



DukeNUS
Medical School



Centre of
Regulatory Excellence

Verification and Validation of In Vitro Diagnostics (IVD) and Software as a Medical Device (SaMD)

27-28 April 2026

WORKSHOP PROGRAMME

Learning Outcomes

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

- Describe the key processes required for successful development of In Vitro Diagnostics (IVD) and Software as a Medical Device (SaMD)
- Understand in detail the verification and validation stages of IVD and SaMD

Target Audience

- Product developers, entrepreneurs and investors with interest in diagnostics, and Academia looking to understand how to take their lead R&D concept through verification and validation to product registration and transfer to GMP manufacturing.

Pre-reads

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

Verification and Validation of IVD and SaMD

27-28 April 2026

Day 1 (27 Apr 2026)

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 DxD Hub
9.15 am	Photo taking session	
9.20 am	Introduction to Diagnostics Development Hub	Ms Ho Yuan Lu Vice President Project & Outreach DxD Hub
9.45 am	Knowledge Check (Pre-read) • Regulatory Controls & QMS	Ms Tan Hwee Ee Founder and Director DH RegSys Consulting Pte Ltd
10.30 am	Break	
10.45 am	Regulatory submission requirements: Essential principles, CLSI guidelines for IVD and SaMD	Mr Ang Wei Jun Senior Manager QARA DxD Hub
11.45 am	ISO 14971 and Risk Management: IVD and SaMD	Ms Tan Hwee Ee DH RegSys Consulting Pte Ltd
12.30 pm	Lunch	
1.30 pm	Design Verification & Analytical Validation requirements: IVD and SaMD	Dr Lin You Bin Senior Manager Molecular Dx DxD Hub Mr Henry Johnson Susainathan Principal Manager Digital Dx DxD Hub
2.30 pm	Pilot Manufacturing: IVD and SaMD	Dr Lin You Bin Mr Henry Johnson Susainathan DxD Hub
3.15 pm	Break	

**The Programme is accurate as of 11 December 2025 and may be subjected to further refinement if necessary, before the actual workshop.*

Time	Agenda	Speaker/Facilitator
3.30 pm	<u>Case Study</u> Populating the Essential Principles Templates - Resolute®	Dr Lin You Bin Mr Henry Johnson Susainathan Mr Ang Wei Jun DxD Hub Ms Tan Hwee Ee DH RegSys Consulting Pte Ltd
5.00 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	



Day 2 (28 Apr 2026)

Time	Agenda	Speaker/Facilitator
8.00 am	Registration	
8.30 am	SaMD development guidelines IEC62304	Harold Goh Project Manager Digital Dx DxD Hub
9.00 am	Labeling and Packaging: IVD and SaMD	Jessica Yap Senior Manager QARA DxD Hub
9.30 am	Clinical Performance evaluation: IVD	Daniel Wu Senior Scientist DxD Hub
10.15 am	Break	
10.30 am	Clinical Performance evaluation: SaMD	Mr Henry Johnson Susainathan DxD Hub
11.30 am	Document and Record Control	Janet Poh Senior Manager QARA DxD Hub
12.30 pm	Lunch	
1.30 pm	<u>Case Study</u> Populating the Essential Principles Templates - Inspecta®	Dr Lin You Bin Mr Henry Johnson Susainathan Mr Ang Wei Jun DxD Hub Ms Tan Hwee Ee DH RegSys Consulting Pte Ltd
3.15 pm	Break	
3:30 pm	<u>Case Study (cont'd)</u> Populating the Essential Principles Templates - Inspecta®	Dr Lin You Bin Mr Henry Johnson Susainathan Mr Ang Wei Jun DxD Hub Ms Tan Hwee Ee DH RegSys Consulting Pte Ltd
4.15 pm	End-of-Course Assessment	Ms Janet Poh DxD Hub
5.15 pm	Closing remarks with Lessons Learnt	Ms Janet Poh DxD Hub
5.30 pm	End of Day 2	

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