GRADUATE CERTIFICATE IN MEDICAL TECHNOLOGY REGULATION

GMS5008 Regulation and Clinical Evaluation of Medical Devices

12 Aug 2024 – 16 Aug 2024

WORKSHOP PROGRAMME

Learning Outcomes

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

- Describe the regulatory concepts and major frameworks governing the development and regulatory management of medical devices and technologies
- List the key regulatory guidance and requirements
- Explain the important considerations for assessing the clinical performance of medical devices and technologies.

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 – 12 Aug, Mon

Time	Topic	Speaker/ Organization
8.30am	**Registration**	
9.00am	**Welcome**	**Dr Rathi Saravanan** Lead Education Associate Lead, Graduate Certificate Programmes Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
9.10am	**Course overview**	**Dr Gideon Praveen Kumar** Associate Director Strategy & Business Excellence Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
Session 1: Introduction & Overview		
9.30am	**Medical device regulations in the context of healthcare** Understand the role of medical device regulations and its contributions to the healthcare environment	**Mr Michael Gropp** Advisory Board Member and Visiting Expert Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
10.30am	**Refreshment Break**	
10.45am	**Overview of development journey of medical technologies** • Total product life cycle • Design and Development • Verification and validation • Building the QMS along the development journey	**Mr Gaurav Verma** Regional Regulatory Affairs Director Becton Dickinson (BD)
11.30am	**Group Activity** Regulatory organisations for medical technologies and harmonization efforts	**CoRE**
12.30pm	**Lunch**	

1.30pm	**Key regulatory principles for medical technologies** • Overview of device classification across products • Essential principles • Requirements and standards	**Ms Mariammah Krishnasamy** Principal Assistant Director Medical Device Authority (MDA) Malaysia
2.15pm	**Key regulatory principles for medical technologies** • Conformity assessment • Safety and risk classification • Grouping of medical devices	**Ms Mariammah Krishnasamy** Medical Device Authority (MDA) Malaysia
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	**Mr Winson Teng** Global Regulatory Intelligence Manager Becton Dickinson (BD)
4.15pm	**Quiz**	
4.45pm	**Brightspace briefing**	**Ms Osman bin Mohamad** Senior Education Associate Lead, Online Courses Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
5.00pm	**End**	

Day 2 – 13 Aug, Tue

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	**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
10.45am	**Refreshment break**	
11.00am	**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
11.45am	**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
12.30pm	**Lunch**	
1.30pm	**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	**Dr T S Kumaravel** Chairman GLR Laboratories Pvt Ltd
2.15pm	**Review of pre-clinical documentation, data, statistical methods and analysis** • Key considerations in reviewing preclinical tests and documentation • Biocompatibility and functional tests • Understanding the statistical methods and analysis used in pre-market regulatory submissions	**Dr T S Kumaravel** GLR Laboratories Pvt Ltd
3.00pm	**Refreshment Break**	
3.15pm	**Practicum I** • Creating pre-clinical documentation and preparing for regulatory submission	**Dr T S Kumaravel** GLR Laboratories Pvt Ltd
5.00pm	**End**	

Day 3 – 14 Aug, Wed

Time	Topic	Speaker/ Organization
8.30am	**Registration**	
9.00am	**Individual and Group Readiness Assessment**	
Session 3: Clinical evaluation		
10.00am	**Clinical Evidence (Medical Devices)** • Overview of ISO 14155 • Clinical evidence in device development and regulatory submissions • Clinical Evaluation Report	**Ms Mariammah Krishnasamy** Medical Device Authority (MDA) Malaysia
11.00am	**Refreshment Break**	
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 Mariammah Krishnasamy** Medical Device Authority (MDA) Malaysia
12.00pm	**Lunch**	
1.00pm	**Practicum II** Evaluating clinical datasets to support regulatory decisions	**Ms Mariammah Krishnasamy** Medical Device Authority (MDA) Malaysia
3.00pm	**Refreshment Break**	
3.15pm	**Practicum II (cont'd)** Evaluating clinical datasets to support regulatory decisions	**Ms Mariammah Krishnasamy** Medical Device Authority (MDA) Malaysia
4.00pm	**Clinical evaluation report: Review for regulatory professionals**	**Ms Danielle Giroud** CEO MD-Clinicals SA
5.00pm	**End**	

Day 4 – 15 Aug, Thursday

Time	Topic	Speaker/ Organization
8.30am	**Registration**	
Session 3: Clinical evaluation		
9.00am	**Medical device risk analysis and management – Implementing ISO 14971**	**Ms Tan Hwee Ee** DH RegSys Private Limited
10.00am	**Benefit-risk analysis for medical technologies** • Key processes • Compliance with Regulatory Standards • Facilitating Regulatory Approval	**Ms Mariammah Krishnasamy** Medical Device Authority (MDA) Malaysia
10.45am	**Refreshment Break**	
11.00am	**Device Safety and Performance** • Understand the safety of medical devices, based on Pre-Market evaluation, assessment, and analysis of clinical data • Verify clinical safety and performance when used as intended by the manufacturer • Singapore Essential Principles on Safety and Performance (EPSP)	**Ms Tan Hwee Ee** DH RegSys Private Limited
12.00pm	**Lunch**	
1.00pm	**Practicum III** • Essential Principles on Safety and Performance	**Ms Mariammah Krishnasamy** Medical Device Authority (MDA) Malaysia **Ms Tan Hwee Ee** DH RegSys Private Limited
3.00pm	**Refreshment Break**	
3.15pm	**Practicum III (cont'd)** • Essential Principles on Safety and Performance	**Ms Mariammah Krishnasamy** Medical Device Authority (MDA) Malaysia **Ms Tan Hwee Ee** DH RegSys Private Limited
3.45pm	**Case Discussion** 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 Private Limited
5.00pm	**End**	

Day 5 – 16 Aug, Friday

Time	Topic	Speaker/ Organization
8.30am	**Registration**	
9.00am	**End-of-Module (EOM) Assessment**	
10.00am	**Review of EOM**	
10.30am	**Refreshment break**	
10.45am	**Peer Learning**	**Dr Rathi Saravanan** CoRE Duke-NUS Medical School
11.30am	**Brainstorming for Panel Session**	
12.15pm	**Lunch** **Helix Immersion Programme**	**Dr Vanessa Ding** Deputy Director, Talent SGInnovate
Session 5: Emerging trends in MedTech		
1.15pm	**Emergence of smart materials and innovative medical devices**	**Dr Gideon Praveen Kumar** CoRE Duke-NUS Medical School
2.00pm	**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
2.45pm	**Refreshment Break**	
3.00pm	**Regulatory challenges in innovative medical technologies**	TBC
3.30pm	**Challenges in bringing In Vitro Diagnostics into market**	**Ms Ho Yuan Lu** Vice President Outreach & Talent Development DxDHub
4.00pm	**Panel Session** Addressing challenges in bringing medical technologies into ASEAN	
4.45pm	**Workshop Conclusion**	**Asst Prof James Leong** Head, Health Products and Regulatory Science Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
5.00pm	**End**	