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.

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Day 1 – 16 November 2026, Mon

Time	Topic	Speaker/ Organization
8.30am	**Registration**	
9.00am	**Introduction to Graduate Certificate Programme**	**CoRE Education Team**
9.15am	**Workshop Briefing** • Programme overview • Brightspace briefing • Ice breaker activity	**CoRE Education Team**
9.55am	**Photo Taking Session**	**CoRE Education Team**
8.30am	**Registration**	
10.00am	**Refreshment break**	
Session 1:	**Foundation of Quality Management System (QMS)**	
10.15am	**Overview of Medical Device Standards** • 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** • Understand the relationship between risk class and QMS expectations	**CoRE Education Team**
12.30pm	**Lunch**	
1.30pm	**Overview of ISO 13485** • General flow of the standard • Key definitions and common terms • Quiz (ungraded)	
2.15pm	**QMS Documentation: Requirements and Structure** • Focus on ISO13485 Clause 4.2 and traceability • Quality Manual, policies, procedures and records	
3.15pm	**Regulatory Inspections of QMS** • ISO1911 principles for audits • Audit inspections and concerns	
4.00pm	**Refreshment break**	
4.15pm	**Resource Management (Clause 6)** • Human resources	
5.00pm	**End**	

Day 2 – 17 November 2026, Tue

Time	Topic	Speaker/ Organization
8.30am	**Registration**	
9.00am	**Human Factors and Usability Engineering** • Overview of IEC62366 • Human Error as a root cause • Designing of workstations, SOPs, labels	
9.45am	**Group Activity 2**	**CoRE Education Team**
Session 2: Quality Control and Assurance		
10.30am	**Refreshment break**	
10.45am	**Supplier Controls** • Supplier selection and qualification • Supplier audits and performance monitoring	
11.30am	**Batch Release and Certification** • Introduction to batch release and its role in MD manufacturing • Examples of tests and evaluations to verify that the product conformity • Routine and non-routine batch release	
12.15pm	**Lunch**	
1.15pm	**Principles of Risk Management** • Overview of ISO14971 and risk-based approach How it links to ISO13485	
2.15pm	**Practicum 1: Risk Management in Manufacturing**	
3.45m	**Refreshment Break**	
4.00pm	**Practicum 1 (Cont.)**	
5.30pm	**End**	

Day 3 – 18 November 2026, Wed

Time	Topic	Speaker/ Organization
8.30am	Registration	
9.00 am	Individual and Group Readiness Assessment (IRA/GRA)	CoRE Education Team
10.15am	Refreshment Break	
Session 3: Manufacturing Practices and Process Controls		
10.30am	**Design & Development Controls (Clause 7.3)** • Requirements for each stage, from planning to inputs & outputs, review, verification, validation and transfer • How to control D&D changes	
11.15am	**Production and Process Controls** • SOPs for production • In-process controls and monitoring • Validation and verification of processes (Clause 7.5.6)	
12.15pm	Lunch	
1.15pm	**Group Activity 3**	CoRE Education Team
2.15pm	**Process Validation** • 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, Thurs

Time	Topic	Speaker/ Organization
8.30am	**Registration**	
Session 4: Continuous Improvement of the QMS		
9.00am	**Nonconforming Product Controls** • ISO13485 Clause 8.2.4 • Planning a risk-based internal audit program	
9.45am	**Refreshment Break**	
10.00am	**CAPA and Improvements** • ISO13485 Clauses 8.5.1 – 8.5.3 • What are the triggers for CAPA	
10.45am	**Risk-Based Internal Audits** • Clause 8.2.4: rules for internal audits • Risk-based auditing Planning a risk-based internal audit program	
11.45am	**Post-Market Surveillance Activities** Examples of PMS practices	
12.30pm	**Lunch**	
1.30pm	**Group Activity 4: RWE for Post-Market Surveillance**	
2.30pm	**Using inspections for continuous improvement of QMS** • Sampling plans (AQL) • Tolerance vs. specification Visual inspection techniques	
3.15pm	**Case Discussion 1** • Contract manufacturing	
3.45pm	**Refreshment Break**	
4.00pm	**Case Discussion 1 (cont.)**	
5.15pm	**End**	

Day 5 – 20 November 2026, Fri

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 • 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) • QMS components related to LDTs • Differences in QMS implementation: clinical labs vs. commercial manufacturers	
2.30pm	Transition to Industry 4.0	
3.30pm	Refreshment Break	
3.45pm	Reflection and Peer Sharing	
4.45pm	Closing Remarks	
5.00pm	End	