Centre of Regulatory Excellence
@ Duke-NUS Medical School

Regulation of In Vitro Diagnostic Devices

1st – 2nd September 2020
Mode: Zoom

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
- Explain the conformity assessment methods by major regulatory authorities
- Identify the relevant standards and their role in product design verification and validation
- Describe the key considerations in change management and post-market activities of IVDDs

Target Audience

- Regulators, Industry QA/RA professionals and Academia

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Draft Programme

Day 1

Time	Agenda	Speaker/Facilitator
8:30 am	**Zoom Briefing**	**Mr Osman Bin Mohamad** Senior Associate Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
9.00 am	**Welcome Address**	**Prof John Lim** Executive Director Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
9.10 am	**Introduction to IVDDs** • Medical Device Definition • General Medical Device vs IVDDs	**Mr Ananda P Muthalagu** Associate II Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
9.30 am	**Regulatory requirements of IVDDs** • Overview of IVDDs regulatory guidelines • Total product life cycle approach in regulation • Key principles in regulation	**Ms Beverly Liew** Senior Regulatory Specialist Medical Devices Branch Health Sciences Authority
10.15 am	**Tea Break**	
10.45 am	**Risk classification, Grouping and Conformity assessment in selected regions** • International Medical Device Regulators Forum(IMDRF) • US FDA • EU (IVDDs) • ASEAN	**Dr Adelheid Schneider** Head Quality and Regulatory Asia Pacific Roche Diagnostics Asia Pacific Pte Ltd
11.30 am	**Updates on EU IVDR and it impacts** • Existing IVD regulation in EU • In Vitro Diagnostic Devices requirements (IVDR) and implementation timelines • Challenges with notified bodies approval • Impact of IVDR in ASEAN and APAC	**Ms Joyce Tan** Director Regulatory Affairs SEA BD
12.15pm	**Lunch**	
1.15 pm	**General Safety and Performance Requirements** • Essential principles of safety and performance requirements • Labelling information	**Ms Sumati Randeo** Head External Affairs, Roche Diagnostics India
2.00 pm	**Pre-clinical/Analytical Performance validation**	**Dr John Thornback** Chief Operating Officer Diagnostics Development Hub
2.45 pm	**Tea break**	
3.15 pm	**Role of standards and guidelines** • ISO/IEC Standards for IVDDs • IMDRF guidelines on IVDR	**Mr Danny Ong** Senior Regulatory Specialist Medical Devices Branch Health Sciences Authority

**The Programme is accurate as of 28 August 2020 and may be subjected to further refinement if necessary before the actual workshop.*

4.00 pm	**Team activity** • Risk classification and regulatory requirements	
5.30 pm	**End of Day 1**	

Day 2

Time	Agenda	Speaker/Facilitator
8.45 am	**Registration**	
9.00 am	**Software in IVD products** • Performance validation • Pre-certification process for SaMD (Software as a Medical Device)	**Dr John Thornback** Chief Operating Officer Diagnostics Development Hub **Dr Maple Ye Hongye** Senior Manager Diagnostics Development Hub
9.45 am	**Clinical performance** • Clinical performance studies and report • Clinical risk benefit assessment	**Ms Shelley Tang** Principal Stellar consulting
10.30 am	**Tea Break**	
11.00 am	**Change management** • Types of changes • Key regulatory considerations in IVD design change	**Dr Adelheid Schneider** Head Quality and Regulatory Asia Pacific Roche Diagnostics Asia Pacific Pte Ltd
11.45am	**Post market surveillance** • AE and FSCA case discussions ○ Example: Software upgrade	**Dr Kelsen Bastari** Senior Regulatory Specialist Medical Devices Branch Health Sciences Authority
1.00 pm	**Lunch**	
2.00 pm	**IVD Technology trends** • Next Generation Sequencing • Companion diagnostics • Personalised Healthcare	**Mr Varun Veigas** Regional Manager Regulatory Affairs Asia Pacific Roche Diagnostics Asia Pacific Pte. Ltd
2.45 pm	**Panel discussion** • Novel regulatory approaches for innovative IVD products • Regulatory in enabling timely product access and safety interventions	**Moderator:** **Prof John Lim** CoRE **Panelists:** **Dr John Thornback** Diagnostics Development Hub **Ms Beverly Liew** Health Sciences Authority **Dr Adelheid Schneider** Roche Diagnostics Asia Pacific Pte Ltd
3.45 pm	**Q&A**	
4.00 pm	**Workshop Conclusion**	**A/Prof Silke Vogel** Deputy Director, CoRE Senior Associate Dean Graduate Studies

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4.10 pm	**End of Workshop**	

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