GRADUATE CERTIFICATE IN MEDICAL TECHNOLOGY REGULATION

GMS5008 Regulation and Clinical Evaluation of Medical Devices

07 Jul 2025 – 11 Jul 2025

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, clinical evidence generation, and statistical analysis.

Target Audience

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

Graduate Certificate in Health Products Regulation

GMS5008 Regulation and Clinical Evaluation of Medical Devices

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Day 1 – 07 Jul, 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**	**Jaineet Arora** Education Associate CoRE, Duke-NUS Medical School
9.30am	**Brightspace Briefing and Ice-breaker activity** Brightspace familiarization Introduction of team members Goal setting	**Mr Osman Bin Mohamad** Senior Education Associate CoRE, Duke-NUS Medical School
9:55am	**Photo-taking Session: Faculty & Participants**	**Education Team, CoRE**
10.00am	**Refreshment Break**	
Session 1: Introduction to Medical Technologies & their Regulatory Principles		
10.15am	**Overview of Medical Device Regulatory Trends**	**TBD**
11.00am	**Total Product Lifecycle Journey of Medical Technologies** • Total product life cycle • Design and Development • Verification and validation	**TBD**
11.45am	**Group Activity-I** • Regulatory organisations for medical technologies and harmonization efforts	**Education Team, CoRE**
12.30pm	**Lunch**	

1:30pm	**Key Regulatory Principles for Medical Technologies** • Overview of device classification across products • Essential principles • Requirements and standards	**TBD**
2:15pm	**Fundamentals of Medical Device Classification and Conformity Assessment** • Conformity assessment • Safety and risk classification • Grouping of medical devices	**TBD**
3.15pm	**Refreshment Break**	
3.30pm	**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	**TBD**
4.15pm	**Case Discussion I** Medical Device Regulatory Failures and Lessons Learned	**Education Team, CoRE**
5.30pm	**End**	

Day 2 – 08 Jul, 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	TBD
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	TBD
11.15pm	**Regulatory Submission and Approval Process in the EU** • Importance of regulatory submission packages • Types of regulatory submissions • Registration process, submission and approval	TBD
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	TBD
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	TBD
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	TBD
3.45pm	**Group Activity-II** Creating pre-clinical documentation and preparing for regulatory submission	TBD
5.30pm	**End**	

Day 3 – 09 Jul, 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	**TBD**
11.15am	**Clinical Evidence (IVDs)** • Overview of ISO 20916 • Clinical evidence in device development and regulatory submissions • ISO 23640 Stability of in vitro diagnostics	**TBD**
12.15pm	**Lunch**	
1.15pm	**Practicum I** • Evaluating clinical datasets to support regulatory decisions	**TBD**
3.00pm	**Refreshment Break**	
3.15pm	**Practicum I (cont'd)** • Evaluating clinical datasets to support regulatory decisions	**TBD**
4.30pm	**Clinical evaluation report: Review for regulatory professionals** • Product Claims • Clinical Development Plan (CDP) • Clinical Investigation Design	**TBD**
5.30pm	**End**	

Day 4 – 10 Jul, 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**	**TBD**
10.00am	**Refreshment Break**	
10.15am	**Benefit-Risk Analysis for Medical Technologies** • Key processes • Compliance with Regulatory Standards • Facilitating Regulatory Approval	**TBD**
11.00am	**Device Safety and Performance** • Overview of Essential Principles of Safety and Performance of Medical Device • Understanding of Essential Principles • Application of Standards	**TBD**
12.00pm	**Lunch**	
1.00pm	**Practicum II** • Essential Principles of Safety and Performance	**TBD**
3.00pm	**Refreshment Break**	
3.15pm	**Practicum II (cont'd)** • Essential Principles of Safety and Performance	**TBD**
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	**TBD**
5.0pm	**End**	

Day 5 – 11 Jul, 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
Session 5: Emerging trends in MedTech		
10:45am	Challenges in bringing In Vitro Diagnostics into the market	TBD
11.45am	Brainstorming for Panel Session	CoRE Education Team
12.00pm	Lunch	
1.00pm	Emerging Regulations for Emerging Technologies Regulatory Sandboxes and Innovation Hubs	TBD
2.00pm	Navigating the Regulatory Landscape for Combination Products: Compliance, Challenges, and Market Approval	TBD
2.45pm	Refreshment Break	
3.00pm	Cybersecurity Requirements for Connected Medical Devices	TBD
3.30pm	Panel Session: • Navigating Regulatory Pathways for Emerging Medical Technologies: Ensuring Innovation with Compliance	TBD
4.30pm	Reflection and Peer Sharing	**Dr Rathi Saravanan** Lead Education Associate Lead, Graduate Certificate Programmes CoRE, Duke-NUS Medical School
5.15pm	Workshop Conclusion	**Prof Silke Vogel** Senior Associate Dean- Graduate Studies Deputy Director- Centre of Regulatory Excellence Head- Centre for Lifelong Learning Duke-NUS Medical School
5.30pm	End of GMS5008 Workshop	