pm	**Lunch**	
1.00pm	**International Standards related to Post-Market Surveillance** • QMS and risk frameworks: ISO13485, ISO14971, ISO/TR20416	**Mr. Jaineet Arora** Education Associate II CoRE, Duke-NUS Medical School
1.45pm	**Risk Evaluation and Risk Management** • What are risks, residual risks etc • Link to ISO14971? How to relate back to PMS?	**Dr. Alfred Chia** Partnerships and Innovation, NUHS Research and Innovation Office National University Health System
2.45pm	**Refresher on Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA)**	**Asst. Prof James Leong** Assistant Professor Head, Health Products & Regulatory Science CoRE, Duke-NUS Medical School
3.45pm	**Refreshment Break**	
4.00pm	**Practicum I** • Describe and carry out the RCA and CAPA workflow for IVD device	
5.30pm	**End**	

Day 3 – 11 March 2026, Wed

Time	Topic	Speaker/ Organization
8.30am	**Registration**	
9.00 am	**Individual and Group Readiness Assessment (IRA/GRA)**	**CoRE Education Team**
10.15am	**Refreshment Break**	
Session 3: Post-Market Surveillance Actions: Adverse Events & FSCA Reporting		
10.30am	**Adverse Event Reporting Process (MDA)** • Defining and categorizing adverse events • Reporting adverse events	**Mr. Muhammad Ikhwan Hafiz Bin Zainuddin** Senior Assistant Director, Vigilance Unit, Post-Market and Enforcement Division Medical Device Authority
11.15am	**Unique Device Identification (UDI) for Medical Devices** • Utility of UDI in post-market activities • Relation of UDI to AE reporting	**Ms. Remee Binti Awang Jalil** Senior Assistant Director, Vigilance Unit, Post-Market and Enforcement Division Medical Device Authority
12.00pm	**Lunch**	
1.00pm	**Case Discussion I** • Identification of reportable and non-reportable AE cases	**Expert Faculty:** **MDA**
2.15pm	**Management of FSCA and Quality Deviations for Medical Device and IVDs** • Evaluation of FSCA • Filing and tracking of Field Safety Notices	**Mr. Muhammad Ikhwan Hafiz Bin Zainuddin** Senior Assistant Director, Vigilance Unit, Post-Market and Enforcement Division Medical Device Authority
3.00pm	**Refreshment Break**	
3.15pm	**Practicum II** FSCA reporting: process for medical devices	**Expert Faculty:** **MDA**
5.30pm	**End**	

Day 4 – 12 March 2026, Thurs

Time	Topic	Speaker/ Organization
8.30am	**Registration**	
9.00am	**Recall Mechanisms of Defect MDs in Malaysia**	**Mr. Muhammad Ikhwan Hafiz Bin Zainuddin** Senior Assistant Director, Vigilance Unit, Post-Market and Enforcement Division Medical Device Authority
10.00am	**Refreshment Break**	
10.15am	**Change Management** • Risk-based change classification in Malaysia for medical devices and IVDs • End-to-end change notification process, roles and responsibilities • Linking change management to post-market surveillance • Common pitfalls and best practices	**Ms. Remee Binti Awang Jalil** Senior Assistant Director, Vigilance Unit, Post-Market and Enforcement Division Medical Device Authority
Session 4: QMS Audits and Inspections		
11.15am	**Ensuring Ongoing Compliance of High-Risk MDs through Regulatory Inspections**	**Ms. Remee Binti Awang Jalil** Senior Assistant Director, Vigilance Unit, Post-Market and Enforcement Division Medical Device Authority
12.00pm	**Lunch**	
1.00pm	**Overview of Audits and Inspections for Medical Technology** • Definition, purpose, and role of audits and inspections • Application of QMS standards (ISO13485, EU MDR)	**Ms. Tan Hwee Ee** Founder and Director DH RegSys Private Limited
2.00pm	**Audit Process for MDs and IVDs** • Development of an audit plan and people involved • Elements of an audit • Reporting and documents in an audit	**Ms. Tan Hwee Ee** Founder and Director DH RegSys Private Limited
3.00pm	**Case Discussion 2**	**Expert: Tan Hwee Ee**
3.15pm	**Refreshment Break**	
3.30pm	Case Discussion 2 (cont.)	
5.00pm	**End**	

Day 5 – 13 March 2026, Fri

Time	Topic	Speaker/ Organization
8.30am	**Registration**	
9.00am	**End-of-Module (EOM) Assessment**	**CoRE Education Team**
10.00am	**Refreshment break**	
10.15am	**EOM Review**	
Session 5: Lifecycle Management of Medical Technologies		
10.45am	**Group Activity 3** • End-of-life products management: Medical Devices	**CoRE Education Team**
11.45am	**Dealing with Counterfeit Medical Devices**	**Mr. Andy Chua** Director, Global Brand Protection, Asia Pacific Johnson & Johnson
12.30pm	**Lunch**	
1.30pm	**Decommissioning of MDs and IVD** • Factors that make decommissioning important • Decommissioning process and stakeholders involved • Disposal and recycling of decommissioned devices	**Mr. Ang Wei Jun** Quality and Regulatory Manager Diagnostics Development Hub (DxD Hub)
2.30pm	**Post-Market Challenges Faced by SMEs and Startups** • Unique challenges that MNCs might not face/might find it easier to handle • What are some resource constraints faced by SMEs? • How does a lean workflow look like for complaint process? • Low-volume data and signal detection: With sparse complaints and weak denominator data, how to decide what's a true signal vs noise?	
3.30pm	**Refreshment Break**	
3.45pm	**Reflection and Peer Sharing**	**Dr. Rathi Saravanan** Lead Education Associate CoRE, Duke-NUS Medical School
4.45pm	**Closing Remarks**	**Asst. Prof James Leong** Head, Health Products and Regulatory Science CoRE, Duke-NUS Medical School
5.00pm	**End**	

**The Programme is accurate as of 03 March 2026 and may be subjected to further revisions*