GRADUATE CERTIFICATE IN MEDICAL TECHNOLOGY REGULATION

GMS5106 Regulation of Digital Health Products

04 May 2026 – 08 May 2026

WORKSHOP PROGRAMME

Learning outcomes

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

- Articulate the definitions of different digital health products, including Artificial Intelligence and Machine Learning
- Identify and apply the relevant regulatory standards and guidance for digital health products, relating to the development, testing and documentation of these products
- List the risk management requirements for digital health products, including cybersecurity measures, and other activities applicable to successful life cycle management of digital health products

Target Audience

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

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Day 1 – 04 May, Monday

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**	**Mr. Jaineet Arora** Education Associate II 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**	**Core Education Team**
Session 1: Lifecycle and Classification of Digital Health Products		
10.00am	**Refreshment Break**	
10.15am	**Foundations of Digital Health: Concepts, Products, and Service Classifications** • Define digital health and its components (e.g., mHealth, telemedicine, AI-powered diagnostics) • Highlight the differences between digital health products and traditional medical devices/services • Categorise digital health products (e.g., wearables, SaMD, mobile apps, AI/ML models) & popular digital health tools such as fitness trackers, virtual care platforms • Discuss overlaps and distinctions between consumer and regulated products	**Asst Prof. Kavitha Palaniappan** Project Lead, Health Services Regulation CoRE
Session 2: SaMD Regulatory Landscape		
11:15am	**Software as a Medical Device (SaMD) Qualification** • Contrast between traditional medical devices vs SaMD • Identifying SaMD and non-regulated software • Examples of SaMD and non-regulated software	**Mr. Jaineet Arora** Education Associate II CoRE, Duke-NUS Medical School
12.00pm	**Lifecycle Management Principles – From concept to decommissioning** • Overview of lifecycle stages: development, deployment, maintenance, decommissioning • Importance of lifecycle thinking in regulatory compliance • Discuss tools for effective lifecycle management	**Henry Johnson** Principal Manager Diagnostics Development Hub (DxD Hub)
12.30pm	**Lunch**	

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1.30pm	**Regulation of Software as Medical Device - IMDRF and GHWP** Insights into SaMD regulatory frameworks – global perspective	**Winson Teng** Senior Manager, Regulatory Intelligence & Policy Bector Dickinson (BD)
2:00pm	**Regulation of Software as Medical Device – ASEAN** Regulatory landscape for SaMD in ASEAN	**Winson Teng** Bector Dickinson (BD)
2.30pm	**Regulation of Software as Medical Device – EU framework and US FDA** • Definition of Software as Medical Device. • EU and US SaMD framework and key regulations • Documentation requirements for SaMD	**Latha Puttaswamy** Regulatory Affairs Program Lead, Philips Medical Systems Nederland B.V.
3.45pm	**Refreshment Break**	
4.00pm	**Group Activity** SaMD risk classifications across major markets	**Core Education Team**
5.30pm	**End**	

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Day 2 – 05 May, Tuesday

Time	Topic	Speaker/ Organization
8.30am	**Registration**	
Session 3: Market Approvals of SaMD		
9.00am	**Pre-Market Submission Requirements for SaMD** Documentary requirement for submission to obtain market approvals	**Lah Lin Chin** Medical Devices Cluster Health Products Regulation Group Health Sciences Authority (HSA)
10.00am	**Refreshment break**	
10.15am	**Pre-clinical Studies for SaMD** • Types of clinical testing and standards for SaMD • Requirements for pre-clinical trials for SaMD	**Henry Johnson** DxD Hub
11.15am	**Clinical Evaluation of SaMD** • Key requirements for clinical evaluation of SaMD performance • Stages of the clinical evaluation processes • Contrast between the clinical requirements for SaMD and general medical devices	**Phyllis Yeo** Senior Regulatory Specialist Medical Devices Cluster Health Products Regulation Group Health Sciences Authority (HSA)
12.15pm	**Lunch**	
1.15pm	**Real-World Evidence (RWE)** • Define real-world data (RWD) and RWE • Interoperability, data quality, bias and confounding in RWD • Methodology for generating reliable RWE • Efficacy vs Effectiveness	**Yvonne Lee** Principal and Head of Real-World Evidence, Asia Pacific IQVIA
Session 4: Quality and Risk Management Frameworks		
2.15pm	**Risk Management Principles and Overview of Tools** • Define risk management for digital health products • Introduction to ISO 14971 (risk management for medical devices) • Discuss the importance of risk-benefit analysis in digital health • Risk identification and assessment tools • Risk control and mitigation tools • Risk monitoring and post-market surveillance tools	**Elio Suriyanto Tan** Staff Software/Design Quality Engineer Illumina
3.15pm	**Refreshment Break**	
3.30pm	**Overview of ISO13485 Quality Management System – Best Practices in Manufacturing**	**Ms. Tan Hwee Ee** Founder DH RegSys
5.30pm	**End**	

