Centre of Regulatory Excellence
@ Duke-NUS Medical School

Functional Training:
Regulatory frameworks and requirements for IVD

10 – 12 November 2025
Duke Kunshan University

WORKSHOP PROGRAMME

Learning Outcomes

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

- Describe key regulatory requirements of In Vitro Diagnostic Devices (IVDDs) throughout the product life cycle for major markets
- Differentiate product classifications across major markets and apply risk management based on global regulatory requirements
- Apply good practices for IVD asset building and comply with required standards

Regulatory frameworks and requirements for IVD

10-12 November 2025

Day 1 (10 Nov 2025)

Time	Agenda	Speaker/Facilitator
8.30 am	**Registration**	
9.00 am	**Welcome remarks**	**Prof Fujie XU** Co-Director Global Health Program Duke Kunshan University **Asst Prof James Leong** Head, Health Products and Regulatory Science Centre of Regulatory Excellence (CoRE) Duke-NUS
9.15 am	**Overview of regulatory frameworks** • US FDA • EU • ASEAN	**Mr Andrew HO** Co-Founder DH RegSys
10.00 am	**Updates on EU IVDR and impact on manufacturers**	**Mr Eustace CHAI** Consultant, QARA DH RegSys
10.30 am	**Group photo and Break**	
11.00 am	**Case Discussion 1** **IVD risk classifications across major markets**	**DH RegSys** **Mr Jaineet ARORA** Education Associate **Ms Jessalyn CHAN** Research Associate CoRE Duke-NUS
12.30 pm	**Lunch**	
1.30 pm	**Case Discussion 1 (cont'd)**	
3.00 pm	**WHO Pre-qualification processes for IVD**	**Dr Susie BRANIFF** Scientist Prequalification Assessment Medical Device Team World Health Organization (WHO)
3.30 pm	**Break**	
4.00 pm	**Singapore's IVD registration processes**	**Ms Shuhui LIU** Senior Regulatory Specialist Medical Device Cluster Health Products Regulation Group Health Sciences Authority (HSA), Singapore
4.30 pm	**Life cycle management of IVD**	**Ms Hwee Ee TAN** DH RegSys
5.30 pm	**End of Day 1**	

**The Programme is accurate as of 05 November 2025 and may be subjected to further refinement if necessary before the actual workshop.*

Day 2 (11 Nov 2025)

Time	Agenda	Speaker/Facilitator
8.30 am	**Registration**	
9.00 am	**Risk management**	**Ms Hwee Ee TAN** DH RegSys
9.30 am	**Case Discussion 2** **Using Annexes A and H – Risk management**	**DH RegSys** **Mr Jaineet ARORA** **Ms Jessalyn CHAN** CoRE Duke-NUS
10.30 am	**Tea Break**	
11.00 am	**Case Discussion 2 (cont'd)** **Using Annexes A and H – Risk management**	
12.30 pm	**Lunch**	
1.30 pm	**Case Discussion 3** **Key activities in life cycle management**	**DH RegSys** **Mr Jaineet ARORA** **Ms Jessalyn CHAN** CoRE Duke-NUS
3.30 pm	**Tea break**	
4.00 pm	**Case Discussion 3 (cont'd)** **Key activities in life cycle management**	
4.30 pm	**Device safety and performance**	**Ms Hwee Ee TAN** DH RegSys
5.30 pm	**End of Day 2**	

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Day 3 (12 Nov 2025)

Time	Agenda	Speaker/Facilitator
8.30 am	**Registration**	
9.00 am	**Case Discussion 4** **Essential Principles of Safety and Performance (EPSP)**	**DH RegSys** **Mr Jaineet ARORA** **Ms Jessalyn CHAN** CoRE Duke-NUS
10.30 am	**Tea Break**	
11.00 am	**Case Discussion 4 (cont'd)** **Essential Principles of Safety and Performance (EPSP)**	
11.30 am	**Role of academia in supporting global IVD clinical development**	**Prof Chen YAO** Director Medical Statistics Office Peking University First Hospital
12.15 pm	**Group work - Briefing** **IVD asset building**	**DH RegSys** **Mr Jaineet ARORA** **Ms Jessalyn CHAN** CoRE Duke-NUS
12.30 pm	**Lunch**	
1.30 pm	**Group work (cont'd)** **IVD asset building**	
3.30 pm	**Tea break**	
4.00 pm	**Group work (cont'd)** **IVD asset building**	
4.30 pm	**Reliance mechanisms for facilitating IVD approvals**	**Mr Eustace CHAI** DH RegSys
4.50 pm	**Considerations for market access**	**Mr Andrew HO** DH RegSys
5.20 pm	**Workshop conclusion**	**Asst Prof Wei Chuen TAN-KOI** Lead, Regulatory System Strengthening CoRE Duke-NUS
5.30 pm	**End**	

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