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 and clinical evidence generation.

Target Audience

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

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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**	**Mr. Jaineet Arora** Education Associate II 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**	**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	**Education Team, CoRE**
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	**Ms. Sugashine Jeganathan** Regulatory Affairs Manager – BD Interventional Becton Dickinson (BD)
3.00pm	**Refreshment Break**	
3.15pm	**<u>Case Discussion I</u>** Medical Device Regulatory Failures and Lessons Learned	**Education Team, CoRE**
5.00pm	**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	**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	**Mr. Andrew See** Senior Regulatory Affairs & Business Development Consultant PureHSA Pte Ltd
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	**Mr. Andrew See** PureHSA Pte Ltd
3.45pm	**Group Activity-II** Creating pre-clinical documentation and preparing for regulatory submission	**Mr. Andrew See** PureHSA Pte Ltd
5.00pm	**End**	

Day 3 – 09 Jul, Wednesday

Time	Topic	
8.30am	**Registration**	
9.00am	**Individual and Group Readiness Assessments (IRA/GRA)**	**Education Team, CoRE**
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. Beverly Liew** Senior Assistant Director, Medical Devices Innovation Office 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. Liu Shuhui** Senior Regulatory Specialist, Medical Devices Cluster Health Sciences Authority (HSA)
12.15pm	**Lunch**	
1.15pm	**Practicum I** • Evaluating clinical datasets to support regulatory decisions	**Ms. Beverly Liew** Health Sciences Authority (HSA) **Ms. Liu Shuhui** Health Sciences Authority (HSA)
3.00pm	**Refreshment Break**	
3.15pm	**Practicum I (cont'd)** • Evaluating clinical datasets to support regulatory decisions	**Ms. Beverly Liew** Health Sciences Authority (HSA) **Ms. Liu Shuhui** Health Sciences Authority (HSA)
4.00pm	**Clinical evaluation report: Review for regulatory professionals** • Product Claims • Clinical Development Plan (CDP) • Clinical Investigation Design	**Ms. Danielle Giroud** CEO MD-Clinicals SA
5.00pm	**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**	**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**	**Education Team, CoRE**
1.15pm	**Practicum II** • Essential Principles of Safety and Performance	**Ms. Tan Hwee Ee** DH RegSys Consulting Pte Ltd
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
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	**Ms. Tan Hwee Ee** DH RegSys Consulting Pte Ltd
5.00pm	**End**	

Day 5 – 11 Jul, Friday

Time	Topic	Speaker/ Organization
8.30am	Registration	
9.00am	End-of-Module (EOM) Assessment	Education Team, CoRE
10.00am	Refreshment break	
10.15am	Review of EOM Assessment	Education Team, CoRE
10:45 am	Reflection and Peer Sharing	**Dr. Rathi Saravanan** CoRE, Duke-NUS Medical School
11:30 am	Networking Session	**Mr. Osman Mohamed** CoRE, Duke-NUS Medical School
12:15 pm	Lunch	
Session 5: Emerging trends in MedTech		
1:00 pm	**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
2.00pm	**Challenges in bringing In Vitro Diagnostics into the market**	**A/Prof. Jack Wong** Chief Executive Officer- RNAscence Biotechnology Founder- ARPA - Asia Regulatory Professionals Association
3.00pm	Refreshment Break	
3.15pm	**Cybersecurity Requirements for Connected Medical Devices**	**Mr. Leonard Ong** Director, Sector Governance (SGO) Synapxe
3.45pm	**Panel Session:** *Navigating Regulatory Pathways for Emerging Medical Technologies: Ensuring Innovation with Compliance*	**Moderator: Asst Prof. James Leong** Head- Health Products & Regulatory Science Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School **Mr. Henry Johnson** Principal Manager A*STAR **A/Prof. Jack Wong** RNAscence Biotechnology **Mr. Leonard Ong** Synapxe

4.45pm	**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
5.00pm	**End of GMS5008 Workshop**	