GRADUATE CERTIFICATE IN MEDICAL DEVICE REGULATION

GMS5009 Manufacturing and Quality Management System for Medical Devices

17 Nov 2025 – 21 Nov 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

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

Day 1 – 17 Nov, Mon

Time	Topic	Speaker / Organization
8.45am	**Registration**	
9.00am	**Welcome and Workshop Briefing**	
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	
9.45am	**Quality Management System (QMS)** • Introduction to QMS principles • Overview of ISO 13485 requirements • Risk management requirements	
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	

11.45am	**Design Control and Development (Part 2)**
	• Design verification and validation
	  • Role of process validation and
	• Design outputs
	  • Manufacturing SOP
	  • Design transfer	

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	

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	

3.00pm	**Refreshment Break**	
3.15pm	**Practicum 1 - EPSP and relevant standards**	
5.15pm	**Wrap up & Fill up feedback form for Day 1**	
5.30pm	**End**	

Day 2 – 18 Nov, 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	
9.45am	**QMS Documentation – Controls** • Document control, record-keeping and retention • Good Documentation Practice	
10.30am	**Refreshment break**	
10.45am	**Management responsibilities in implementing ISO 13485** • Policy and objectives setting • Customer relationships	
11.30am	**Resource management** • Human resources – Clause 6.2 • Infrastructure – Clause 6.3 • Work environment and contamination controls – Clause 6.4	
12.30pm	**Lunch**	
1.30pm	**Practicum 2 – Risk Management**	
3.00pm	**Refreshment Break**	
3.15pm	**Practicum 2 – Risk Management (cont'd)**	
4.00pm	**Networking**	
4.45pm	**Wrap up & Fill up feedback form for Day 2**	
5.00pm	**End**	

Day 3 – 19 Nov, 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	
11.00am	**Process Validation** • Overview of process validation • Developing validation protocols and reports	
12.00pm	**Lunch**	
1.00pm	**Case Discussion 1 – Process Validation**	
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**	
5.00pm	**End**	

Day 4 – 20 Nov, 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)	
9.45am	**Supplier Quality Management / Supplier Control** • Supplier selection and qualification • Supplier audits and performance monitoring	
10.45am	**Case Discussion 2a – Considerations for setting up a QMS**	
12.30pm		
1.30pm	**Case Discussion 2a– Considerations for setting up a QMS (cont'd)**	
3.00pm	**Refreshment Break**	
3.15pm	**Case Discussion 2b – Potential challenges for implementing the QMS**	
4.00pm	**Post Market Surveillance**	
4.45pm	**Wrap up & Fill up feedback form for Day 4**	
5.00pm	**End**	

Day 5 – 21 Nov, Fri

Time	Topic	Speaker/ Organization
8.45am	Registration	
9.00am	End-of-Module (EOM) Assessment	
10.00am	Review of EOM Questions	
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	
11.45am	Artificial Intelligence in Medical Device Design and Development	
12.30pm	Lunch	
1.30pm	3D printing for IVD	
2.15pm	Peer Learning Activity	
3.00pm	Refreshment Break	
3.15pm	Peer Learning Activity (cont'd)	
4.00pm	Workshop Conclusion	
4.45pm	Closing Remarks & Fill in feedback form for Day 5	
5.00 pm	End	