Manufacturing and Quality Management System

24 – 25 April 2024

WORKSHOP PROGRAMME

Ensuring quality of healthcare products is one of the key pillars in regulatory responsibilities, for industry, manufacturers and regulators. The contribution of manufacturing and quality controls in health technologies and devices spans from product development to the final product, as well as for measures to monitor compliance to standards. This course illustrates the key considerations in achieving and maintaining product quality, using optimal quality management system.

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
- Explain the conformity assessment methods by major regulatory authorities
- Describe the key considerations in change management and post-market activities of IVDDs

Target Audience

- Regulators, Industry QA/RA professionals, product developers, entrepreneurs and investors with interest in diagnostics, and Academia

Manufacturing and Quality Management System

Academia, SGH Campus

24 – 25 April 2024

Day 1 (24 Apr 2024)

Time	Agenda	Speaker/Facilitator
8.00 am	**Registration**	
8.30 am	**Welcome address**	**Centre of Regulatory Excellence (CoRE)** **Duke-NUS Medical School**
8.40 am	**Workshop briefing**	**Dr Rahul Pandey** Outreach & Talent Development Diagnostics Development Hub (DxDHub)
8.50 am	**Photo taking session**	
9.00 am	**Recap: Design & Development and Verification & Validation**	**Dr Rahul Pandey** Outreach & Talent Development Diagnostics Development Hub (DxDHub)
10.00 am	**Dossier Preparation and Product Registration for IVD and SaMD**	**Ms Ng Szu Shien** Quality Assurance and Regulatory Affairs (QARA) DxDHub
10.45 am	**Tea Break**	
11.00 am	**Labeling and Packaging for IVD and SaMD**	**Ms Jessica Yap** QARA DxDHub
11.45 am	**Document and Record Control**	**Ms Janet Poh** QARA DxDHub
12.30 pm	**Lunch**	

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1.30 pm	**Quality Management System (QMS) application in a Medical Device Organization**	**Ms Tan Hwee Ee** Founder and Director DH RegSys Private Limited
2.30 pm	**Determining Sites and Facility Requirements for IVD and SaMD**	**Dr Lin You Bin** Senior Manager Biomedical Project DxDHub **Mr Henry Johnson Susainathan** Principal Manager DxDHub
3.15 pm	**Tea break**	
3.30 pm	**Case Discussion** Manufacturing and QMS	**Ms Tan Hwee Ee** DH RegSys Private Limited **Dr Rahul Pandey** **Dr Lin You Bin** DxDHub
5.15 pm	**Wrap Up and Lessons Learnt**	**Dr Rahul Pandey** DxDHub
5.30 pm	**End of Day 1**	

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Day 2 (25 Apr 2024)

Time	Agenda	Speaker/Facilitator
8.00 am	**Registration**	
8.30 am	**Process Validation for Scale-Up Manufacturing: IVD and SaMD**	**Dr Lin You Bin** **Mr Henry Johnson Susainathan** DxDHub
9.30 am	**Customer Related Processes for IVD and SaMD**	**Ms Tan Hwee Ee** Founder and Director DH RegSys Private Limited
10.15 am	**Tea Break**	
10.30 am	**Device History Records (Batch Records)**	**Ms Chan Yang Sun** Quality Assurance & Regulatory Affairs DxDHub
11.30 am	**HSA Post-market Regulatory Requirements**	**Ms Jessica Yap** QARA DxDHub
12.30 pm	**Lunch**	
1.30 pm	**Case Discussion** Manufacturing and QMS	**Ms Tan Hwee Ee** DH RegSys Private Limited **Dr Rahul Pandey** **Mr Henry Johnson Susainathan** DxDHub
3.30 pm	**Tea break**	
3.45 pm	Quiz	**Dr Rahul Pandey** DxDHub
4.30 pm	Recap • Learnings from Day 1 & 2 • Learning across the three workshops	**Dr Rahul Pandey** DxDHub
5.00 pm	**Closing remarks**	**CoRE**
5.30 pm	**End of Day 2**	

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