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
- Articulate the key regulatory guidance and requirements
- Classify 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**	
9.10am	**Course overview and Brightspace Briefing**	
Session 1: Introduction & Overview		
9.30am	**Overview and regulatory landscape of medical technologies** • Definition and classification of medical technologies • Local, Regional and Global regulatory frameworks	
10.30am	**Refreshment Break**	
10.45am	**Overview of development journey of medical technologies** • Design and Development • Verification and validation	
11.30am	**Regulatory organisations for medical technologies and harmonization efforts** • Roles of IMDRF and GHWP • WHO • Regional associations	
12.30pm	**Lunch**	
1.30pm	**Key regulatory principles for medical technologies** • Overview of device classification across products • Essential principles • Requirements and standards	
2.15pm	**Key regulatory principles for medical technologies** • Conformity assessment • Safety and risk classification • Grouping of technologies	
3.15pm	**Refreshment Break**	
3.30pm	**Medical device product life cycle** • Introduction to medical device product life cycle • Relation to quality management systems • Relation to post-market activities	
4.15pm	**Quiz**	
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	
10.00am	**Regulatory submission and approval process in the US** • Importance of regulatory submission packages • Types of regulatory submissions • Registration process, submission and approval	
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	
11.45am	**Regulatory submission and approval process in ASEAN** • Importance of regulatory submission packages • Types of regulatory submissions • Registration process, submission and approval	
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	
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	
3.00pm	**Refreshment Break**	
3.15pm	**Practicum I** • Creating pre-clinical documentation and preparing for regulatory submission	
5.00pm	**End**	

Day 3 – 14 Aug, Wed

Time	Topic	Speaker/ Organization
8.30am	**Registration**	
9.00 am	**Individual and Group Readiness Assessment**	
Session 3:	**Clinical evaluation**	
10.00am	**Overview of Clinical evaluation** • Importance of clinical evaluation in medical device development (verification and validation) • Regulatory requirements and guidelines	
10.45am	**Refreshment Break**	
11.00am	**ISO 14155 - Clinical investigation of medical devices for human subjects** • Design, conducting, recording and reporting of clinical investigations carried out in human subjects • Good Clinical Practices (GCP)	
11.45am	**Clinical Evaluation Report (CER)** • How to write a CER • Compilation of findings • Regulatory Submission	
12.30pm	**Lunch**	
1.30pm	**Clinical Evidence (Medical Devices & SaMD)** • Clinical evidence in device development and regulatory submissions	
2.15pm	**Clinical Evidence (IVDs)** • Clinical evidence in device development and regulatory submissions • ISO 23640 Stability of in vitro diagnostics	
3.00pm	**Refreshment Break**	
3.15pm	**Practicum II** • How to assemble a clinical evaluation report for regulatory submissions	
5.00pm	**End**	

Day 4 – 15 Aug, Thursday

Time	Topic	Speaker/ Organization
8.30am	**Registration**	
Session 3: Clinical evaluation		
9.00am	**Key guidelines and standards for clinical evaluation of medical technologies**	
10.00am	**Clinical evaluation methods, including literature review and clinical investigations** • Literature Review • Clinical Investigations • Post-Market Surveillance	
10.45am	**Refreshment Break**	
11.00am	**Risk benefit assessment for Medical Technologies – Industry perspective**	
11.45am	**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	
12.30pm	**Lunch**	
1.30pm	**Medical device risk analysis and management – Implementing ISO14971**	
2.15pm	**Risk-benefit analysis for medical technologies** • Key processes • Compliance with Regulatory Standards • Facilitating Regulatory Approval	
3.00pm	**Refreshment Break**	
3.15pm	**Practicum III** • Evaluating clinical datasets to support regulatory decisions	
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 Questions	
10.30am	Refreshment break	
10.45am	Peer Learning	
11.30am	Brainstorming for Panel Session	
12.15pm	Lunch	
Session 5: Emerging trends in MedTech		
1.15pm	Emergence of smart materials and innovative medical devices	
2.00pm	Emerging technologies in MedTech Regulations • Regulatory Sandboxes and Innovation Hubs • Regulations for 3D Printing • Regulations for patient specific devices	
2.45pm	Refreshment Break	
3.00pm	Panel Session • Review of clinical evaluation, its importance in regulatory compliance and regulatory approval processes • Insights and 'real live' examples from the experts	
4.15pm	Workshop Conclusion	
5.00 pm	End	