GRADUATE CERTIFICATE IN HEALTH PRODUCTS REGULATION

GMS5106: Regulation of Digital Health Products

30 Oct 2023 – 3 Nov 2023

WORKSHOP PROGRAMME

Learning outcomes

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

- Determine what are Digital Health (DH) and medical device (MD)
- Identify and apply the relevant standards and guidance for DH in MD
- List the risk management requirements for DH in MD
- Understand the importance of data, artificial intelligence and cybersecurity in healthcare
- Review of upcoming trends in DH

Target Audience

- Software developers, engineers, researchers, and SME developing Medical Device Software and regulatory/quality assurance professionals.

Graduate Certificate in Health Products Regulation
GMS5106: Regulation of Digital Health Products

30 Oct-30 Nov 2023

Day 1 – 30 Oct, Mon

Time	Topic	Speaker/ Organisation
8.00am	**Registration**	
8.30am	**Welcome Address**	
8.40am	**Workshop Briefing and Brief Intro to Digital Health**	
8.55am	**Photo Taking Session**	
Session 1:	**SaMD Regulatory Landscape, Requirements and Embracing DH**	
9.00am	**Regulatory Intelligence (Software as a Medical Device)** • Regulatory landscape for SaMD in ASEAN	**Mr Winson Teng** Manager Regulatory Affairs Intelligence Becton Dickinson (BD)
9.30am	**Software as a Medical Device (SaMD) Qualification** • Contrast between traditional medical device vs SaMD • Identifying SaMD and non-regulated software • Examples of SaMD and non-regulated software	**Dr. Karthik GM** Associate Director Regulatory Affairs, AMEA (Asia,Middle East & Africa) Guardant Health
10.00am	**Refreshment Break**	
10.15am	**Regulation of Software as Medical Device- EU** • Definition of Software as Medical device. • Software as a Medical Device framework • Identify key regulations for Software as Medical Devices • List the documentation requirements for Software as Medical Device	**Mr Tibor Zechmeister** Managing Partner CommuModo GmbH
11.15am	**Regulation of SaMD (IMDRF and HSA)** • SaMD framework • Identify key regulations for SaMDA	**Dr. Karthik GM** Associate Director Regulatory Affairs, AMEA (Asia, Middle East & Africa) Guardant Health
12.30pm	**Lunch**	
1.30pm	**Bridging Technology and Healthcare** • Navigate through complex regulations to provide a better state of the art device to the patient	**Dr Hishamuddin Badaruddin** Chief Medical Officer Chi Longevity
2.00pm	**Embracing Technology for Better Patient Outcomes** • Understand how digital health has facilitated practitioners in their routines • Highlight currently how patient benefits from DH compared to using the conventional approach	**Dr Hishamuddin Badaruddin** Chief Medical Officer Chi Longevity
2.30pm	**Premarket Submission Requirement (SaMD)** • List of basic documents required for submission	**TBC**
3.30pm	**Refreshment Break**	

Session 2: Ensuring Quality, Safety and Efficacy of SaMD		
3.45pm	**Preclinical Studies of SaMD** • List the types of clinical testing and standards for SaMD • List the requirements for preclinical trial of SaMD	**Dr John Thornback** Senior Advisor Diagnostics Development Hub
4:45pm	**Clinical Evaluation of SaMD** • List the key requirements for clinical evaluation • Highlight the contrast between SaMD and general medical device clinical requirements • Stages of the clinical evaluation processes	**Dr Sarah Daud** Head of Research & Development (Technology-device Section) Cell ID **Mr Jaime** Regional Senior Manager RA-QA Kyowa Hakko Bio Singapore Pte Ltd
5.25pm	**Feedback Session**	**Attendees**
5.30pm	**End**	

Day 2 – 31 Oct, Tue

Time	Topic	Speaker/ Organisation
8.00am	**Registration**	**Attendees**
8.30am	**Individual and Group Assessment I**	**Attendees**
9.30am	**The Quality Management System of SaMD** • Hardware and software preparation and submission • Significant software and hardware testing difference	**TBC**
10.30am	**Refreshment break**	
10.45am	**Design Validation and Verification of SaMD** • List the different type of testing for SaMD validation and verification	**Mr. Henry Johnson** Senior Manager Agency for Science, Technology and Research (A*STAR)
11.30am	**Software Testing** • Identify SaMD development processes reference to IEC 62304 • Identify the challenges of SaMD testing phases	**TBC**
12.30pm	**Lunch**	
1.30pm	**Good Coding Practices** • Understand the good coding practices for SaMD • Coding for SaMD reference to IEC 62304, coding standards MISRA or ISO 26262 • Ensure safety (including testing), reliability, and meeting the intended use	**TBC**
2.00pm	**Risk Management for SaMD** • Identify the potential risk and hazards with SaMD • Evaluate and analyze the potential risk of SaMD	**Mr. Henry Johnson** Senior Manager Agency for Science, Technology and Research (A*STAR)
2.30pm	**Lifecycle Management of SaMD** • Key considerations in software design change • Navigate regulatory compliance for SaMD lifecycle management	**TBC**
3.00pm	**Refreshment Break**	
3.15pm	**Practicum I** • Quality and lifecycle management for SaMD	**TBC**
5:25pm	**Feedback Session**	**Attendees**
5.30pm	**End**	

