Regulation of In Vitro Diagnostic Devices

29 – 30 November 2022
Mode: Face to Face

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
- Describe the key considerations in change management and post-market activities of IVDDs

Target Audience

- Regulators, Industry QA/RA professionals, and Academia with interest in In Vitro Diagnostic Devices

Regulation of In Vitro Diagnostic Devices
Duke-NUS Medical School
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Day 1 (29th Nov 2022)

Time	Agenda	Speaker/Facilitator
8.00 am	**Registration**	**Attendees**
8.30 am	**Welcome Address**	**Prof John Lim** Executive Director Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
8.40 am	**Workshop Briefing and Introduction to IVDDs**	**Mr Sheikh Muhd** Senior Education Associate Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School **Dr John Thornback** Senior Advisor Diagnostics Development Hub
8.55 am	**Photo taking session**	**Attendees & CoRE**
9.00 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**	
10.30 am	**Risk classification, Grouping and Conformity assessment in selected regions** • International Medical Device Regulators Forum (IMDRF) • ASEAN	**Dr Adelheid Schneider** Head Quality and Regulatory Asia Pacific Roche Diagnostics Asia Pacific Pte Ltd
11.15 am	**Updates on EU IVDR and it impacts** • Existing IVD regulation in EU • In Vitro Diagnostic Devices requirements (IVDR) and implementation timelines • Impact of IVDR in ASEAN and APAC	**Ms Yasha Huang** Head of Regulatory Policy Asia Pacific, Global Regulatory Policy & Intelligence, Roche Diagnostics
12.00 pm	**Lunch**	
1.00 pm	**General Safety and Performance Requirements** • Essential principles of safety and performance requirements • Labelling information	**Ms Sumati Randeo** Head External Affairs, Roche Diagnostics India
1.45 pm	**Role of standards and guidelines** • ISO/IEC Standards for IVDDs	**Dr Melissa Robins** Life Sciences Regulatory Affairs Manager Becton Dickinson (BD) Australia and New Zealand
2.45 pm	**Tea break**	

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3.00 pm	**Strategies for successful market entry of IVD** • Introducing IVD innovation globally and in ASEAN • Overcoming regulatory challenges • Engaging relevant stakeholders e.g. other government organizations related to the use of the IVD	**Mr Karan Bindra** Director NKG Advisory Business & Consulting Services Pvt Ltd
4.00 pm	**Team activity** • Risk classification and regulatory requirements	CoRE
5.30 pm	**End of Day 1**	

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Day 2 (30th Nov 2022)

Time	Agenda	Speaker/Facilitator
8.00 am	**Registration**	**Attendees**
8.30 am	**Pre-clinical/Analytical Performance validation**	**Dr John Thornback** Senior Advisor Diagnostics Development Hub
9.15 am	**Clinical performance** • Clinical performance studies and report • Clinical risk benefit assessment	**Dr Melissa Robins** Life Sciences Regulatory Affairs Manager Becton Dickinson (BD) Australia and New Zealand
10.00 am	**Tea break**	
10.15 am	**Software in IVD products** • Performance validation • Pre-certification process for SaMD (Software as a Medical Device)	**Mr Lijoy George** AVP, Digital Health | Diagnostics Development Hub (DxD Hub) at A*STAR - Agency for Science, Technology and Research
11.00 am	**Preparing a dossier for submission** • Manufacturer and registration communication for documentation preparation • Alternative technical documents to expedite registration approval • Documentation archiving and retrieval best practices • Common mistakes while preparing for documentation submission.	**Mr Winson Teng** Global Regulatory Intelligence Manager Becton Dickinson (BD)
11.45 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
12.30 pm	**Lunch**	
1.30 pm	**Team activity** • Change management	**Dr Adelheid Schneider** Head Quality and Regulatory Asia Pacific Roche Diagnostics Asia Pacific Pte Ltd
2.30 pm	**ASEAN updates on IVD** • Updates on the requirements and changes in IVD • Updates on the Vietnam market for IVD	**Ms Nhi Hang Nguyen** Senior Regulatory Affairs Specialist Andaman Medical
3.15 pm	**Tea break**	
3.30 pm	**Brainstorming for the panel discussion** • Regulatory innovations in enabling timely product access and safety interventions for IVDDs	**Attendees**

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4.20 pm	**Panel discussion** • Regulatory innovations in enabling timely product access and safety interventions for IVDDs • Q&A	**Moderator** **Dr John Thornback** Senior Advisor Diagnostics Development (DxD) Hub **Panelist** **Ms Beverly Liew** Senior Regulatory Specialist Medical Devices Cluster Health Products Regulation Group Health Sciences Authority **Ms Yasha Huang** Head of Regulatory Policy Asia Pacific, Global Regulatory Policy & Intelligence, Roche Diagnostics **Ms Maria Cecilia C. Matienzo** Director IV, Center for Device Regulation, Radiation Health and Research, Food and Drug Administration, The Philippines
5.20 pm	**Workshop Conclusion**	**A/Prof Silke Vogel** Deputy Director, CoRE Senior Associate Dean Graduate Studies Duke-NUS Medical School
5.30 pm	**End of Workshop**	

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