GRADUATE CERTIFICATE IN MEDICAL DEVICE REGULATION

GMS5009 Manufacturing and Quality Management System for Medical Devices

2 Dec 2024 – 6 Dec 2024

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

- Software developers, engineers, researchers, and SME developing Medical Device

Day 1 – 2 Dec, Mon

Time	Topic	Speaker / Organization
8.45am	**Registration**	
9.00am	**Welcome and Workshop Briefing**	**Dr Rathi Saravanan** Lead Education Associate Lead, Graduate Certificate Programmes Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School **Mr Osman Mohamad** Senior Education Associate Lead, Online Programmes Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
9.10am	**Photo Taking Session**	
Session 1:	**Regulatory frameworks, Requirements and Standards**	
9.15am	**Overview of Medical Device Industry and Regulatory Landscape** • Medical device classifications • Key regulatory and standards organisations • US FDA QMSR / GMP	**Mr Sharad Shukla** Director Regulatory Affairs, MedTech Head, Regulatory Affairs, SEA APAC Regulatory Affairs Lead Johnson & Johnson
9.45am	**Quality Management System (QMS)** • Introduction to QMS principles • Overview of ISO 13485 requirements • Risk management requirements	**Ms Tan Hwee Ee** Founder/Director DH RegSys
10.30am	**Refreshment Break**	
10.45am	**Design Control and Development (Part 1)** • Design and Development Planning • Design inputs, manufacturability and marketability • Role of Clause 7.2 – clinical and user inputs	**Dr John Thornback** Senior Advisor Diagnostic Development Hub DxD Chair, Centre for Probe Development and Commercialization, Hamilton Canada

11.45am	**Design Control and Development (Part 2)**
	• Design verification and validation
	  • Role of process validation and
	• Design outputs
	  • Manufacturing SOP
	  • Design transfer
		Dr John Thornback
		Senior Advisor
		Diagnostic Development Hub
		DxD

12.30 pm	**Lunch**	
1.30pm	**Risk Management** • Understanding ISO 14971 and risk-based approach • Identify sources of risk • Quantify and evaluate risk • Create and implement risk control measures	**Ms Tan Hwee Ee** Founder/Director DH RegSys

2.30pm	**Overview of Medical Device Standards**
	• Essential Principles of Safety and Performance (EPSP) and regulatory requirements
	• Applicable standards relating to medical devices
	  ○ Country-specific requirements
	  ○ Differences in risk classifications
		Mr Sharad Shukla
		Director Regulatory Affairs, MedTech
		Head, Regulatory Affairs, SEA
		APAC Regulatory Affairs Lead
		Johnson & Johnson

3.00pm	**Refreshment Break**	
3.15pm	**Practicum 1 - EPSP and relevant standards**	**Mr Sharad Shukla** Director Regulatory Affairs, MedTech Johnson & Johnson
5.15pm	**Wrap up & Fill up feedback form for Day 1**	**CoRE Education Team**
5.30pm	**End**	

Day 2 – 3 Dec, Tue

Time	Topic	Speaker/ Organization
8.45am	**Registration**	
Session 2:	**Quality Management System (QMS) Implementation**	
9.00am	**QMS Documentation – Requirements and Structure** • Understanding ISO 13485 Clause 4 • Quality manual, policies, procedures and records	**Mr Nichol Lim** Vice President, Services Standard
9.45am	**QMS Documentation – Controls** • Document control, record-keeping and retention • Good Documentation Practice	**Mr Nichol Lim** Vice President, Services Standard
10.30am	**Refreshment break**	
10.45am	**Management responsibilities in implementing ISO 13485** • Policy and objectives setting • Customer relationships	**Mr Nichol Lim** Vice President, Services Standard
11.30am	**Resource management** • Human resources – Clause 6.2 • Infrastructure – Clause 6.3 • Work environment and contamination controls – Clause 6.4	**Mr Nichol Lim** Vice President, Services Standard
12.30pm	**Lunch**	
1.30pm	**Practicum 2 – Risk Management**	**Ms Tan Hwee Ee** Founder/Director DH RegSys
3.00pm	**Refreshment Break**	
3.15pm	**Practicum 2 – Risk Management (cont'd)**	
4.00pm	**Networking**	**Mr Osman Mohamad** Senior Education Associate Lead, Online Programmes Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
4.45pm	**Wrap up & Fill up feedback form for Day 2**	**CoRE Education Team**
5.00pm	**End**	

