

GRADUATE CERTIFICATE IN MEDICAL TECHNOLOGY REGULATION
**GMS5009 Manufacturing and Quality Management System for
Medical Devices**

16 – 20 November 2026

Venue: Duke-NUS Medical School, Training Room 5C

WORKSHOP PROGRAMME

Learning outcomes

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

- Explain the fundamentals of Good Manufacturing Practices for medical technology
- Articulate the concepts and basis of Quality Management Systems in relation to regulatory requirements (in particular the ISO 13485)
- Describe key quality management processes for raw materials, sites, and facilities in manufacturing of medical devices

Target Audience

- Medical devices and in-vitro diagnostics engineers, researchers, and regulatory/quality assurance professionals.

Day 1 – 16 November 2026, Monday

Time	Topic	Speaker/ Organization
8.30am	Registration	
9.00am	Introduction to Graduate Certificate Programme	Dr. Rathi Saravanan Lead Education Associate Centre of Regulatory Excellence (CoRE), Duke-NUS Medical School
9.15am	Workshop Briefing	Ms. Faith Tan Education Associate CoRE, Duke-NUS Medical School
9.30am	Brightspace Briefing and Ice Breaker Activity	Ms. Faith Tan Education Associate CoRE, Duke-NUS Medical School
9.55am	Photo Taking Session	CoRE Education Team
10.00am	Refreshment break	
Session 1: Foundation of Quality Management System (QMS)		
10.15am	Overview of Medical Device Standards <ul style="list-style-type: none"> Examples of standards applicable to medical devices and how they support regulatory compliance and safe manufacturing 	
11.00am	Group Activity 1: Risk Classification and QMS <ul style="list-style-type: none"> Understand the relationship between risk class and QMS expectations 	CoRE Education Team
12.15pm	Lunch	
1.15pm	QMS Documentation: Requirements and Structure <ul style="list-style-type: none"> Focus on ISO13485 Clause 4.2 and traceability Quality Manual, policies, procedures and records 	
2.00pm	Regulatory Inspections of QMS <ul style="list-style-type: none"> ISO1911 principles for audits 	
2.45pm	Documentation Requirements (Clause 4.2) <ul style="list-style-type: none"> Overview of quality manual, medical device file Document control, record-keeping and retention Good Documentation Practices 	
3.30pm	Refreshment break	
3.45pm	Documentation Requirements (Clause 4.2) <ul style="list-style-type: none"> Overview of quality manual, medical device file Document control, record-keeping and retention Good Documentation Practices 	
4.30pm	Resource Management (Clause 6) <ul style="list-style-type: none"> Human resources Controlled environments e.g., cleanroom 	

requirements

5.30pm End

Day 2 – 17 November 2026, Tuesday

Time	Topic	Speaker/ Organization
8.30am	Registration	
9.00am	Human Factors and Usability Engineering <ul style="list-style-type: none"> • Overview of IEC62366 • Human Error as a root cause • Clause 7.2 	
9.45am	Group Activity 2	CoRE Education Team
Session 2: Quality Control and Assurance		
10.30am	Refreshment break	
10.45am	Supplier Controls <ul style="list-style-type: none"> • Supplier selection and qualification • Supplier audits and performance monitoring 	
11.30am	Ensuring Traceability <ul style="list-style-type: none"> • Expand on clause 4.2 (GDP) • Types of records to maintain for specific devices (e.g., implantable vs other device types) 	
12.15pm	Principles of Risk Management <ul style="list-style-type: none"> • Overview of ISO14971 and risk-based approach • How it links to ISO13485 	
1.15pm	Lunch	
2.15pm	Practicum 1: Risk Management in Manufacturing	
3.45pm	Refreshment Break	
4.00pm	Practicum 1 (Cont.)	
5.30pm	End	

Day 3 – 18 November 2026, Wednesday

Time	Topic	Speaker/ Organization
8.30am	Registration	
9.00 am	Individual and Group Readiness Assessment (IRA/GRA)	CoRE Education Team
10.15a m	Refreshment Break	
Session 3: Manufacturing Practices and Process Controls		
10.30a m	Design & Development Controls (Clause 7.3) <ul style="list-style-type: none"> Requirements for each stage, from planning to inputs & outputs, review, verification, validation and transfer How to control D&D changes 	
11.15a m	Production and Process Controls <ul style="list-style-type: none"> SOPs for production In-process controls and monitoring Validation and verification of processes (Clause 7.5.6) 	
12.15p m	Lunch	
1.15pm	Group Activity 3	CoRE Education Team
2.15pm	Process Validation <ul style="list-style-type: none"> What is process validation? IQ/OQ/PQ framework Developing validation protocols and reports 	
3.00pm	Practicum 2: Process validation	
3.30pm	Refreshment Break	
3.45pm	Practicum 2 (cont.)	
5.30pm	End	

Day 4 – 19 November 2026, Thursday

Time	Topic	Speaker/ Organization
8.30am	Registration	
Session 4: Continuous Improvement of the QMS		
9.00am	Nonconforming Product Controls <ul style="list-style-type: none"> ISO13485 Clause 8.2.4 Planning a risk-based internal audit program 	
10.00am	Refreshment Break	
10.15am	CAPA and Improvements <ul style="list-style-type: none"> ISO13485 Clauses 8.5.1 – 8.5.3 What are the triggers for CAPA 	
11.00am	Post-Market Surveillance Activities Examples of PMS practices	
11.45am	Group Activity 4: RWE for Post-Market Surveillance	
12.45pm	Lunch	
2.00pm	Using inspections for continuous improvement of QMS <ul style="list-style-type: none"> Sampling plans (AQL) Tolerance vs. specification Visual inspection techniques 	
2.45pm	Case Discussion 1 <ul style="list-style-type: none"> Contract manufacturing 	
3.45pm	Refreshment Break	
4.00pm	Case Discussion 1 (cont.)	
5.00pm	End	

Day 5 – 20 November 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	EOM Review	
Session 5: Trends and Innovation in QMS and Manufacturing		
10.45am	3D Printed Medical Devices	
11.30am	General Criteria for Medical Testing Laboratories <ul style="list-style-type: none"> • ISO15189: Medical laboratories – Particular requirements for quality and competence • Med lab services include arrangements for requisition, patient preparation, patient identification, collection of samples, transportation, storage, processing and examination of clinical samples, together with subsequent validation, interpretation, reporting and advice, in addition to the considerations of safety and ethics in medical laboratory work 	
12.30pm	Lunch	
1.30pm	Quality Management Systems for Lab Developed Tests (LDTs) <ul style="list-style-type: none"> • QMS components related to LDTs • Differences in QMS implementation: clinical labs vs. commercial manufacturers 	
2.30pm	Introduction to Medical Device Single Audit Programme (MDSAP)	
3.30pm	Refreshment Break	
3.45pm	Reflection and Peer Sharing	
4.45pm	Closing Remarks	
5.00pm	End	