Centre of Regulatory Excellence
@ Duke-NUS Medical School

Manufacturing and Quality Management System

25 – 26 April 2023

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:

- Articulate the principles of Good Manufacturing Practices
- Relate regulatory requirements to development of Quality Management Systems
- Articulate key processes for quality management of raw materials, site and facilities
- List the considerations for choosing contract manufacturers

Target Audience

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

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Day 1 (25 Apr 2023)

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) **Dr John Thornback** Senior Advisor DxDHub
8.50 am	**Photo taking session**	
9.00 am	**Overview of key processes in production: Design & Development and Verification & Validation**	**Dr John Thornback** DxDHub
10.00 am	**Dossier preparation and product registration for IVD and SaMD**	**Ms Ng Szu Shien** QARA DxDHub
10.45 am	**Tea Break**	
11.00 am	**Labeling and packaging for IVD and SaMD**	**Ms Jayashree Chandrasekaran** Regulatory Affairs Manager 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 John Thornback** DxDHub **Mr Henry Johnson Susainathan** Senior Manager DxDHub
3.15 pm	**Tea break**	
3.30 pm	**Case Discussion** Manufacturing and QMS	**Dr John Thornback** **Dr Rahul Pandey** DxDHub **Dr Lin You Bin** Senior Manager, Biomedical Project DxDHub
5.15 pm	**Wrap Up and Lessons Learnt**	**Dr John Thornback** **Dr Rahul Pandey** DxDHub
5.30 pm	**End of Day 1**	

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Day 2 (26 Apr 2023)

Time	Agenda	Speaker/Facilitator
8.00 am	**Registration**	
8.30 am	**Process validation for Manufacturing: IVD and SaMD**	**Dr Lin You Bin** **Mr Henry Johnson Susainathan** DxDHub
9.30 am	**Customer related processes for IVD and SaMD**	**Dr John Thornback** DxDHub **Ms Ho Yuan Lu** Vice President, Outreach & Talent Development DxDHub
10.15 am	**Tea Break**	
10.30 am	**Device history records (Batch records)**	**Ms Tan Hwee Ee** Founder and Director DH RegSys Private Limited **Ms Chan Yang Sun** Quality Assurance & Regulatory Affairs DxDHub
11.30 am	**Post-market requirements**	**Ms Jessica Yap** QARA DxDHub
12.30 pm	**Lunch**	
1.30 pm	**Case Discussion** Manufacturing and QMS	**Dr John Thornback** **Dr Rahul Pandey** **Mr Henry Johnson Susainathan** DxDHub
3.30 pm	**Tea break**	
3:45 pm	Quiz	**Dr John Thornback** **Dr Rahul Pandey** DxDHub
4.30 pm	**Wrap Up and Lessons Learnt**	**Dr John Thornback** **Dr Rahul Pandey** DxDHub
5.00 pm	**Closing remarks**	**CoRE**
5.30 pm	**End of Day 2**	

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