GRADUATE CERTIFICATE IN HEALTH PRODUCTS REGULATION
GMS5107: In Vitro Diagnostics and Precision Medicine

4 October 2021 – 08 October 2021

Venue: Zoom

WORKSHOP PROGRAMME

Learning outcomes

- Describe key regulatory requirements of IVDs through the total product life cycle
- Explain the regulatory frameworks by major authorities
- Identify the relevant standards and its role in product design verification and validation for regulatory submissions
- Describe the key considerations in change management and post-market activities of IVDs
- Explain the regulation of IVDs in precision medicine

Graduate Certificate in Health Products Regulation

GMS5107: In Vitro Diagnostics and Precision Medicine

04 October 2021 – 08 October 2021

Day 1 – 04 October, Mon

	Topic	Speaker/ Organisation
8.15am	**Zoom Briefing**	**Mr Osman Mohamad** Senior Associate Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School Singapore
Session 1: Introduction to IVDs and Precision medicine		
8.30am	**Welcome Graduate Certificate Students**	**Professor John Lim** Executive Director Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School Singapore
8.45am	**Workshop Briefing**	
9.00am	**Overview of IVD devices** • Value of Diagnostics in healthcare systems • Covid test kits in fighting the pandemic • Market size and growth potential in APAC	**Dr Rahul Pandey** Principal Manager Diagnostics Development (DxD) Hub
9.45am	**Total Product Lifecycle of IVD devices** • Concept development and design • Design Verification and Validation • Manufacturing and QMS • Placing on market • Marketing – Post market • **Out phasing - Termination**	**Dr Shaqireen Moinuddeen** Senior Regulatory Specialist Medical Devices Cluster Health Sciences Authority Singapore
10.30am	**Refreshment Break**	
11.00am	**RUOs and Laboratory Developed Tests (LDT) and how they relate to IVD** • Definition of RUOs and LDTs • Labs use LDTs • Roles and responsibilities • Understanding LDT regulation	**Dr John Thornback** Chief Operating Officer Diagnostics Development Hub (DxD Hub)
11.45pm	**Introduction to precision medicine** • What is precision medicine? • Role of IVDs • Opportunities and challenges in enabling precision medicine	**Ms Lubna Syed** Global Director Regulatory Affairs Janssen
12.30pm	**Lunch**	
Session 2: Regulatory Frameworks for IVDs		
1.30pm	**IMDRF** • Background of IMDRF • IMDRF Regulatory Framework • Guidelines on IVDs • Risk Classification (Examples) • Clinical Evidence • Post market requirement • Dossier requirement • Adopting IMDRF guidelines	**Mr Danny Ong** Senior Regulatory Specialist Medical Devices Branch Health Sciences Authority Singapore

2.45pm	**US FDA** • Background of FDA • FDA Regulatory Framework • Regulatory pathways	**Ms Lubna Syed** Global Director Regulatory Affairs Janssen
3.30pm	**Refreshment Break**	
4.00pm	**EU IVDR** • Introduction • IVDR impact for marketed products in APAC • Current regulatory practices and trends in handling IVDR changes among APAC authorities	**Ms Yasha Huang** Regional Regulatory Affairs and Policy Lead Regional VDR Program Lead Roche Diagnostics Asia Pacific
4.45am	**ASEAN** • Background of ASEAN • AMDD the ASEAN Regulatory Framework • AMDD origin and mandates • Stipulations of IVD requirements • Risk classification • AMDD ratification status in ASEAN member states	**Ms Low Lai Peng** Deputy Director Medical Devices Branch Health Sciences Authority Singapore
5.30pm	**End**	

Day 2 – 05 October, Tue

	Topic	Speaker/ Organisation
8.30am	**Individual and Group assessment I**	
Session 3: Pre-market requirements: Part I *(Risk Class, grouping, EP checklist and analytical performance)*		
9.30am	**Risk Classification** • IVD Definition and product classification (eg., IVD instruments, reagents) • IMDRF, AMDD risk classification • Case studies (eg., POC IVDs, Software)	**Dr Adelheid Schneider** Head of Quality and Regulatory Asia Pacific Roche Diagnostics Asia Pacific Pte Ltd
10.15am	**Refreshment Break**	

10.45am	**Grouping**
	• What is grouping?
	• Grouping concepts
	• Case studies
	  ○ ASEAN
	  ○ US FDA
	  ○ EU, TGA (GMDN code)
		Dr Adelheid Schneider
		Head of Quality and Regulatory Asia Pacific
		Roche Diagnostics Asia Pacific Pte Ltd

