GRADUATE CERTIFICATE IN MEDICAL TECHNOLOGY REGULATION

GMS5009 Manufacturing and Quality Management System for Medical Devices

17 – 21 November 2025

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 – 17 November 2025, Mon

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**	
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	**Dr. Debbie Ko** Regulatory Consultant Medical Device Cluster, Health Sciences Authority
11.15am	**Group Activity 1: Risk Classification and QMS** • Understand the relationship between risk class and QMS expectations	**CoRE Education Team**
12.30pm	**Lunch**	
1.30pm	**Goal Setting Session**	**Dr. Rathi Saravanan** Lead Education Associate Centre of Regulatory Excellence (CoRE), Duke-NUS Medical School
1.45pm	**QMS Documentation: Requirements and Structure** • Focus on ISO13485 Clause 4.2 and traceability • Quality Manual, policies, procedures and records	**Mr. Viknesvaran Kandasamy** Manager, Quality Systems Insulet Malaysia
2.45pm	**Regulatory Inspections of QMS** • Based on ISO19011 • Types of inspections	**Mr. Viknesvaran Kandasamy** Manager, Quality Systems Insulet Malaysia
3.45pm	**Refreshment Break**	
4.00pm	**Controlled Environments for Device Quality** • Cleanroom requirements, particle monitoring, gowning, microbial control, etc.	**Mr. Viknesvaran Kandasamy** Manager, Quality Systems Insulet Malaysia
5.00pm	**End**	

Day 2 – 18 November 2025, 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	**Mr. Soma Sundaram** Global Program Management Lead, MedTech Beyonics Pte Ltd
Session 2: Quality Control and Assurance		
10.00am	**Refreshment break**	
10.15am	**Personnel Training and Competence** • ISO13485 Clause 6	**Mr. Nichol Lim** Vice President, Services Standard
11.15am	**Supplier Quality Management (Supplier Controls)** • Supplier selection and qualification • Supplier audits and performance monitoring	**Mr. Nichol Lim** Vice President, Services Standard
12.15pm	**Lunch**	
1.15pm	**Principles of Risk Management** • Overview of ISO14971 and risk-based approach	**Ms. Tan Hwee Ee** Founder DH RegSys Consulting Pte Ltd
2.30pm	**Practicum 1: Risk Management in Manufacturing**	**Ms. Tan Hwee Ee** Founder DH RegSys Consulting Pte Ltd
3.45m	**Refreshment Break**	
4.00pm	**Practicum 1 (Cont.)**	
5.00pm	**End**	

Day 3 – 19 November 2025, 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**	
10.30am	**Core Manufacturing Controls and Documentation** • Document control, record-keeping and retention • Good Documentation Practices	**Mr. Nichol Lim** Vice President, Services Standard
11.30am	**Production and Process Controls** • SOPs for production • In-process controls and monitoring • Validation and verification of processes (Clause 7.5.6)	**Mr. Nichol Lim** Vice President, Services Standard
12.30pm	**Lunch**	
1.30pm	**Process Validation** • What is process validation? • IQ/OQ/PQ framework • Developing validation protocols and reports	**Mr. Nichol Lim** Vice President, Services Standard
2.30pm	**Practicum 2: Process validation**	**Ms. Tan Hwee Ee** Founder DH RegSys Consulting Pte Ltd
3.30pm	**Refreshment Break**	
3.45pm	**Practicum 2 (cont.)**	
5.00pm	**End**	

Day 4 – 20 November 2025, 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	**Dr. Emmanuel Damian** Regulatory Affairs Manager DEXCOM
10.15am	**Refreshment Break**	
10.30am	**CAPA and Improvements** • ISO13485 Clauses 8.5.1 – 8.5.3 • What are the triggers for CAPA	**Dr. Emmanuel Damian** Regulatory Affairs Manager DEXCOM
11.30am	**Post-Market Surveillance Activities** Examples of PMS practices	**Dr. Emmanuel Damian** Regulatory Affairs Manager DEXCOM
12.00pm	**Group Activity 2: RWE for Post-Market Surveillance**	**CoRE Education Team**
12.30pm	**Lunch**	
1.30pm	**Using inspections for continuous improvement of QMS** • Sampling plans (AQL) • Tolerance vs. specification • Visual inspection techniques	**Dr. Emmanuel Damian** Regulatory Affairs Manager DEXCOM
2.30pm	**Case Discussion 1** • Contract manufacturing	**CoRE Education Team**
3.30pm	**Refreshment Break**	
3.45pm	**Case Discussion 1 (cont.)**	
4.45pm	**Workshop Debrief**	
5.00pm	**End**	

Day 5 – 21 November 2025, 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**	**Mr. Noor Mohammad Nisar Ahamed** Singapore General Hospital 3D Printing Centre **Dr. Mark Tan** Clinical Lead Singapore General Hospital 3D Printing Centre
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	**Dr Sharon Saw** Principal Scientist National University Hospital
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	**Dr. Kelsen Bastari** Senior Regulatory Specialist Medical Device Cluster, Health Sciences Authority
2.30pm	**Introduction to Medical Device Single Audit Programme (MDSAP)**	**Mr. Sharad Shukla** Director Regulatory Affairs, MedTech Johnson & Johnson
3.30pm	**Refreshment Break**	
3.45pm	**Reflection and Peer Sharing**	**Dr. Rathi Saravanan** Lead Education Associate CoRE, Duke-NUS Medical School
4.45pm	**Closing Remarks**	**Prof Silke Vogel** Deputy Director CoRE, Duke-NUS Medical School
5.00pm	**End**	