Day 3 – 4 Dec, Wed

Time	Topic	Speaker/ Organization
8.45am	**Registration**	
9.00am	**Individual and Group Readiness Assessment**	
10.00am	**Refreshment Break**	
Session 3:	**Manufacturing Practices and Process Control**	
10.15am	**Production and Process Controls** • SOPs for production • In-process controls and monitoring • Validation and verification of processes – Clause 7.5.6 • Control of non-conformance	**Mr Aufar Rahadiandy** VP of Business Operations Stendard
11.00am	**Process Validation** • Overview of process validation • Developing validation protocols and reports	**Mr Aufar Rahadiandy** VP of Business Operations Stendard
12.00pm	**Lunch**	
1.00pm	**Case Discussion 1 – Process Validation**	**Ms Tan Hwee Ee** Founder/Director DH RegSys
3.30pm	**Refreshment Break**	
3.45pm	**Group Presentation: Contract manufacturing** • Selection and controls for rebranding an existing product • Using your design for a subcontracted manufacturer	
4.45pm	**Wrap up & Fill up feedback form for Day 3**	**CoRE Education Team**
5.00pm	**End**	

Day 4 – 5 Dec, Thurs

Time	Topic	Speaker/ Organization
8.45am	**Registration**	
Session 4:	**Quality Control and Assurance**	
9.00am	**Quality Assurances Practices** • QA activities in the manufacturing process • Internal and external auditing process • Supplier quality management and audits • Continuous improvement and CAPA (Corrective and Preventive Actions)	**Mr Aufar Rahadiandy** VP of Business Operations Stendard
9.45am	**Supplier Quality Management / Supplier Control** • Supplier selection and qualification • Supplier audits and performance monitoring	**Mr Aufar Rahadiandy** VP of Business Operations Stendard
10.30am	Refreshment Break	
10.45am	**Case Discussion 2a – Considerations for setting up a QMS**	**Ms Tan Hwee Ee** Founder/Director DH RegSys
12.30pm	Lunch	
1.30pm	**Case Discussion 2a– Considerations for setting up a QMS (cont'd)**	**Ms Tan Hwee Ee** Founder/Director DH RegSys
3.00pm	Refreshment Break	
3.15pm	**Case Discussion 2b – Potential challenges for implementing the QMS**	**Ms Tan Hwee Ee** Founder/Director DH RegSys
4.00pm	**Post Market Surveillance** • Overview of regulatory requirements (FDA, MDR, ISO 13485 Clause 8) • Key elements of a PMS plan and 8.2.1. • Examples of PMS activities and data collection methods • Complaint handling 8.2.2	**Mr Tibor Zechmeister** Head of Regulatory and Quality Flinn.ai
4.45pm	**Wrap up & Fill up feedback form for Day 4**	**CoRE Education Team**
5.00pm	End	

Day 5 – 6 Dec, Fri

Time	Topic	Speaker/ Organization
8.45am	Registration	
9.00am	End-of-Module (EOM) Assessment	CoRE Education Team
10.00am	Review of EOM Questions	CoRE Education Team
10.30am	Refreshment break	
Session 5: Trends in Manufacturing of Medical Devices		
10.45am	**Emerging Trends and Technologies in QC and QA** • Automation and digitalization in quality control • Use of data analytics and machine learning • Regulatory updates and future trends	**Dr M Fahed Aziz Qureshi** Senior Research Scientist College of Engineering NUS
11.45am	**Artificial Intelligence in Medical Device Design and Development**	**Mr Daryl Lim** Co-Founder and Partner DesignThinkers Academy Singapore DesignThinkers Asia
12.30pm	Lunch	
1.30pm	**3D printing for IVD**	**Dr Mark Tan** Radiologist and Clinical Lead Singapore General Hospital 3D Printing Centre
2.15pm	**Peer Learning Activity**	**Mr Osman Mohamad** Senior Education Associate Lead, Online Programmes Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
3.00pm	Refreshment Break	
3.15pm	**Peer Learning Activity (cont'd)**	
4.00pm	**Workshop Conclusion**	**Prof Silke Vogel** Deputy Director, CoRE Senior Associate Dean Graduate Studies Duke-NUS Medical School
4.45pm	**Closing Remarks & Fill in feedback form for Day 5**	**CoRE Education Team**
5.00 pm	End	