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**	**Dr. Rathi Saravanan** Lead Education Associate Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
9.15am	**Workshop Briefing** • Programme overview • Brightspace briefing • Ice breaker activity	**Asst Prof James Leong** Head, Health Products and Regulatory Science 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** • 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
11.00am	**Group Activity 1: Risk Classification and QMS** • Understand the relationship between risk class and QMS expectations	**Expert Faculty: Dr. Debbie Ko** **Facilitator: CoRE Education Team**
12.30pm	**Lunch**	
1.30pm	**Overview of ISO 13485** • General flow of the standard • Key definitions and common terms • Quiz (ungraded)	**Mr. Jaineet Arora** Education Associate CoRE Duke-NUS Medical School
2.15pm	**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
3.15pm	**Regulatory Inspections of QMS** • ISO1911 Guidelines for Auditing Management Systems • Audit inspections and concerns	**Mr. Viknesvaran Kandasamy** Manager, Quality Systems Insulet Malaysia
4.00pm	**Refreshment break**	

4.15pm	**Resource Management (Clause 6)** • Human resources	**Mr. Viknesvaran Kandasamy** Manager, Quality Systems Insulet Malaysia
5.00pm	**End**	

Day 2– 17 November 2026, Wed

Time	Topic	Speaker/ Organization
8.30am	**Registration**	
9.00am	**Human Factors and Usability Engineering (Clause 7.2)** • Overview of IEC62366 • Human Error as a root cause • Designing of workstations, SOPs, labels	*TBC*
9.45am	**Group Activity 2: Identification of Root Causes**	**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	**Mr. Kenny Chong** Director & Principal Consultant Cogence
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	**Mr. Kenny Chong** Director & Principal Consultant Cogence
12.15pm	**Lunch**	
1.15pm	**Principles of Risk Management** • Overview of ISO14971 and risk-based approach • How it links to ISO13485	**Ms. Tan Hwee Ee** Founder and Principal Consultant DH RegSys Consulting Pte Ltd
2.15pm	**Practicum 1: Risk Management in Manufacturing**	**Ms. Tan Hwee Ee** Founder and Principal Consultant DH RegSys Consulting Pte Ltd
3.45pm	**Refreshment Break**	
4.15pm	**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	**Mr. Kenny Chong** Director & Principal Consultant Cogence
11.15am	**Production and Process Controls** • SOPs for production • In-process controls and monitoring • Validation and verification of processes (Clause 7.5.6)	**Mr. Kenny Chong** Director & Principal Consultant Cogence
12.15pm	**Lunch**	
1.15pm	**Group Activity 3: From Design to Stable Production**	**CoRE Education Team**
2.15pm	**Process Validation** • What is process validation? • IQ/OQ/PQ framework • Developing validation protocols and reports	**Ms. Tan Hwee Ee** Founder and Principal Consultant DH RegSys Consulting Pte Ltd
3.00pm	**Practicum 2: Process validation**	**Ms. Tan Hwee Ee** Founder and Principal Consultant DH RegSys Consulting Pte Ltd
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** • Clause 8.3: intro to nonconforming pdt, how to segregate and determine end point	**Dr. Emman Damien** Regulatory Affairs Manager DEXCOM
9.45am	**Refreshment Break**	
10.00am	**CAPA and Improvements** • ISO13485 Clauses 8.5.1 – 8.5.3 • What are the triggers for CAPA	**Dr. Emman Damien** Regulatory Affairs Manager DEXCOM
10.45am	**Risk-Based Internal Audits r** • Clause 8.2.4: rules for internal audits • Risk-based auditing • Planning a risk-based internal audit program	**Dr. Alfred Chia** Partnerships & Innovation NUHS Research & Innovation Office
11.45am	**Post-Market Surveillance Activities** Examples of PMS practices	**Dr. Emman Damien** Regulatory Affairs Manager DEXCOM
12.30pm	**Lunch**	
1.30pm	**Group Activity 4: RWE for Post-Market Surveillance**	**Expert Faculty: Dr. Emman Damien** **Facilitator: CoRE Education Team**
2.30pm	**Using inspections for continuous improvement of QMS** • Sampling plans (AQL) • Tolerance vs. specification • Visual inspection techniques	**Dr. Emman Damien** Regulatory Affairs Manager DEXCOM
3.15pm	**Case Discussion 1** • Contract manufacturing	**Expert Faculty: Dr. Emman Damien** **Facilitator: CoRE Education Team**
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**	**Mr. Noor Mohamed Nisar Ahamed** Centre Manager SGH 3D Printing Centre (3DPC) Singapore General Hospital
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 Scientific Officer Department of Laboratory Medicine National University Hospital System Adjunct Asst Professor Nanyang Technological University Singapore
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	*TBC*
2.30pm	**Transition to Industry 4.0**	*TBC*
3.30pm	**Refreshment Break**	
3.45pm	**Reflection and Peer Sharing**	**Dr. Rathi Saravanan** Lead Education Associate Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
4.45pm	**Closing Remarks**	**Asst Prof James Leong** Head, Health Products and Regulatory Science CoRE Duke-NUS Medical School
5.00pm	**End**	