Day 3 – 1 Nov, Wed

Time	Topic	Speaker/ Organisation
8.00am	**Registration**	**Attendees**
8.30 am	**Individual and Group Assessment II**	**Attendees**
Session 3:	**A.I. Regulations and Safety**	
9.30am	**Regulations and Guidelines of Artificial Intelligence (A.I.)_EU** • List the regulation and guidelines of A.I. • Identify the challenges of regulating A.I.	**Mr Tibor Zechmeister** Managing Partner CommuModo GmbH
10.30am	**Refreshment Break**	
10.45am	**Regulations and Guidelines of A.I. _ASEAN/ASIA** • List the regulation and guidelines of A.I. • Identify the challenges of regulating A.I.	**Mr. Abhineet Kaul** Director Access Partnership
11.30am	**Risk Management for A.I.** • Understanding AI risk management framework to serve society and organizations better • Managing A.I bias	**TBC**
12.30pm	**Lunch**	
1.30pm	**Practicum II** • **Risk management approach of using A.I in healthcare, reference to ISO 14971**	**TBC**
3.00pm	**Refreshment Break**	
3.15pm	**AI/ML in Digital Healthcare** • List the types of AI/ML in healthcare • Identify the process clinical decision-making using AI/ML	**TBC**
4.00pm	**Clinical AI Application** • Highlighting AI progress and development in clinical application • Opportunities and challenges in adopting clinical AI	**TBC**
4.45pm	**ASEAN Approaches to Responsible AI** • Highlighting the pillars on the responsibility use and impact of AI in ASEAN • Identifying the current healthcare focus	**TBC**
5.25pm	**Feedback Session**	**Attendees**
5.30pm	**End**	

**The Programme is accurate as at 30-May-23 and may be subjected to further revisions*

Day 4 – 2 Nov, Thurs

Time	Topic	Speaker/ Organisation
8.00am	**Registration**	**Attendees**
8.30am	**Individual and Group Assessment III**	**Attendees**
Session 4: Digital Therapeutics, Benefits and Challenges		
9.30am	**Digital Therapeutic (DTx)_US** • Definition and benefit in healthcare • Regulatory and legal issues • Opportunities and challenges	**TBC**
10.30am	**Refreshment Break**	
10.45am	**Obtaining Regulatory Approval for DTx_(US FDA)** • Product that has obtained regulatory approval • Challenges of obtaining an approval	**TBC**
11.30am	**Digital Biomarkers_I** • What they are and what forms they can take • Potential use includes providing real-time insights into drug effectiveness (aid drug trials)	**TBC**
12.00pm	**Digital Biomarkers_II** • Potential use using DBM for therapeutic application	**TBC**
12.30pm	**Challenges f Regulating DTx in Singapore**	**TBC**
1.00pm	**Lunch**	
Session 5: Data Regulation and Safety		
2.00pm	**Regulation for Data Usage** • List of government bodies regulating data (e.g PDPA, NEHR • List the requirements for data usage • List of standards, regulations, and guidelines • Prevent data loss, and protect information and infrastructure • Understanding of sharing data and defending confidentiality, integrity and availability of data	**Mr. Anand Sampathkumar** Project Manager Data protection & GDPR KEYTEO Singapore
2.45pm	**Risk Management in Data for Healthcare** • Identify risks and risk assessment, data storage, potential data loss, data breaches, and unauthorized access • Plan for data breaches. Good practices of mitigating risk	**Dr. Clive Tan** Assistant Chief Group Integrated Care (Population Health) National Health Group
3.30pm	**Refreshment Break**	
3.45pm	**Case Discussion** • Data management, good practices of data sharing	**Dr. Clive Tan** Assistant Chief Group Integrated Care (Population Health) National Health Group
5.25pm	**Feedback Session**	**Attendees**
5.30pm	**End**	

Day 5 – 3 Nov, Fri

Time	Topic	Speaker/ Organisation
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: Cybersecurity Regulation and Safety		
10.45am	**Cybersecurity in Healthcare** • Fundamentals of cybersecurity in healthcare • Types of cyberattacks in healthcare • Examples of cybersecurity healthcare	**TBC**
11.15am	**Regulations and Challenges for Cybersecurity in Healthcare** • List of regulatory compliance for the US and EU (e.g. HIPAA and GDPR) • Adopting the guideline, prioritizing the organization's effort in launching a safe medical device to the market	**Mr. Lee Walsh** Founder and Managing Director Platypus Medtech Consulting
11.45am	**Healthcare Cybersecurity Framework** • Lists of guidelines (e.g. NIST, HITRUST, CIS, ISO, COBIT) for cybersecurity • Adopting the guideline, prioritizing the organization's effort in launching a safe medical device to the market	**Mr. Paul Chua** Vice-Chairman Cybersecurity Group Digital Health APACMED & Cybersecurity Officer Greater Asia BD
12.30pm	**Lunch**	
1.30pm	**Risk Management of Cybersecurity** • Navigate the systematic approach to cybersecurity management • Threat modeling helps with risk identification and risk quantification • Reducing friction between security and development	**Mr. Vinod Shankar** Cyber Security Leader Managing Director Accenture
2.15pm	**Group Brainstorming for the Panel Discussion**	**Attendees**
3.00pm	**Refreshment Break**	
3.15pm	**Panel Session**: Implementing Digital Health and securing patient trust. Q&A with Industry and Regulators	**Moderator:** **Dr. Clive Tan** Assistant Chief, Group Integrated Care (Population Health) National Health Group **Panelists:** **Dr. Hishamuddin Badaruddin** Chief Medical Officer Chi Longevity **Mr. Paul Chua** Vice-Chairman Cybersecurity Group Digital Health APACMED & Cybersecurity Officer Greater Asia BD **Ms. Ai Ling**

		Deputy Director Advocacy and Engagement Lee Kong Chian School of Medicine
4.15pm	**Workshop Conclusion and Feedback Session**	
5.00pm	**Closing Remarks**	
5.30 pm	**End**	