Centre of Regulatory Excellence
@ Duke-NUS Medical School

Functional Training:
Meeting ISO 13485 QMS Requirements for IVD

21 – 23 May 2026
Duke Kunshan University

WORKSHOP PROGRAMME

Learning Outcomes

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

- Describe key elements and requirements of ISO 13485 for the Quality Management System in manufacturing of In Vitro Diagnostic Devices (IVDDs)
- Relate ISO 13485 to regulatory requirements across the IVD product life cycle and utility in major markets
- Identify and resolve non-conformances to ISO 13485

Meeting ISO 13485 QMS Requirements for IVD

21-23 May 2026

Day 1 (21 May 2026)

Time	Agenda	Speaker/Facilitator
8.30 am	**Registration**	
9.00 am	**Welcome remarks**	Gates Representative **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	**Goal setting**	
9.30 am	**ISO 13485 – Role in regulation and product life cycle management**	**Ms Hwee Ee TAN** Founder and Principal Consultant DH RegSys
10.00am	**Application of ISO 13485 – Clauses 0 to 3** • Definitions	DH RegSys
10.30 am	**Group photo and Break**	
11.00 am	**Application of ISO 13485 – Clauses 0 to 3** • Process approach to QMS	DH RegSys
12.30 pm	**Lunch**	
1.30 pm	**Application of ISO 13485 – Clauses 4 to 6** • Risk-based approach in QMS • Control of documents and records	DH RegSys
2.30 pm	**Case Discussion** Understanding ISO 13485 Clauses 0-6	**DH RegSys** **Ms Faith TAN** Education Associate **Ms Jessalyn CHAN** Research Associate CoRE Duke-NUS
3.30 pm	**Break**	
4.00 pm	**Webinar** **Update on Good Manufacturing Practice for Medical Devices** *Representative from NMPA* **Role of industry in the successful implementation of GMP** *Representative from IVD industry association*	

**The Programme is accurate as of 29 Jan 2026 and may be subjected to further refinement if necessary before the actual workshop.*

	Panel Discussion/ Q&A *Moderator: Prof Fujie XU*	
5.00 pm	**Networking and Refreshments**	

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Day 2 (22 May 2026)

Time	Agenda	Speaker/Facilitator
8.30 am	**Registration**	
9.00 am	**Case Discussion (cont'd)** Understanding ISO 13485 Clauses 0-6	**DH RegSys** **Ms Faith TAN** Education Associate **Ms Jessalyn CHAN** Research Associate CoRE Duke-NUS
10.00 am	**Application of ISO 13485 – Clauses 7 and 8** • Product realisation and improvement	
10.30 am	**Tea Break**	
11.00 am	**Case Discussion** Understanding ISO 13485 Clauses 7 and 8	
12.00 pm	**Lunch**	
1.00 pm	**Case Discussion (cont'd)** Understanding ISO 13485 Clauses 7 and 8	
2.00 pm	**Global utility of ISO 13485** • IVDR • MDSAP	**Ms Hwee Ee TAN** Founder and Principal Consultant DH RegSys
2.45 pm	**Case Discussion** • Design inputs	
3.30 pm	**Tea break**	
4.00 pm	**Case Discussion (cont'd)** • Design inputs	
5.30 pm	**End of Day 2**	

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Day 3 (23 May 2026)

Time	Agenda	Speaker/Facilitator
8.30 am	**Registration**	
9.00 am	**Experience sharing – ISO 13485 audits**	**Ms Hwee Ee TAN** Founder and Principal Consultant DH RegSys
9.45 am	**Case Discussion** Identifying and addressing ISO 13485 non-conformance	**DH RegSys** **Ms Faith TAN** Education Associate **Ms Jessalyn CHAN** Research Associate CoRE Duke-NUS
10.30 am	**Tea Break**	
11.00 am	**Case Discussion (cont'd)** Identifying and addressing ISO 13485 non-conformance	
12.00 pm	**Workshop conclusion**	**Asst Prof Wei Chuen TAN-KOI** Lead, Regulatory System Strengthening CoRE Duke-NUS
12.30 pm	**Lunch and End of Workshop**	

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