11.30am	**Essential Principles checklist** • EP Checklist in Design and development • Understanding the general requirements • Determining applicable clauses • Role of standards	**Dr Melissa Robins** Regulatory Affairs Manager BD Life Sciences Australia and New Zealand
12.15 pm	**Lunch**	
1.15pm	**Analytical Performance** • Accuracy • Precision • Specificity, sensitivity • Limit of Detection, Range, Interfacing substances, etc	**Dr John Thornback** Chief Operating Officer Diagnostics Development Hub (DxD Hub)
2.00pm	**Stability studies** • Reagent, analyte and control • Packaging and shipment validation • Real time vs accelerated ageing studies	**Dr John Thornback** Chief Operating Officer Diagnostics Development Hub (DxD Hub)
2.45pm	**Refreshment Break**	
3.30pm	**Practicum I** • Risk Classification and Grouping • Analytical performance	
5.30pm	**End**	

Day 3 – 06 October, Wed

	Topic	Speaker/ Organisation
8.30am	**Individual and Group assessment II**	
Session 3:	**Pre-market requirements: Part II *(Clinical, Software, labelling and QMS)***	
9.30am	**Clinical Evidence - Clinical Performance** • When is clinical data required? • Risk benefit assessment • Clinical study requirements • Sample and site requirements • IMDRF	
10.15am	**Refreshment Break**	
10.45am	**Software in IVD devices** • Qualification of Software • Fit for purpose risk categorization of software (eg., IMDRF Framework) • Software with multiple functions • Alternative regulatory pathways for regulating software	**Dr Melissa Robins** Regulatory Affairs Manager BD Life Sciences Australia and New Zealand
11.30am	**Labelling requirements and considerations** • Instructions for use • IVD labelling • Self-diagnose vs Professional use only devices • Reviewing marketing materials	
12.15pm	**Lunch**	
Session 3:	**Post market and QMS**	
1.15pm	**Change management** • Types of changes • Instrument with reagent • Regulatory approval in APAC	**Dr Adelheid Schneider** Head of Quality and Regulatory Asia Pacific Roche Diagnostics Asia Pacific Pte Ltd
2.00pm	**Post market vigilance of IVD** • Case discussion: - Adverse events and Field Safety Corrective Action	**Dr Kelsen Bastari** Senior Regulatory Specialist Medical Devices Branch Health Sciences Authority Singapore
2.45pm	**Refreshment Break**	
3.30pm	**Practicum II** • Clinical risk benefit analysis	
5.30pm	**End**	

Day 4 – 07 October, Thurs

	Topic	Speaker/ Organisation
8.30am	**Individual and Group assessment III**	
9.30am	**Quality Management system** • ISO 13485 general requirements • Distribution vs manufacturing • Manufacturing process	
10.15am	**Refreshment Break**	
Session 3: IVDs in Precision Medicine		
10.45am	**Precision Medicine and IVDs – Physician's perspective** • Impact on patient care • Practical challenges encountered	
11.30am	**Companion Diagnostics** • What is a CDx • Regulatory Pathway of CdX across the globe • Co-development of CDx with Therapeutic product • Bridging studies • CDx specific regulatory requirements	**Ms Carly McWilliams** Head of Regulatory Policy Roche
12.15pm	**Lunch**	
1.15pm	**Digital Pathology** • Use of AI in improving patient care	
2.00pm	**Next generation sequencing: Opportunities and challenges for CDx and NGS products registration** • NGS based IVDs – Regulatory Requirements and Considerations • CDx - Regulatory approach in Singapore	**Mr Ming Hao Ong** Senior Regulatory Specialist Health Sciences Authority Singapore
2.45pm	**Refreshment Break**	
3.30pm	**SaMD for Precision Medicine**	**Mr Varun Veigas** Regional Regulatory Affairs and Policy Lead, Asia Pacific Roche Diagnostics Asia Pacific Pte. Ltd
4.00pm	**Case Discussion**	
5.30pm	**End**	

Day 5 – 08 October, Fri

	Topic	Speaker/ Organisation
9.00am	**End-of-Module (EOM) Assessment**	
10.00am	**EOM Review**	
10.30am	**Refreshment Break**	
11.00am	**Networking**	
Session 7: Regulating IVD products - Challenges and Opportunities		
11.45am	**Digitalization of IVD industry** • Clinical decision support • Artificial Intelligence • Regulatory concerns and considerations	**Mr Varun Veigas** Regional Regulatory Affairs and Policy Lead, Asia Pacific Roche Diagnostics Asia Pacific Pte. Ltd
12.30pm	**Lunch**	
1.30pm	**Regulatory Harmonization and Convergence Initiatives** • WHO • APEC-RHSC • GHWP	**Mr Neo Cherng Yeu** Associate Director, Strategy Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School Singapore
2.15pm	**Regulatory Agility** • Reliance and recognition • Examples	**Ms Yasha Huang** Regional Regulatory Affairs and Policy Lead Regional VDR Program Lead Roche Diagnostics Asia Pacific
3.00pm	**Panel Session** • Direction shift in companion diagnostics • Pandemic preparedness and changes in IVD realm • Regulatory agility towards innovation • Precision medicine as a mainstream reality	
4.00pm	**Graduate Certificate Workshop Conclusion**	
4.15pm	**End**	