GRADUATE CERTIFICATE IN HEALTH PRODUCTS REGULATION

GMS5106 Regulation of Digital Health Products

26 – 30 May 2025

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.

Graduate Certificate in Health Products Regulation

GMS5106 Regulation of Digital Health Products

26 – 30 May 2025

Day 1 – 26 May, Mon

Time	Topic	Speaker/Organisation
8.30am	**Registration**	
9.00am	**Welcome and Workshop Briefing**	
9.25am	**Photo Taking Session**	
Session 1:	**Foundations of Digital Health Products and Services**	
9.30am	**Introduction to Digital Health** • Define digital health and its components (e.g., mHealth, telemedicine, AI-powered diagnostics) • Discuss the role of digital health in transforming patient care and improving outcomes	
10.00am	**Classification of Digital Health Products and Services** • 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	
10.30am	**Tea Break**	
11.00am	**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	
12.00pm	**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	
1.00pm	**Lunch**	
Session 2:	**Concepts and Principles Underlying Regulatory Framework**	
2.00pm	**Key Regulatory Frameworks, Guidance and Standards** • Overview of key regulatory bodies such as FDA, EMA, HSA, IMDRF • Role of harmonized standards like ISO and IEC in ensuring safety and interoperability • Discuss the significance of regulatory compliance in global markets	
3.00pm	**Tea Break**	
3.30pm	**Risk Management Principles and Overview of Tools for Risk Management** • 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
4.30pm	**Networking Session**
5.30pm	**End**

Day 2 – 27 May, Tue

Time	Topic	Speaker/Organisation
8.30am	**Registration**	
Session 3: SaMD Regulatory Landscape		
9.00am	**Regulation of Software as Medical Device - IMDRF and GHWP** • Insights into SaMD regulatory frameworks – global perspective	
9.45am	**Regulation of Software as Medical Device – EU framework and/or US FDA** • Definition of Software as Medical Device. • EU SaMD framework and key regulations • Documentation requirements for SaMD	
10.30am	**Tea Break**	
11.00am	**Regulation of Software as Medical Device – AMDD/ Singapore/ TGA** • Regulatory landscape for SaMD in ASEAN	
Session 4: Market Approvals of SaMD		
12.00pm	**Pre-Market Submission Requirements for SaMD** • Documentary requirement for submission to obtain market approvals	
1.00pm	**Lunch**	
2.00pm	**Pre-clinical Studies for SaMD** • Types of clinical testing and standards for SaMD Requirements for pre-clinical trials for SaMD	
2.45pm	**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	
3.30pm	**Tea Break**	
4.00pm	**Practicum I** • Conceptualise the commercialization of a SaMD • Application of risk classification and product licence requirements for SaMD • Gallery Walk: Presentation and peer review of group work	
5.30pm	**End**	

Day 3 – 28 May, Wed

Time	Topic	Speaker/Organisation
8.30am	**Registration**	
9.00 am	**Individual and Group Readiness Assessment**	
10.30am	**Tea Break**	
Session 5:	**Quality Management of SaMD**	
10.45am	**Overview of ISO13485 Quality Management System – Best Practices in Manufacturing** • Hardware and software preparation and submission • Significant software and hardware testing difference	
11.30am	**Design Validation and Verification of SaMD** • Types of testing for validation and verification of SaMD	
12.15pm	**Software Testing** • SaMD development processes with reference to IEC 62304 • Challenges of SaMD testing phases	
1.00pm	**Lunch**	
2.00pm	**Good Coding Practices** • Overview of information security (e.g., ISO 27001) • Ensuring safety (including testing), reliability, and fulfilling the intended use of a SaMD	
Session 6:	**Post-Market and Change Management for Digital Health Products**	
2.45pm	**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	
3.30pm	**Tea Break**	
3.45pm	**Real-World Evidence (RWE) in Compliance** • Define real-world evidence (RWE) and its role in regulatory decision-making • Examples of how RWE supports safety, efficacy and market access • Discuss challenges in collecting and using RWE	
4.15pm	**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	
5.30pm	**Adapting to Evolving Technologies and Regulations** • Discuss how regulatory landscapes evolve with technology • Tools and resources to monitor regulatory updates	
5.30pm	**End**	

Day 4 – 29 May, Thur

Time	Topic	Speaker/Organisation
8.30am	**Registration**	
Session 7: AI Regulations and Safety in Digital Health Products		
9.00am	**Clinical AI Application** • AI progress and development in clinical applications • Opportunities and challenges in adopting AI in clinical settings	
9.45am	**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	
10.30am	**Tea Break**	
10.45am	**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	
11.30am	**Regulations and Guidelines for Artificial Intelligence (AI) – Europe Union**	
12.15pm	**ASEAN Approaches to Responsible AI** Responsible use and the impact of AI in ASEAN	
1.00pm	**Lunch**	
2.00pm	**Group Activity / Practicum II** Risk management process, design and development for SaMD	
3.30pm	**Tea Break**	
Session 8: Digital Therapeutics		
3.45pm	**Introduction to Digital Therapeutics (DTx)** • Definitions and key characteristics of DTx • Differentiating DTx from other digital health solutions (e.g., wellness apps, SaMD)	
4.15pm	**Classifying DTx – Risks and Regulations** • 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)	
4.45pm	**Development and Documentation for DTx solutions – Best Practices** • Key development considerations – usability, interoperability and patient safety • Essential components of a regulatory dossier – clinical evidence, software validation and risk analysis	
5.30pm	**End**	

Day 5 – 30 May, 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	**Tea Break**	
11.00am	**Peer Learning**	
12.00pm	**Lunch**	
Session 9: Cybersecurity Regulation and Safety		
1.00pm	**Vulnerabilities of the Healthcare System to attacks on Cybersecurity** • Fundamentals of cybersecurity in healthcare • Types of cyberattacks in healthcare • Examples of cybersecurity healthcare	
1.45pm	**Current Practices and Guidelines for Cybersecurity in Healthcare** • Examples of essential guidelines for cybersecurity such as NIST, HITRUST, CIS, ISO, COBIT	
2.30pm	**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	
3.15pm	**Tea Break**	
3.30pm	**Panel Discussion – Protecting Consumers: Priorities in Digital Health Products in enhancing Cybersecurity**	
4.30pm	**Workshop Conclusion**	
5.00pm	**Closing Remarks**	
5.30 pm	**End**	