



GRADUATE CERTIFICATE IN MEDICAL TECHNOLOGY REGULATION

GMS5106 Regulation of Digital Health Products

04 May 2026 – 08 May 2026

Venue: Duke-NUS Medical School, Training Room 5C

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 <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> Overview of lifecycle stages: development, deployment, maintenance, decommissioning Importance of lifecycle thinking in regulatory compliance Discuss tools for effective lifecycle management 	Mr. 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	Mr. 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	Mr. Winson Teng Bector Dickinson (BD)
2.30pm	Regulation of Software as Medical Device – EU framework and US FDA <ul style="list-style-type: none"> • Definition of Software as Medical Device. • EU and US SaMD framework and key regulations • Documentation requirements for SaMD 	Ms. Latha Puttaswamy Regulatory Affairs Program Lead, Philips Medical Systems Nederland B.V.
3.45pm	Refreshment Break	
4.00pm	Networking Session	CoRE Education Team
4.30pm	AI and Machine Learning in Healthcare <ul style="list-style-type: none"> • 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
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	Ms. Lah Lin Chin Senior Regulatory Specialist Medical Devices Cluster Health Products Regulation Group Health Sciences Authority (HSA)
10.00am	Refreshment break	
10.15am	Pre-clinical Studies for SaMD <ul style="list-style-type: none"> Types of clinical testing and standards for SaMD Requirements for pre-clinical trials for SaMD 	Mr. Henry Johnson DxD Hub
11.15am	Clinical Evaluation of SaMD <ul style="list-style-type: none"> 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 	Ms. 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) <ul style="list-style-type: none"> Define real-world data (RWD) and RWE Interoperability, data quality, bias and confounding in RWD Methodology for generating reliable RWE Efficacy vs Effectiveness 	Ms. 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 <ul style="list-style-type: none"> 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 	Dr. 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 <ul style="list-style-type: none"> SaMD development processes with reference to IEC 62304 	Dr. Elio Suriyanto Tan Illumina
11.30am	Software Verification and Validation <ul style="list-style-type: none"> Introduction to software verification and validation Requirement traceability Unit, integration, and system testing Test cases, automated testing, and traceability matrices 	Dr. Elio Suriyanto Tan Illumina
12.30pm	Lunch	
1.30pm	Risk Management of SaMD against Cybersecurity Attacks <ul style="list-style-type: none"> Systematic approach to cybersecurity management Threat modeling for risk identification and quantification Reduction of friction between security and development 	Mr. Vinod Shankar Managing Director Accenture
2.15pm	Practicum I <ul style="list-style-type: none"> End-to-End Design Control: From Risk to Verification & Validation in SaMD 	Dr. Elio Suriyanto Tan Illumina CoRE Education Team
3.30pm	Refreshment Break	
3:45pm	Practicum I (cont'd) <ul style="list-style-type: none"> End-to-End Design Control: From Risk to Verification & Validation in SaMD 	Dr. 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) <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> Introduction to digital health wearables Regulation and risk management of wearables 	Mr. 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 <ul style="list-style-type: none"> 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 	Ms. Seow Xing Ting Regulatory Specialist Medical Devices Cluster Health Products Regulation Group Health Sciences Authority (HSA)
10.30am	Refreshment Break	
Session 7: AI Regulations and Safety in Digital Health Products		
10.45am	Clinical AI Application <ul style="list-style-type: none"> AI progress and development in clinical applications Opportunities and challenges in adopting AI in clinical settings 	Mr. 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 <ul style="list-style-type: none"> Government bodies regulating data Overview of standards, regulations, and requirements for data usage Approaches for preventing data loss and protecting information and infrastructure 	Mr. Sankha Mukerjee Danone Master Digital Health & Clinical Studies
12.15pm	Identifying Risks in AI/ML Models <ul style="list-style-type: none"> 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	Mr. Kenneth Shaw Founder & Lead Consultant Specculo

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3.00pm	Practicum II <ul style="list-style-type: none"> • Identifying Risks in AI/ML Models under EU Regulations (EU AI Act & MDR) 	Mr. Kenneth Shaw Specculo Asst Prof. Kavitha Palaniappan CoRE CoRE Education Team
3.45pm	Refreshment Break	
4.00pm	Practicum II (cont'd) <ul style="list-style-type: none"> • Identifying Risks in AI/ML Models under EU Regulations (EU AI Act & MDR) 	Mr. Kenneth Shaw Specculo Asst Prof. Kavitha Palaniappan CoRE 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
10.45am	Group Activity SaMD risk classifications across major markets	CoRE Education Team
11.45am	Reflection and Peer Sharing	Dr. Rathi Saravanan CoRE, Duke-NUS Medical School
12.30pm	Panel Brainstorming	CoRE Education Team
12.45pm	Lunch	
Session 8: Cybersecurity Regulation and Safety		
1.45pm	Vulnerabilities of the Healthcare System to attacks on Cybersecurity <ul style="list-style-type: none"> Fundamentals of cybersecurity in healthcare Types of cyberattacks in healthcare Examples of cybersecurity healthcare 	Mr. Dave Gurbani CEO Cybersafe Pte Ltd
2.45pm	Current Practices and Guidelines for Cybersecurity in Healthcare <ul style="list-style-type: none"> Examples of essential guidelines for cybersecurity such as NIST, HITRUST, CIS, ISO, COBIT 	Mr. Paul Chua Asia Pacific Operations Director Health-ISAC
3.45pm	Refreshment Break	
4.00pm	Panel Discussion <i>Building Trust in Digital Health: Standards, Compliance, and Emerging Challenges</i>	Moderator: Asst Prof. Kavitha Palaniappan CoRE Panellists: 1. Mr. Dave Gurbani Cybersafe Pte Ltd 2. Mr. Ellil Mathiyan Lakshmanan President Ostomy Association of Singapore 3. Mr. Paul Chua Health-ISAC
5.00pm	Workshop Conclusion & Closing Remarks	Asst. Prof James Leong Head, Health Products and

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5.30 pm End