Centre of Regulatory Excellence
@ Duke-NUS Medical School

Manufacturing and Quality Management System (QMS)

14 – 15 October 2025

Spaces@Clarke Quay
Room 630, Level 6, 21 Merchant Road, Singapore
058267

WORKSHOP PROGRAMME

Learning Outcomes

At the end of this workshop, participants should be able to:

- Describe key regulatory requirements of In Vitro Diagnostic Devices (IVDDs) throughout the product life cycle
- Explain the conformity assessment methods by major regulatory authorities
- Describe the key considerations in change management and post-market activities of IVDDs

Target Audience

- Regulators, Industry QA/RA professionals, product developers, entrepreneurs and investors with interest in diagnostics, and Academia

Pre-reads

1. Total Product Lifecycle & Introduction to Risk Management
2. Introduction to Regulatory Controls & QMS
3. Project Management

Manufacturing and Quality Management System

14-15 October 2025

Day 1 (14 Oct 2025)

Time	Agenda	Speaker/Facilitator
8.00 am	**Registration**	
8.30 am	**Welcome Address**	**Asst Prof James Leong** Head, Health Products & Regulatory Science Centre of Regulatory Excellence (CoRE) Duke-NUS
8.40 am	**Introduction on the Singapore Standardisation Programme**	**Standards Development Organisation (SDO)** **CoRE, Duke-NUS**
9.00 am	**Workshop Briefing**	**Ms Janet Poh** Training Manager QARA DxDHub
9.15 am	**Photo taking session**	
9.20 am	**Introduction to Diagnostics Development Hub**	**Ms Ho Yuan Lu** Vice President Project & Outreach DxDHub
9.45 am	**Dossier preparation and Product registration: IVD and SaMD**	**Mr Ang Wei Jun** Senior Manager QARA DxD Hub
10.45 am	**Break**	
11.00 am	**Manufacturing Transfer and Batch Records: IVD and SaMD**	**Dr Lin You Bin** Senior Manager Molecular Dx DxD Hub **Mr Henry Johnson Susainathan** Principal Manager Digital Dx DxD Hub
11.45 am	**Case Discussion** • **Medical Device File**	**Ms Tan Hwee Ee** Founder and Director DH RegSys Private Limited
12.30 pm	**Lunch**	
1.30 pm	**QMS application in a Medical Device Organization (MDO)**	**Ms Tan Hwee Ee** DH RegSys Private Limited
2.30 pm	**Determining Sites and facility requirements: IVD and SaMD**	**Dr Lin You Bin** **Mr Henry Johnson Susainathan** DxD Hub

**The Programme is accurate as of 30 June 2025 and may be subjected to further refinement if necessary before the actual workshop.*

3.15 pm	**Break**	
3.30 pm	**Manufacturing and QMS Case Study: Resolute®**	**Dr Lin You Bin** DxD Hub **Ms Tan Hwee Ee** DH RegSys Private Limited
4.45 pm	**Knowledge Check**	**Ms Janet Poh** DxD Hub
5.15 pm	**Wrap Up and Lessons Learnt**	**Ms Janet Poh** DxD Hub
5.30 pm	**End of Day 1**	

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Day 2 (15 Oct 2025)

Time	Agenda	Speaker/Facilitator
8.00 am	**Registration**	
8.30 am	**Process validation for scale-up Manufacturing: IVD and SaMD**	**Dr Lin You Bin** **Mr Henry Johnson Susainathan** DxDHub
9.30 am	**Gallery Walk** Customer related processes: IVD and SaMD	**Ms Tan Hwee Ee** DH RegSys Private Limited
10.00 am	**Tea Break**	
10.15 am	**Gallery Walk (cont'd)** Customer related processes: IVD and SaMD	**Ms Tan Hwee Ee** DH RegSys Private Limited
11.30 am	**HSA Post-market Regulatory Requirements**	
12.15 pm	**Lunch**	
1.30 pm	**Manufacturing and QMS Case Study: INSPECTA®**	**Mr Henry Johnson Susainathan** DxDHub **Ms Tan Hwee Ee** DH RegSys Private Limited
2.30 pm	**TBD**	
3.30 pm	**Tea break**	
3.45 pm	**End-of-Course Assessment**	**Ms Janet Poh** DxD Hub
4.45 pm	**Closing remarks with Lessons Learnt**	**Ms Janet Poh** DxD Hub
5.30 pm	**End of Day 2**	

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