Centre of Regulatory Excellence
@ Duke-NUS Medical School

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

23-24 March 2023

WORKSHOP PROGRAMME

In today's digital world, technologies and software play an increasingly important role in healthcare management - diagnosis, treatment, patient monitoring and Real World Data collection. This course aims to better understand the regulatory perspectives and standards expected for a commercially approved health product, including risk assessment and mitigation plans. This will aid in the development, market entry and utility of IVDs and SaMDs.

Learning Outcomes

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

- Explain the key processes required for successful development of In Vitro Diagnostics (IVD) and Software as a Medical Device (SaMD)
- Articulate the importance of the verification and validation stages for 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.

Validation and Verification of IVD and SaMD

Duke-NUS Medical School

23 – 24 March 2023

Day 1 (23 Mar 2023)

Time	Agenda	Speaker/ Facilitator
8.00am	**Registration**	
8.30am	**Welcome address**	CoRE
8.40am	**Workshop briefing**	**Dr Rahul Pandey** Outreach & Talent Development Diagnostics Development Hub (DxDHub) **Dr John Thornback** Senior Advisor DxDHub
8.50am	**Photo taking session**	
9.00am	**Recap on Design and Development and Total Product Lifecycle**	**Dr John Thornback** Senior Advisor DxDHub
9.30am	**Regulatory submission requirements** • Essential principles • Clinical & Laboratory Standards Institute (CLSI) guidelines for IVD and SaMD	**Ms Jayashree Chandrasekaran** Regulatory Affairs Manager DxDHub
10.30am	**Break**	
10.45am	**ISO14971 and Risk Management**	**Ms Tan Hwee Ee** Founder and Director DH RegSys Private Limited
11.30am	**Design verification & analytical validation requirements**	**Dr Lin You Bin** Senior Manager, Biomedical Project DxDHub **Mr Henry Johnson Susainathan** Senior Manager DxDHub
1.00pm	**Lunch**	
2.00pm	**Pilot manufacturing**	**Dr Lin You Bin** **Mr Henry Johnson Susainathan** DxDHub
2.45pm	**Break**	
3.00pm	**Case discussion 1** Populating the Essential Principles Templates	**Dr John Thornback** **Dr Rahul Pandey** DxDHub
5.00pm	**Wrap Up and Lessons Learnt**	**Dr John Thornback** **Dr Rahul Pandey** DxDHub
5.30pm	**End of Day 1**	

**The Programme is accurate as of (22 March 2023) and may be subjected to further refinement if necessary before the actual workshop.*

Day 2 (24 Mar 2023)

Time	Agenda	Speaker/Facilitator
8.00am	**Registration**	
8.30am	**SaMD development guidelines IEC62304**	**Mr Harold Goh** Product Development Engineer DxDHub
9.15am	**Clinical performance evaluation**	**Dr John Thornback** **Mr Henry Johnson Susainathan** DxDHub
10.15 am	**Break**	
10.30am	**QC protocol refinement**	**Dr John Thornback** Senior Advisor DxDHub
11.30am	**Design and Development File Structure**	**Ms Jessica Yap** QARA DxDHub
12.30 pm	**Lunch**	
1.30pm	**Manufacturing transfer**	**Ms Tan Hwee Ee** Founder and Director DH RegSys Private Limited
2.15pm	**Case discussion 2** Populating the Essential Principles Templates	**Dr John Thornback** **Dr Rahul Pandey** DxDHub
3.15pm	Break	
3:30pm	**Case discussion 2 (Cont'd)**	**Dr John Thornback** **Dr Rahul Pandey** DxDHub
4.15pm	**Quiz**	**Dr John Thornback** **Dr Rahul Pandey** DxDHub
5.00pm	**Closing remarks with Lessons Learnt**	**Dr John Thornback** **Dr Rahul Pandey** DxDHub
5.30pm	**End of Day 2**	

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