GRADUATE CERTIFICATE IN MEDICAL TECHNOLOGY REGULATION

GMS5114 Post-Market for Medical Technologies

21 – 25 April 2025

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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Day 1 – 21 April 2025, 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 CoRE, Duke-NUS Medical School
9.30am	**Brightspace Briefing and Team Icebreaker Activity** • Brightspace familiarization • Team introductions • Goal setting	**Mr. Osman Mohamed** Senior Education Associate CoRE, Duke-NUS Medical School
9.55am	**Photo Taking Session**	
10.00am	**Refreshment break**	
Session 1:	**Overview of Post-market Systems**	
10.15am	**Medical Device Regulations in the Context of Healthcare** • Role and impact of medical device regulations	**Mr. Michael Gropp** Advisory Board Member and Visiting Expert CoRE, Duke-NUS Medical School
11.00am	**Post-Market Activities for Medical Devices (MDs) and In Vitro Diagnostic Devices (IVDs)** • Lifecycle management of MDs and IVDs • 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	**Post-Market Activities for Software as a Medical Device (SaMD)** • Lifecycle management of SaMD • Examples of post-market activities for SaMD • Challenges of post-market surveillance unique to SaMD	**Dr. Rama Sethuraman** Head of Quality and Regulatory, APAC Roche Diagnostics Asia Pacific
2.30pm	**Post-Market Surveillance System from the Perspective of a Healthcare Professional (HCP)** • Role of HCPs in post-market surveillance systems • Current challenges faced by HCPs in ensuring the safe and effective use of medical technologies	**Dr. Hishamuddin Badaruddin** Founder Noviu Heath
3.30pm	**Challenges of Post-Market Surveillance for Medical Devices from the Industry Perspective** • Challenges faced by companies in releasing MDs into market	**Mr. Sharad Mi. Shukla** Director, MedTech Regulatory Affairs Johnson & Johnson MedTech

4.15pm	**Refreshment Break**	
4.30pm	**Networking Session**	**Mr. Osman Mohamed** Senior Education Associate CoRE, Duke-NUS Medical School
4.55pm	**Workshop Debrief**	
5.00pm	**End**	

Day 2 – 22 April 2025, Tue

Time	Topic	Speaker/ Organization
8.30am	**Registration**	
Session 2:	**Regulatory Frameworks and Standards for Robust Post-Market Systems**	
9.00am	**Post-Market Requirements for Medical Technology** • Overview of post-market systems for MDs and IVDs • Stakeholders' involvement in post-market systems • Regulatory frameworks for post-market requirements (EU, US FDA, AMDD)	**Ms. Faith Tan** Education Associate CoRE, Duke-NUS Medical School
9.45am	**Refreshment break**	
10.00am	**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	**Ms. Zahroh Hasanah Darwis** Head, Medical Device Vigilance Unit Medical Device Authority
11.00am	**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
12.00pm	**Lunch**	
1.00pm	**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. Rae Ann Farrow** Senior Advisor Roche Diagnostics
2:00pm	**Quality Management System and Post-Market Surveillance** • ISO 13485 and QMS essentials for post-market processes	**Mr. Uroš Tacar** CEO TUKO Medical Devices
3.00pm	**Refresher on Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA)**	**CoRE Education Team**
3.30pm	**Refreshment Break**	
3.45pm	**Practicum I** • Describe and carry out the RCA and CAPA workflow for IVD device	
5.30pm	**End**	

Day 3 – 23 April 2025, 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	**Ms. Zahroh Hasanah Darwis** Head, Medical Device Vigilance Unit Medical Device Authority
11.30am	**Unique Device Identification (UDI) for Medical Devices** • Utility of UDI in post-market activities • Relation of UDI to AE reporting	**Ms. Zahroh Hasanah Darwis** Head, Medical Device Vigilance Unit Medical Device Authority
12.30pm	**Lunch**	
1.30pm	**Case Discussion I** • Identification of reportable and non-reportable AE cases	**Ms. Zahroh Hasanah Darwis** Head, Medical Device Vigilance Unit Medical Device Authority
3.00pm	**Management of FSCA and Quality Deviations for Medical Device and IVDs** • Evaluation of FSCA • Filing and tracking of Field Safety Notices	**Ms. Cha Wan Zhen** Senior Regulatory Specialist, Medical Devices Branch Health Science Authority
3.45pm	**Refreshment Break**	
4.00pm	**Post-market risk assessment and management (SaMD)** • Software risk management and risk control • Health hazard and risk-benefit ratio	**Mr. Sundeep Agarwal** Vice President, Regulatory Affairs & Quality Assurance Remidio Innovative Solutions
4.45pm	**Workshop Debrief**	
5.00pm	**End**	

Day 4 – 24 April 2025, Thurs

Time	Topic	Speaker/ Organization
8.30am	**Registration**	
9.00am	**Recall Mechanisms of Defect MDs in Singapore**	**Mr. Siaw Kai Lun** Senior Regulatory Specialist, Medical Devices Branch Health Science Authority
10.00am	**Practicum II** • FSCA reporting: process for medical devices	**Ms. Zahroh Hasanah Darwis** Head, Medical Device Vigilance Unit Medical Device Authority
10.45am	**Refreshment Break**	
11.00am	**Practicum II (cont.)**	
Session 4: QMS Audits and Inspections		
12.00pm	**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
12.45pm	**Lunch**	
1.45pm	**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
2.45pm	**Ensuring Ongoing Compliance of High-Risk MDs - Inspections**	**Ms. Zahroh Hasanah Darwis** Head, Medical Device Vigilance Unit Medical Device Authority
3.45pm	**Refreshment Break**	
4.00pm	**Handling Non-Conformities** • Documentation requirements • Regulatory actions	**Mr. Nichol Lim** Vice President, Services Stendard
4.45pm	**Workshop Debrief**	
5.00pm	**End**	

Day 5 – 25 April 2025, 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** • End-of-life products management: Medical Devices	**CoRE Education Team**
11.45am	**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)
12.45pm	**Lunch**	
1.45pm	**Dealing with Counterfeit Medical Devices**	**Mr. Andy Chua** Director, Global Brand Protection, Asia Pacific Johnson & Johnson
2.45pm	**Post-Market Challenges Faced by SMEs and Startups** • Unique challenges that MNCs might not face/might find it easier to handle • Types of resource constraints	**Mr. Gjan Lim** Healthcare Essentials Founder
3.45pm	**Refreshment Break**	
4.00pm	**Reflection and Peer Sharing**	**Dr. Rathi Saravanan** Lead Education Associate CoRE, Duke-NUS Medical School
4.45pm	**Closing Remarks**	**Prof. Silke Vogel** Deputy Director CoRE, Duke-NUS Medical School
5.00pm	**End**	