GRADUATE CERTIFICATE IN HEALTH PRODUCTS REGULATION

GMS5114 Post Market Surveillance of Medical Technologies

06 May 2024 – 10 May 2024

WORKSHOP PROGRAMME

Learning outcomes

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

- Describe various post-market surveillance activities for different types of medical technologies (i.e., medical devices, In-Vitro Diagnostic (IVD) devices and Software as a Medical Device (SaMD)).
- Compare post-market surveillance activities between medical devices and IVD devices.
- Assess scenarios and determine the ideal regulatory actions for medical technologies.

Target Audience

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

Graduate Certificate in Health Products Regulation

GMS5114 Post Market Surveillance of Medical Technologies

06 May – 10 May 2024

Day 1 – 06 May, Mon

Time	Topic	Speaker/ Organization
8.00am	**Registration**	
8.30am	**Welcome**	**Asst. Prof. James Leong** Head, Health Products and Regulatory Science, Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
8.40am	**Course overview and Workshop Briefing**	**Ms. Faith Tan** Education Associate, Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
8.55am	**Photo Taking Session**	
Session 1:	**Overview of Post Market Surveillance Systems**	
9.00am	**Medical device regulations in the context of Healthcare** • Understand the role of medical device regulations and its contributions to the healthcare environment	**Mr. Michael Gropp** Advisory Board Member and Visiting Expert, Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
9.45am	**Medical Device and In-Vitro Diagnostic (IVD) Devices Lifecycle** • Focus on the post-market phase • Examples of post-market activities for medical devices and IVD • Importance of post-market surveillance systems	**Dr. Rama Sethuraman** Head of Quality and Regulatory, APAC Roche Diagnostics Asia Pacific
11.00am	**Refreshment Break**	
11.15am	**Software as a Medical Device (SaMD): Lifecycle** • Focus on the post-market phase • Examples of post-market activities for SaMD • Challenges of post-market surveillance for SaMD	**Dr. Rama Sethuraman** Head of Quality and Regulatory, APAC Roche Diagnostics Asia Pacific
12.15pm	**Lunch**	
1.15pm	**Ideal Post-Market Surveillance System from the Perspective of a Healthcare Professional** • Elements of a good post-market surveillance system for a medical device	**Dr. Hishamuddin Badaruddin** Founder Noviu Heath

2.00pm	**Challenges of Post-Market Surveillance for Medical Devices** • General challenges when it comes to releasing medical device into market (in terms of compliance)	**Mr. Sharad Mi. Shukla** Director, MedTech Regulatory Affairs Johnson & Johnson MedTech
2:45pm	**Role of Physicians and Patients in Post-Market Systems for Digital Health Products** • Based on physicians' observations: how inputs and feedback from physicians and patients can benefit post-market systems • Focus will be on digital health products designed for mental health	**Dr. Anne-Claire Stona** Research Fellow, Centre for Outbreak Preparedness, Centre for Regulatory Excellence (CoRE) Duke-NUS Medical School
3.30pm	**Refreshment Break**	
3.45pm	**Bridging Medical Technology and Healthcare** • Overview of medical technologies • Types of technologies in healthcare • Challenges of monitoring safe and effective use of medical technology	**Dr. Hishamuddin Badaruddin** Founder Noviu Heath
4.30pm	**Brightspace Briefing and Networking Session**	**Mr. Osman Bin Mohamed** Senior Education Associate, Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
5.30pm	**End**	

Day 2 – 07 May, Tue

Time	Topic	Speaker/ Organization
8.00am	**Registration**	
8.30am	**Individual and Group Readiness Assessment I**	
Session 2:	**Regulatory Frameworks and Standards for Robust Post-Market Systems**	
9.30am	**Quality Management System and Post-Market Surveillance:** • QMS essentials for post-processes (standard) that should be in place. • Training to stakeholders as part of PMS	**Mr. Tibor Zechmeister** Strategic Advisor Regulatory Affairs Flinn.ai
10.30am	**Refreshment break**	
10.45am	**Lifecycle Management of SaMD** • Key considerations in software design change • Regulatory compliance for SaMD lifecycle management	**Dr. G.V. Praveen Kumar** Associate Director, Regulatory Science & Health Policy, Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
11.30am	**Post-Market Requirements for Medical Technology (EU)** • Likely for medical devices, cos no specific ones for SaMD • Change management	**Dr. Gaston German Westergaard** Senior Safety Process Director (Medical Devices) Roche Diagnostics International AG
12.30pm	**Lunch**	
1.30pm	**Post-Market Requirements for Medical Technology (AMDD)** • Likely for medical devices, cos no specific ones for SaMD • Differences from AMDD from EU/FDA • Whether there are country specific requirements	**Mr. Sharad Mi. Shukla** Director, MedTech Regulatory Affairs Johnson & Johnson MedTech
2.30pm	**Post-Market Requirements for Medical Technology (FDA)** Likely for medical devices, cos no specific ones for SaMD	**Dr. Karthik G.M.** Regulatory Affairs Lead (Asia, Middle East and Africa) Guardant Health Asia
3.15pm	**Refreshment Break**	
3.30pm	**Refresher on Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA)** • What activities are carried out for ongoing clinical evaluation for products already on the market	**CoRE Education Team**
4.00pm	**Practicum I** • Describe and carry out the RCA and CAPA workflow	**Mr. Sharad Mi. Shukla** Director, MedTech Regulatory Affairs Johnson & Johnson MedTech
5.30pm	**End**	