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Day 3 – 06 May, Wednesday

Time	Topic	Speaker/ Organization
8.30am	**Registration**	
9.00 am	**Individual and Group Readiness Assessment**	
10.15am	**Refreshment Break**	
10.30am	**Design Validation and Verification of SaMD** • SaMD development processes with reference to IEC 62304	**Elio Suriyanto Tan** Illumina
11.30am	**Software Verification and Validation** • Introduction to software verification and validation • Requirement traceability • Unit, integration, and system testing • Test cases, automated testing, and traceability matrices	**Elio Suriyanto Tan** Illumina
12.30pm	**Lunch**	
1.30pm	**Risk Management of SaMD against Cybersecurity Attacks** • Systematic approach to cybersecurity management • Threat modeling for risk identification and quantification • Reduction of friction between security and development	**Vinod Shankar** Managing Director Accenture
2.15pm	**Practicum I**	**Elio Suriyanto Tan** Illumina **Core Education Team**
3.30pm	**Refreshment Break**	
3:45pm	**Practicum I (cont'd)**	**Elio Suriyanto Tan** Illumina **Core Education Team**
Session 5: Digital Health Products and Services: Therapeutics and Wearables		
4.30pm	**Introduction, Classification, and Development of Digital Therapeutics (DTx)** • Definitions and key characteristics of DTx • Differentiating DTx from other digital health solutions (e.g., wellness apps, SaMD) • Criteria for classifying DTx based on risk and intended use • Pre-market approval, de novo classification and 510(k) processes • Country-specific considerations (e.g., FDA's Digital Health Centre of Excellence, CE marking in Europe) • Key development considerations – usability, interoperability and patient safety • Essential components of a regulatory dossier – clinical evidence, software validation and risk analysis	**Dr Wilson Goh** Assistant Professor of Biomedical Informatics, Lee Kong Chian School of Medicine, School of Biological Sciences Chief Data Scientist, NTU Center of AI in Medicine Co-Director, Centre for Biomedical Informatics
5.30pm	**End**	

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Day 4 – 07 May, Thursday

Time	Topic	Speaker/ Organization
8.30am	**Registration**	
9.00am	**Digital Health Wearables** • Introduction to digital health wearables • Regulation and risk management of wearables	**Vishal Kanani** Senior Manager, Regulatory Affairs iRhythm Technologies, Inc.
Session 6: Post-Market for Digital Health Products		
9.45am	**Post-Approval Regulatory Requirements / Post Market Surveillance and Incident Reporting** • Discuss safety and performance requirements for SaMD • Steps to take in response to an adverse event or cybersecurity incident • Discuss regulatory requirements for incident reporting and post-market follow-up	**TBC**
10.30am	**Refreshment Break**	
Session 7: AI Regulations and Safety in Digital Health Products		
10.45am	**Clinical AI Application** • AI progress and development in clinical applications • Opportunities and challenges in adopting AI in clinical settings	**Sankha Mukerjee** Senior Team Leader Health Data Science Medical and Nutritional Sciences – Precision Nutrition D-Lab Research & Innovation Danone Master Digital Health & Clinical Studies
11.30am	**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	**Sankha Mukerjee** Danone Master Digital Health & Clinical Studies
12.15pm	**Identifying Risks in AI/ML Models** • Understanding bias in AI systems • The need for transparency & accountability in AI systems • Balancing bias, transparency and accountability – a framework for action	**Asst Prof. Kavitha Palaniappan** CoRE
1.00pm	**Lunch**	
2.00pm	**Regulations and Guidelines for Artificial Intelligence (AI) – Europe Union**	**TBC**
3.00pm	**Practicum II**	**Asst Prof. Kavitha Palaniappan** **CoRE Education Team**

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3.45pm	**Refreshment Break**	
4.00pm	**Practicum II (cont'd)**	**Asst Prof. Kavitha Palaniappan** **CoRE Education Team**
5.15pm	**Panel Brainstorming**	**CoRE Education Team**
5.30pm	**End**	

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Day 5 – 08 May, Friday

Time	Topic	Speaker/ Organization
8.30am	**Registration**	
9.00am	**End-of-Module (EOM) Assessment**	
10.00am	**Refreshment break**	
10.15am	**Review of EOM Questions**	**CoRE Education Team**
Session 8: Cybersecurity Regulation and Safety		
10.45am	**AI and Machine Learning in Healthcare** • Overview of AI/ML techniques used in healthcare • Applications in diagnostics, drug discovery, personalized medicine and predictive analysis • Introduction to Good Machine Learning Practices (GMLP) • Challenges in regulating AI, including algorithm updates and bias	**Asst Prof. Kavitha Palaniappan** CoRE
11.45am	**Reflection and Peer Sharing**	**Dr. Rathi Saravanan** Lead Education Associate CoRE, Duke-NUS Medical School
12.45pm	**Lunch**	
1.45pm	**Vulnerabilities of the Healthcare System to attacks on Cybersecurity** • Fundamentals of cybersecurity in healthcare • Types of cyberattacks in healthcare • Examples of cybersecurity healthcare	**Dave Gurbani** CEO Cybersafe Pte Ltd
2.45pm	**Current Practices and Guidelines for Cybersecurity in Healthcare** • Examples of essential guidelines for cybersecurity such as NIST, HITRUST, CIS, ISO, COBIT	**Paul Chua** Asia Pacific Operations Director Health-ISAC
3.45pm	**Refreshment Break**	
4.00pm	**Panel Discussion** *Building Trust in Digital Health: Standards, Compliance, and Emerging Challenges*	**Panellists:** **Paul Chua** **Dave Gurbani** **TBC**
5.15pm	**Workshop Conclusion & Closing Remarks**	**Asst. Prof James Leong** Head, Health Products and Regulatory Science CoRE, Duke-NUS Medical School
5.30 pm	**End**	