Design and Development

18-19 August 2025

WORKSHOP PROGRAMME

Learning Outcomes

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

- List the key processes required for successful commercialization of In Vitro Diagnostics (IVD) and Software as a Medical Device (SaMD)
- Articulate the significance and contribution of the design and development stages to a successful production of IVD and SaMD

Target Audience

- Product developers, entrepreneurs and investors with interest in diagnostics, and Academia looking to understand how to take their ideas to a commercial IVD or SaMD

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

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18 – 19 August 2025

Day 1 (18 Aug 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	**Workshop Briefing**	**Ms Janet Poh** Training Manager QARA DxD Hub
8.50 am	**Photo taking session**	
9.00 am	**Introduction to Diagnostics Development Hub**	**Ms Ho Yuan Lu** Vice President Project & Outreach DxD Hub
9.15 am	<u>**Knowledge Check (Pre-read)**</u> • Total Product Lifecycle and Introduction to Risk Management • Project Management	**Ms Chan Yang Sun** Vice President QARA DxD Hub
9.45am	**Introduction to Digital Diagnostics**	**Mr Lijoy George** Vice President Digital Health DxD Hub
10.15am	**Tea Break**	
10.30am	**Product Design and Development (IVD)**	**Dr Lin You Bin** Senior Manager Molecular Dx DxD Hub
11.15 am	**Product Design and Development (SaMD)**	**Mr Henry Johnson Susainathan** Principal Manager Digital Dx DxD Hub
12.00 pm	**Lunch**	
1.00 pm	**Target Product Profile (TPP)**	**Mr Ang Wei Jun** Senior Manager QARA DxD Hub

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1.30 pm	**Workshop** Target Product Profile **–** Resolute®	**Dr Lin You Bin** **Mr Henry Johnson Susainathan** **Mr Ang Wei Jun** DxD Hub **Ms Tan Hwee Ee** Founder and Director DHRegSys Private Limited
3.00pm	**Tea Break**	
3.15 pm	**Workshop (cont'd)** Target Product Profile **–** Resolute®	**Dr Lin You Bin** **Mr Henry Johnson Susainathan** **Mr Ang Wei Jun** DxD Hub **Ms Tan Hwee Ee** Founder and Director DHRegSys Private Limited
4.15 pm	**Knowledge Check**	**Ms Janet Poh** DxD Hub
4.30 pm	**Wrap Up and Lessons Learnt**	**Ms Janet Poh** DxD Hub
5.00 pm	**End of Day 1**	

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Day 2 (19 Aug 2025)

Time	Agenda	Speaker/Facilitator
8.00 am	**Registration**	
8.30 am	**Design Change & Optimisation – IVD and SaMD**	**Dr Lin You Bin** **Mr Henry Johnson Susainathan** DxD Hub
9.30 am	**Supplier Identification & Contract Manufacturing**	**Ms Tan Hwee Ee** DHRegSys Private Limited
10.00 am	**Tea Break**	
10.15 am	**Design Freeze and Introduction to Pilot Manufacturing**	**Mr Ang Wei Jun** DxD Hub
10.30 am	**Design and Development File Structure**	**Ms Jessica Yap** Senior Manager QARA DxD Hub
10.45 am	**Workshop** Target Product Profile **– Resolute® / Inspecta®**	**Dr Lin You Bin** **Mr Henry Johnson Susainathan** **Mr Ang Wei Jun** DxD Hub **Ms Tan Hwee Ee** DH RegSys Private Limited
1.00 pm	**Lunch**	
2.00 pm	**Workshop (cont'd)** Target Product Profile **– Resolute® / Inspecta®**	**Dr Lin You Bin** **Mr Henry Johnson Susainathan** **Mr Ang Wei Jun** DxD Hub **Ms Tan Hwee Ee** DH RegSys Private Limited
3.00pm	**Tea Break**	
3:15pm	**Case Studies** Discussion on Product End-of-Life and responsibilities of the Product Owner	**Dr Lin You Bin** **Mr Henry Johnson Susainathan** DxD Hub **Ms Tan Hwee Ee** DH RegSys Private Limited
4.30 pm	**End-of-Course Assessment**	**Ms Janet Poh** DxD Hub
5.00 pm	**Closing remarks with Lessons Learnt**	**Ms Janet Poh** DxD Hub
5.30 pm	**End of Day 2**	

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