Day 3 – 08 May, Wed

Time	Topic	Speaker/ Organization
8.00am	**Registration**	
8.30 am	**Individual and Group Readiness Assessment II**	
Session 3:	**Adverse Event Reporting**	
9.30am	**Reportable vs Non-Reportable Adverse Events** • Reporting process for medical devices	**Ms. Idamazura Idris** Director, Post-Market & Enforcement Division Medical Device Authority
10.15am	**Refreshment Break**	
10.30am	**Unique Device Identification (UDI) for Medical Devices** • Definition, and its importance • Relation of UDI to AE reporting • How it acts as an enabler to traceability	**Ms. Idamazura Idris** Director, Post-Market & Enforcement Division Medical Device Authority
11.15am	**AE reporting for IVD devices** • General differences in reporting between medical devices and IVDs • Fous on the AE reporting section and example of reporting • Examples of reporting challenges	**TBC**
12.00pm	**Lunch**	
1.00pm	**Group Activity: Enablers for Better Monitoring and Tracking** • Discuss and share about feedback channels: how to collect feedback from HCPs, users, distributers	**CoRE Education Team**
2.30pm	**Case Discussion I** • Identification of reportable and non-reportable AE cases	**Ms. Idamazura Idris** Director, Post-Market & Enforcement Division Medical Device Authority **Zahroh Hasanah Darwis** Head of Monitoring & Vigilance Branch Medical Device Authority
3.30pm	**Refreshment Break**	
3.45pm	**Case Discussion I (cont.)**	
4.30pm	**Challenges faced by SMEs and Startups** • Practical and operational barriers when complying with post-market requirements • Focus on IVD devices	**TBC**
5.30pm	**End**	

Day 4 – 09 May, Thurs

Time	Topic	Speaker/ Organization
8.00am	**Registration**	
Session 4: Field Safety Corrective Actions (FSCA) Reporting		
8.30am	**Management of FSCA and Quality Deviations for Medical Device and IVDs** • Definition • Decision making process • Field safety notices: how to track and how to file	**Ms. Tan Tian Ai** Senior Regulatory Specialist, Medical Devices Branch Health Science Authority
9.30am	**Management of FSCA for Software as a Medical Device** • Definition • Decision making process • Field safety notices: when it is applicable, and how to track and file	**Ms. Siew Jie Yee** Senior Regulatory Specialist, Medical Devices Branch Health Science Authority
10.30am	**Refreshment Break**	
10.45am	**Reflection and Peer Learning**	**Dr. Rathi Saravanan** Lead Education Associate, Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
11.45am	**Panel Discussion**	**CoRE Education Team**
12.15pm	**Lunch**	
Session 5: Post-Market Regulatory Decision Making		
1.15pm	**Recall Mechanisms of Defect Medical Devices in Singapore** • How are defect medical devices detected • Include case examples	**Mr. Siaw Kai Lun** Senior Regulatory Specialist, Medical Devices Branch Health Science Authority
2.00pm	**Practicum II** • FSCA reporting	**Ms. Idamazura Idris** Director, Post-Market & Enforcement Division Medical Device Authority
3.15pm	**Refreshment Break**	
4.00pm	**Practicum II (Continued)**	
4.45pm	**Post-market risk assessment and management (SaMD)** • Software risk management and risk control • Health hazard and risk-benefit ratio • Real-life experience/ example in the field	**Mr. Sundeep Agarwal** Vice President, Regulatory Affairs & Quality Assurance Remidio Innovative Solutions
5.30pm	**End**	

Day 5 – 10 May, Fri

Time	Topic	Speaker/ Organization
8.30am	**Registration**	
9.00am	**End-of-Module (EOM) Assessment**	
10.00am	**Review of EOM Questions**	**CoRE Education Team**
10.30am	**Refreshment break**	
Session 6: Lifecycle Management of Medical Technologies		
10.45am	**End-of-life products management: SaMD and IVD** • Managing medical devices' end-of-life support • decommissioning of products and protecting patient data privacy	**Mr. Paul Chua** Cybersecurity Officer, Greater Asia Becton, Dickinson (BD)
11.30am	**Cybersecurity Measures for SaMD** • Include AI-MDs	**Mr. Sundeep Agarwal** Vice President, Regulatory Affairs & Quality Assurance Remidio Innovative Solutions
12.15pm	**Lunch**	
1.15pm	**Dealing with Counterfeit Medical Devices**	**Mr. Andy Chua** Director, Global Brand Protection, Asia Pacific Johnson & Johnson
2.00pm	**Regulation for Data Usage** • Government bodies regulating data • Overview of standards, regulations, and requirements for data usage • Approaches for preventing data loss and protecting information and infrastructure	**Mr. Alvin Toh** Chief Marketing Officer Straits Interactive Pte Ltd
2.45pm	**Refreshment Break**	
3.00pm	**Panel Session** Regional approaches and partnerships for effective supply chain security • How do regulators ensure the quality and safety of MDs are met • Are current risk-based approaches for managing MDs adequate?	**Moderator:** **Dr. Hishamuddin Badaruddin** **Panel:** **Mr. Paul Chua** **Dr. Christopher Lam**
4.15pm	**Workshop Conclusion**	
5.00pm	**Closing Remarks**	
5.30 pm	**End**	