Validation and Verification

14-15 March 2024

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

Academia, SGH Campus

14 – 15 March 2024

Day 1 (14 Mar)

Time	Agenda	Speaker/ Facilitator
8.00am	**Registration**	
8.30am	**Welcome Address**	**CoRE**
8.45am	**Photo taking session**	
9.00am	**Recap on Design and Development and Total Product Lifecycle**	**Dr Rahul Pandey** Outreach & Talent Development DxDHub
9.30am	**Regulatory controls**	**Ms Tan Hwee Ee** Founder and Director DH RegSys Private Limited **Ms Chan Yang Sun** Quality Assurance & Regulatory Affairs DxDHub
10.30am	**Break**	
10.45am	**Regulatory submission requirements** • Essential principles and its purpose • Clinical & Laboratory Standards Institute (CLSI) guidelines for IVD and SaMD	**Dr Ng Szu Shien** Quality Assurance and Regulatory Affairs DxDHub
11.45am	**ISO14971 and Risk Management in IVD and SaMD** • Risks in medical device development	**Ms Tan Hwee Ee** Founder and Director DH RegSys Private Limited
12.30pm	**Lunch**	
1.30pm	**Guideline for SaMD development: IEC 62304**	**Mr Harold Goh** Product Development Engineer DxDHub
2.15pm	**Pilot manufacturing**	**Mr Daniel Wu** Senior Scientist IVD Division DxDHub **Mr Henry Johnson Susainathan** Principal Manager DxDHub

*The Programme is accurate as of (05 March 2024) and may be subjected to further refinement if necessary before the actual workshop.

3.15pm	**Case Discussion 1** Populating the Essential Principles Templates	**Dr Rahul Pandey** **Dr Ng Szu Shien** DxDHub **Ms Janet Poh** Quality Assurance and Regulatory Affairs DxDHub **Ms Tan Hwee Ee** DH RegSys Private Limited
3.30pm	**Break**	
3.45pm	**Case Discussion 1 (Cont'd)** Populating the Essential Principles Templates	
5.00pm	**Wrap Up and Lessons Learnt**	**Dr Rahul Pandey** DxDHub
5.30pm	**End of Day 1**	

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Day 2 (15 Mar)

Time	Agenda	Speaker/Facilitator
8.00am	**Registration**	
8.30am	**Design Verification & Analytical Validation Requirements for IVD and SaMD**	**Mr Daniel Wu** **Mr Henry Johnson Susainathan** DxDHub
10.00 am	**Break**	
10.15am	**Performance Evaluation (IVD) and Clinical Validation (SaMD)**	**Mr Daniel Wu** **Mr Henry Johnson Susainathan** DxDHub
11.15am	**Design History File Structure**	**Ms Jessica Yap** QARA DxDHub
12.00 pm	**Lunch**	
1.00pm	**Design and Manufacturing Transfer**	**Ms Tan Hwee Ee** Founder and Director DH RegSys Private Limited
1.45pm	**Case Discussion 2** Populating the Essential Principles Templates	**Dr Rahul Pandey** **Mr Henry Johnson Susainathan** **Ms Janet Poh** DxDHub **Ms Tan Hwee Ee** DH RegSys Private Limited
3.00pm	**Break**	
3:15pm	**Case Discussion 2 (Cont'd)** Populating the Essential Principles Templates	
4.00pm	**Quiz**	**Dr Rahul Pandey** DxDHub
5.00pm	**Lessons Learnt and Closing Remarks**	**Dr Rahul Pandey** DxDHub
5.30pm	**End of Day 2**	

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