



**Centre of Regulatory Excellence  
@ Duke-NUS Medical School**

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

24-25 September 2025

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

## **WORKSHOP PROGRAMME**

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### **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

**24-25 September 2025**

### Day 1 (24 Sept 2025)

Time	Agenda	Speaker/Facilitator
8.00 am	<b>Registration</b>	
8.30 am	<b>Welcome Address</b>	<b>Asst Prof James Leong</b> Head, Health Products & Regulatory Science Centre of Regulatory Excellence (CoRE) Duke-NUS
8.40 am	<b>Introduction on the Singapore Standardisation Programme</b>	<b>Standards Development Organisation (SDO)</b> CoRE, Duke-NUS
9.00 am	<b>Workshop Briefing</b>	<b>Ms Janet Poh</b> Training Manager QARA DxDHub
9.15 am	<b>Photo taking session</b>	
9.20 am	<b>Introduction to Diagnostics Development Hub</b>	<b>Ms Ho Yuan Lu</b> Vice President Project & Outreach DxD Hub
9.45 am	<b>Knowledge Check (Pre-read)</b> • Regulatory Controls & QMS	<b>Ms Tan Hwee Ee</b> Founder and Director DH RegSys Private Limited
<b>10.30 am</b>	<b>Break</b>	
10.45 am	<b>Regulatory submission requirements: Essential principles, CLSI guidelines for IVD and SaMD</b>	<b>Mr Ang Wei Jun</b> Senior Manager QARA DxDHub
11.45 am	<b>ISO 14971 and Risk Management: IVD and SaMD</b>	<b>Ms Tan Hwee Ee</b> DH RegSys Private Limited
<b>12.30 pm</b>	<b>Lunch</b>	
1.30 pm	<b>Design Verification &amp; Analytical Validation requirements: IVD and SaMD</b>	<b>Dr Lin You Bin</b> Senior Manager Molecular Dx DxD Hub  <b>Mr Henry Johnson Susainathan</b> Principal Manager Digital Dx DxDHub
2.30 pm	<b>Pilot Manufacturing: IVD and SaMD</b>	<b>Dr Lin You Bin</b> <b>Mr Henry Johnson Susainathan</b> DxDHub
<b>3.15 pm</b>	<b>Break</b>	

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

Time	Agenda	Speaker/Facilitator
3.30 pm	<b>Case Study</b> Populating the Essential Principles Templates - Resolute®	<b>Dr Lin You Bin</b> <b>Mr Henry Johnson Susainathan</b> <b>Mr Ang Wei Jun</b> DxDHub  <b>Ms Tan Hwee Ee</b> DH RegSys Private Limited
5.00 pm	<b>Knowledge Check</b>	<b>Ms Janet Poh</b> DxDHub
5.15 pm	<b>Wrap Up and Lessons Learnt</b>	<b>Ms Janet Poh</b> DxDHub
<b>5.30 pm</b>	<b>End of Day 1</b>	

## Day 2 (25 Sept 2025)

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

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