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**	**Asst. Prof. James Leong** Head, Health Products and Regulatory Science Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
9.15am	**Course Overview and Workshop Briefing** • Overview of post-market surveillance and programme flow • Brightspace briefing	**Ms. Faith Tan** Education Associate CoRE Duke-NUS Medical School **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 Surveillance Systems**	
10.15am	**Medical Device Regulations in the Context of Healthcare** • Role of medical device regulations • Impact on healthcare environment	
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	
12.15pm	**Lunch**	
1.15pm	**Post-Market Activities for Software as a Medical Device (SaMD)** • Lifecycle management of SaMDs • Examples of post-market activities for SaMD • Challenges of post-market surveillance unique to SaMD	
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	

3.30pm	**Challenges of Post-Market Surveillance for Medical Devices from the Industry Perspective** • Challenges faced by companies in releasing MDs into market	
4.15pm	**Refreshment Break**	
4.00pm	**Networking**	**Mr. Osman Mohamed** Senior Education Associate CoRE Duke-NUS Medical School
4.45pm	**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)	
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	
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 (21 CFR p803, 21 CFR p820) • Post approval studies and post market surveillance studies	
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)	
2:00pm	**Quality Management System and Post-Market Surveillance** • ISO 13485 and QMS essentials for post-market processes	
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** • Defining and categorizing adverse events • Reporting adverse events	
11.30am	**Unique Device Identification (UDI) for Medical Devices** • Utility of UDI in post market activities • Relation of UDI to AE reporting	
12.30pm	**Lunch**	
1.30pm	**Case Discussion I** • Identification of reportable and non-reportable AE cases	
3.00pm	**Management of FSCA and Quality Deviations for Medical Device and IVDs** • Evaluation of FSCA • Filing and tracking of Field Safety Notices	
4.30pm	**Refreshment Break**	
4.00pm	**Post-market risk assessment and management (SaMD)** • Software risk management and risk control • Health hazard and risk-benefit ratio	
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**	
10.00am	**Practicum II** • FSCA reporting: process for medical devices	
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)	
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	
2.45pm	**Ensuring Ongoing Compliance of High-Risk MDs - Inspections**	
3.45pm		
4.00pm	**Handling non-conformities** • Documentation requirements • Regulatory actions	
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	**End-of-life products management: SaMD** • Managing medical devices' end-of-life support • Decommissioning of products and protecting patient data privacy	
11.45am	**Decommissioning of MDs and IVD** • Factors that make decommissioning important • Decommissioning process and stakeholders involved • Disposal and recycling of decommissioned devices	
12.45pm	**Lunch**	
1.45pm	**Dealing with Counterfeit Medical Devices**	
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	
3.45pm	**Refreshment Break**	
4.00pm	**Reflection and Peer Learning**	**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**	

**The Programme is accurate as of 20 Jan 2025 and may be subjected to further revisions*