GRADUATE CERTIFICATE IN MEDICAL TECHNOLOGY REGULATION

GMS5008 Regulation and Clinical Evaluation of Medical Devices

03 August – 07 August 2026

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

WORKSHOP PROGRAMME

Learning Outcomes

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

- Evaluate fundamental regulatory frameworks and principles governing the development, approval, and lifecycle management of medical devices and technologies.
- Interpret and apply key regulatory guidelines, submission requirements, as well as compliance strategies across major global markets.
- Assess and synthesize critical factors influencing the clinical performance, safety, and risk management of medical devices, including preclinical testing and clinical evidence generation.

Target Audience

- Healthcare professionals, regulatory professionals, product developers, researchers, legal experts

Day 1 – 03 August, Monday

Time	Topic	Speaker/ Organization
8.30am	**Registration**	
9.00am	**Welcome Address**	**Dr. Rathi Saravanan** Lead Education Associate Lead, Graduate Certificate Programmes Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
9.10am	**Workshop Briefing**	**Mr. Jaineet Arora** Education Associate II CoRE, Duke-NUS Medical School
9.30am	**Brightspace Briefing** • **Team Introductions** • **Goal Setting** • **Bright Space Familiarization**	**CoRE Education Team**
9:55am	**Photo-taking Session: Faculty & Participants**	**CoRE Education Team**
10.00am	**Refreshment Break**	
Session 1: Introduction to Medical Technologies & their Regulatory Principles		
10.15am	**Overview of Medical Device Regulatory Trends**	
11.00am	**Total Product Lifecycle Journey of Medical Technologies** • Total product life cycle • Design and Development • Verification and validation	
11.45am	**Group Activity-I** • Regulatory organisations for medical technologies and harmonization efforts	**CoRE Education Team**
12.30pm	**Lunch**	
1:30pm	**Fundamentals of Medical Device Classification** • Overview of device classification across products • Safety and risk classification • Grouping of medical devices	**Mr. Jaineet Arora** CoRE, Duke-NUS Medical School
2:15pm	**Preparing a Dossier for Submission** • Manufacturer and registration communication for documentation preparation • Alternative technical documents to expedite registration approval • Documentation archiving and retrieval best practices • Common mistakes while preparing for documentation submission	
3.00pm	**Refreshment Break**	
3.15pm	**Case Discussion I** Medical Device Regulatory Failures and Lessons Learned	**CoRE Education Team**
5.00pm	**End**	

Day 2 – 04 August, Tuesday

Time	Topic	Speaker/ Organization
8.30am	**Registration**	
Session 2: Pre-Market Regulations		
9.00am	**Regulatory Submission Strategy for MD Approval** • Key Geographies • Launch plans • Go to market strategy for different geographies	
10.00am	**Refreshment Break**	
10.15am	**Regulatory Submission and Approval Process in the US** • Importance of regulatory submission packages • Types of regulatory submissions, Registration process, submission and approval	
11.15am	**Regulatory Submission and Approval Process in the EU** • Importance of regulatory submission packages • Types of regulatory submissions • Registration process, submission and approval	
12.15pm	**Lunch**	
1.15pm	**Regulatory Submission and Approval Process in ASEAN** • Importance of regulatory submission packages • Types of regulatory submissions • Registration process, submission and approval	
2:00pm	**Pre-Clinical Testing in MD Development** • Regulatory guidelines and standards for preclinical testing • Types of preclinical tests and significance in assessing device safety and efficacy	
2.45pm	**Refreshment Break**	
3.00pm	**Review of Pre-Clinical Documentation, Data, Statistical Methods and Analysis** • Key considerations in reviewing preclinical tests and documentation • Biocompatibility and functional tests	
3.45pm	**Group Activity-II** Creating pre-clinical documentation and preparing for regulatory submission	**CoRE Education Team**
5.00pm	**End**	

Day 3 – 05 August, Wednesday

Time	Topic	Speaker/ Organization
8.30am	**Registration**	
9.00am	**Individual and Group Readiness Assessments (IRA/GRA)**	**CoRE Education Team**
10.00am	**Refreshment Break**	
Session 3: Clinical Evaluation		
10.15am	**Clinical Evidence (Medical Devices)** • Overview of ISO 14155 • Clinical evidence in device development and regulatory submissions • Clinical Evaluation Report	
11.15am	**Clinical Evidence (IVDs)** • Overview of ISO 20916 • Clinical evidence in device development and regulatory submissions • ISO 23640 Stability of in vitro diagnostics	
12.15pm	**Lunch**	
1.15pm	**Practicum I** • Evaluating clinical datasets to support regulatory decisions	**CoRE Education Team**
3.00pm	**Refreshment Break**	
3.15pm	**Practicum I (cont'd)** • Evaluating clinical datasets to support regulatory decisions	**CoRE Education Team**
4.00pm	**Clinical evaluation report: Review for regulatory professionals** • Product Claims • Clinical Development Plan (CDP) • Clinical Investigation Design	
5.00pm	**End**	

Day 4 – 06 August, Thursday

Time	Topic	Speaker/ Organization
8.30am	**Registration**	
Session 4: Risk Management, Essential Principles for Medical Device Safety and Regulatory Compliance		
9.00am	**Medical Device Risk Analysis and Management – Implementing ISO 14971**	
10.00am	**Refreshment Break**	
10.15am	**Benefit-Risk Analysis for Medical Technologies** • Key processes • Compliance with Regulatory Standards • Facilitating Regulatory Approval	
11.00am	**Device Safety and Performance** • Overview of Essential Principles of Safety and Performance of Medical Device • Understanding of Essential Principles • Application of Standards	
12.00pm	**Lunch**	
1.00pm	**Brainstorming for Panel Session**	**CoRE Education Team**
1.15pm	**Practicum II** • Essential Principles of Safety and Performance	**CoRE Education Team**
3.00pm	**Refreshment Break**	
3.15pm	**Practicum II (cont'd)** • Essential Principles of Safety and Performance	**CoRE Education Team**
3.45pm	**Case Discussion II** • Annexes A (Medical Devices, Suture) and H (In Vitro Diagnostics, HIV self-test) – Identification of hazards and characteristics related to safety	**CoRE Education Team**
5.00pm	**End**	

Day 5 – 07 August, Friday

Time	Topic	Speaker/ Organization
8.30am	Registration	
9.00am	End-of-Module (EOM) Assessment	CoRE Education Team
10.00am	Refreshment break	
10.15am	Review of EOM Assessment	CoRE Education Team
10:45 am	Reflection and Peer Sharing	Dr. Rathi Saravanan CoRE, Duke-NUS Medical School
11:30 am	Networking Session	CoRE Education Team
12:15 pm	Lunch	
Session 5: Emerging trends in MedTech		
1:00 pm	Emerging Regulations for Emerging Technologies Regulatory Sandboxes and Innovation Hubs	
2.00pm	Challenges in bringing In Vitro Diagnostics into the market	
3.00pm	Refreshment Break	
3.15pm	Regulatory and Practical Challenges in Digital Biomarkers	
3.45pm	Panel Session: *Balancing Evidence, Risk, and Societal Impact in Regulatory Assessment of Emerging Medical Technologies*	
4.45pm	Workshop Conclusion	Asst. Prof James Leong Head, Health Products and Regulatory Science CoRE, Duke-NUS Medical School
5.00pm	End of GMS5008 Workshop	