GRADUATE CERTIFICATE IN MEDICAL TECHNOLOGY REGULATION

GMS5008 Regulation and Clinical Evaluation of Medical Devices

03 Aug 2026 – 07 Aug 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

Graduate Certificate in Medical Technology Regulation
GMS5008: Regulation and Clinical Evaluation of Medical Devices
03 Aug 2026 – 07 Aug 2026

Day 1 – 03 Aug 2026, 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	**Mr. Jaineet Arora** CoRE, Duke-NUS Medical School
9.55am	**Photo-taking Session: Faculty & Participants**	**Mr. Jaineet Arora** CoRE, Duke-NUS Medical School
10.00am	**Refreshment Break**	
Session 1: Introduction to Medical Technologies & their Regulatory Principles		
10.15am	**Overview of Medical Device Regulatory Trends**	**Mr. Gaurav Verma** Regional Regulatory Affairs Director Becton Dickinson (BD)
11.00am	**Total Product Lifecycle Journey of Medical Technologies** • Total product life cycle • Design and Development • Verification and validation	**Mr. Gaurav Verma** Becton Dickinson (BD)
11.45am	**Group Activity-I** • Regulatory organisations for medical technologies and harmonization efforts	**Ms. Faith Tan** Education Associate II CoRE, Duke-NUS Medical School **Asst. Prof James Leong** Head, Health Products and Regulatory Science CoRE, Duke-NUS Medical School **CoRE Education Team**
12.30pm	**Lunch**	
1.30pm	**Fundamentals of Medical Device Classification** • Overview of device classification across products • Safety and risk classification	**Mr. Jaineet Arora** CoRE, Duke-NUS Medical School

	• Grouping of medical devices	
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	**Mr. Charles Lim Chee Hong** Regulatory Affairs Manager Thermo Fisher Scientific
3.00pm	**Refreshment Break**	
3.15pm	**Case Discussion I** Medical Device Regulatory Failures and Lessons Learned	**Mr. Jaineet Arora** CoRE, Duke-NUS Medical School **CoRE Education Team**
5.00pm	**End**	

Day 2 – 04 Aug 2026, 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	**Mr. Sharad Shukla** Director Regulatory Affairs, MedTech Head, Regulatory Affairs, SEA APAC Regulatory Affairs Lead Johnson & Johnson
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	**Mr. Sharad Shukla** Johnson & Johnson
11.15am	**Regulatory Submission and Approval Process in the EU** • Importance of regulatory submission packages • Types of regulatory submissions • Registration process, submission and approval	**Mr. Sharad Shukla** Johnson & Johnson
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	**Ms. Chrissy Huang** Head Regulatory Affairs Emerging Markets Ascensia Diabetes Care
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	**Ms. Surbhi Gupta** Senior Manager, Clinical & Regulatory Affairs Advanced Ophthalmic Innovations (AOI)
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	**Ms. Surbhi Gupta** Advanced Ophthalmic Innovations (AOI)
3.45pm	**Group Activity-II** Pre-Clinical Test Planning and Data Package Review for Regulatory Submission	**Ms. Surbhi Gupta** Advanced Ophthalmic Innovations (AOI) **Mr. Jaineet Arora** CoRE, Duke-NUS Medical School **Dr. Rathi Saravanan** CoRE, Duke-NUS Medical School **CoRE Education Team**
5.00pm	**End**	

Day 3 – 05 Aug 2026, Wednesday

Time	Topic	
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	**Ms. Tee Wei Xuan** Senior Regulatory Specialist Medical Device Cluster, Health Sciences Authority (HSA)
11.15am	**Clinical Evidence (IVDs)** • Overview of ISO 20916 • Clinical evidence in device development and regulatory submissions • ISO 23640 Stability of in vitro diagnostics	**Ms. Beverly Liew** Senior Assistant Director Medical Devices Cluster, HSA
12.15pm	**Lunch**	
1.15pm	**Practicum I** • Evaluating clinical datasets to support regulatory decisions	**Ms. Tee Wei Xuan** HSA **Ms. Beverly Liew** HSA **Dr. Lim Yu Jin** Chief Executive Officer and Chief Technology Officer Osteopore **Mr. Jaineet Arora** CoRE, Duke-NUS Medical School **CoRE Education Team**
3.00pm	**Refreshment Break**	
3.15pm	**Practicum I (cont'd)** • Evaluating clinical datasets to support regulatory decisions	**Ms. Tee Wei Xuan** HSA **Ms. Beverly Liew** HSA **Dr. Lim Yu Jin** Osteopore **Mr. Jaineet Arora** CoRE, Duke-NUS Medical School **CoRE Education Team**
4.00pm	**Clinical evaluation report: Review for regulatory professionals** • Product Claims • Clinical Development Plan (CDP) • Clinical Investigation Design	**Dr. Lim Yu Jin** Chief Executive Officer and Chief Technology Officer Osteopore
5.00pm	**End**	

Day 4 – 06 Aug 2026, 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**	**Ms. Tan Hwee Ee** Founder DH RegSys Consulting Pte Ltd
10.00am	**Refreshment Break**	
10.15am	**Benefit-Risk Analysis for Medical Technologies** • Key processes • Compliance with Regulatory Standards • Facilitating Regulatory Approval	**Ms. Yvonne Lee** Head of Real-World Evidence, Asia Pacific IQVIA
11.00am	**Device Safety and Performance** • Overview of Essential Principles of Safety and Performance of Medical Device • Understanding of Essential Principles • Application of Standards	**Ms. Tan Hwee Ee** DH RegSys Consulting Pte Ltd
12.00pm	**Lunch**	
1.00pm	**Brainstorming for Panel Session**	**CoRE Education Team**
1.15pm	**Practicum II** • Essential Principles of Safety and Performance	**Ms. Tan Hwee Ee** DH RegSys Consulting Pte Ltd **Mr. Jaineet Arora** CoRE, Duke-NUS Medical School **Asst. Prof James Leong** CoRE, Duke-NUS Medical School **CoRE Education Team**
3.00pm	**Refreshment Break**	
3.15pm	**Practicum II (cont'd)** • Essential Principles of Safety and Performance	**Ms. Tan Hwee Ee** DH RegSys Consulting Pte Ltd **Mr. Jaineet Arora** CoRE, Duke-NUS Medical School **Asst. Prof James Leong** CoRE, Duke-NUS Medical School **CoRE Education Team**
3.45pm	**Case Discussion II** • Annexes A and H – Identification of hazards and characteristics related to safety	**Ms. Tan Hwee Ee** DH RegSys Consulting Pte Ltd **Mr. Jaineet Arora** CoRE, Duke-NUS Medical School **CoRE Education Team**
5.00pm	**End**	

Day 5 – 07 Aug 2026, 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
10.45am	Reflection and Peer Sharing	**Dr. Rathi Saravanan** CoRE, Duke-NUS Medical School
11.45am	Networking Session	**Ms. Faith Tan** CoRE, Duke-NUS Medical School **Mr. Jaineet Arora** CoRE, Duke-NUS Medical School **CoRE Education Team**
12.30pm	Lunch	
Session 5: Emerging trends in MedTech		
1.30pm	**Emerging Regulations for Emerging Technologies Regulatory Sandboxes and Innovation Hubs**	**Asst Prof. Kavitha Palaniappan** Project Lead Health Services Regulation Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
2.30pm	**Challenges in bringing In Vitro Diagnostics into the market**	**A/Prof. Jack Wong** Chief Executive Officer- RNAscence Biotechnology Founder- ARPA - Asia Regulatory Professionals Association
3.30pm	Refreshment Break	
3.45pm	**Panel Session:** *Balancing Evidence, Risk, and Impact in Regulatory Assessment of Emerging Medical Technologies*	*Moderator*: **Asst. Prof James Leong** CoRE, Duke-NUS Medical School *Panelists:* **A/Prof. Jack Wong** RNAscence Biotechnology **Asst Prof. Kavitha Palaniappan** CoRE, Duke-NUS Medical School **Mr. Ang Wei Jun** Quality and Regulatory Manager Diagnostics Development Hub (DxD Hub)
4.45pm	**Workshop Conclusion**	**Asst. Prof James Leong** CoRE, Duke-NUS Medical School
5.00pm	End of GMS5008 Workshop	