GRADUATE CERTIFICATE IN PHARMACEUTICAL REGULATION

GMS5003: Fundamentals of Health Products Regulation

9 September 2024 – 13 September 2024

Venue: White Space Room (Level 2), Academia, 20 College Road, Singapore 169856

WORKSHOP PROGRAMME

Learning outcomes

- Explain the foundational basis of regulatory management and decision-making for health products
- Explain the essential principles in managing pharmaceuticals across their life cycles
- Describe the regulatory requirements for the different product development phases
- Relate to the real-life settings in regulatory decision-making through hands-on practical sessions
- Recognize the major regulatory organisations steering the innovation of regulatory processes and focus

Graduate Certificate in Pharmaceutical Regulation

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Day 1 – 9 September 2024, Mon

	Topic	Speaker/ Organisation
8.30 am	**Welcome Graduate Certificate Students**	**Professor John C W Lim** Executive Director CoRE Duke-NUS Medical School
9.00 am	**Workshop Briefing**	**Dr Rathi Saravanan** Lead Education Associate Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
9.15 am	**Brightspace and Assessment Familiarization**	**Mr. Osman Bin Mohamad** Senior Education Associate Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
9.30 am	**Pre-workshop Assessment**	**CoRE Education Team**
Session 1: Health Products Regulatory Overview and Role of Regulatory Professionals		
9.45 am	**Introduction to pharmaceutical regulation in the context of healthcare in resource endowed and resource constrained settings** • Provide broad overview of how regulations are evolving in the context of changing global landscape	**Dr Murray Lumpkin** Deputy Director – Integrated Development Lead, Global Regulatory Systems Initiatives Bill and Melinda Gates Foundation, US
11.00 am	**Refreshment Break**	
11.30 am	**To understand the role of regulation – and different approaches to regulation – in each phase of the product lifecycle** • The role of pharmaceutical regulations and its contribution to the healthcare environment	**Dr Charles Preston** Senior Program Officer Bill & Melinda Gates Foundation, US
12.30 pm	**Lunch**	
1.30 pm	**Role of regulatory professionals** • Role of regulatory professionals • Professional development frameworks	**Mr Thean Soo (TS) LO** Regulatory Affairs Management Consultant TS Consulting
2.15 pm	**Health Products Regulation: Role of stakeholder interactions for effective regulatory decision making** • Pre-consultations in guiding development • Importance of stakeholder interactions in ensuring SEQ of pharmaceutical products	**Mr Thean Soo (TS) LO** TS Consulting
3.00 pm	**Refreshment Break**	
Session 2: Health Products Development Overview and Commercialisation Strategies		
3.15 pm	**Target Product Profiling (TPP) in product development** • Use of TPP significance in product development and market entry	**Dr Deborah Chen** Director Cairnhill Pharma

4.15 pm	**Commercialisation strategies for pharmaceutical products** • Regulatory activities in the context of commercialization and ensuring regulatory compliance in tech transfer • Assessing the commercial potential of innovations and inventions • Case examples	**Mr. Andy Li** NUS Enterprise National University of Singapore
5.20 pm	**Debrief and Announcements**	**CoRE Education Team**
5.30pm	**End of Day 1**	

Day 2 – 10 September 2024, Tue

	Topic	Speaker/ Organisation
Session 3:	**Ensuring Quality, Safety and Efficacy of Pharmaceutical Products**	
8.30 am	**Overview of Chemistry, Manufacturing and Controls** • Concept of pharmaceutical quality (PQ/CMC) • Importance and impact of pharmaceutical quality on patient safety • Pharmaceutical quality initiatives • Key regulatory guidelines and requirements • General practices in the industry providing quality assurance	**Dr Rathi Saravanan** Lead Education Associate CoRE Duke-NUS Medical School
9.30 am	**Manufacturing of pharmaceutical products** • Introduction to regulatory control on quality • Introduction to ICH CTD Module 3 Quality section	**Dr Sannie Chong** Senior Director, APAC Regulatory Policy MSD
10.30 am	**Refreshment Break**	
10.45 am	**Good Manufacturing Practices (GMP): Main Concepts** • Failures in GMP • GMP history • Basic GMP requirements including definition and quality management	**Dr Smitha Kenchath** Consultant Seer Pharma (Singapore) Pte Ltd
11.30 am	**Overview of non-clinical requirements for pharmaceuticals** • Types of nonclinical studies • Data for FIH studies	**Adj Assoc/Prof Cynthia Sung** CoRE Duke-NUS Medical School
12.30 pm	**Lunch**	
1.30 pm	**Overview of Good Clinical Practice (GCP) requirements and clinical trial application (CTA) for pharmaceuticals** • Principles of GCP • Key GCP guidelines (WHO/ICH/HSA) • CTA vs CTN	**Dr Yvanka Gilliam** Head of Clinical Alliances Singapore Clinical Research Institute (SCRI)
2.00 pm	**Overview of pharmaceuticals clinical development** • Phases of Clinical Trials • Design of CT: inclusion exclusion criteria, endpoints	**Dr Yvanka Gilliam** Head of Clinical Alliances Singapore Clinical Research Institute (SCRI)
3.00 pm	**Refreshment Break**	
3.15 pm	**Practicum I** Clinical development of pharmaceuticals	**Expert Faculty: Dr Yvanka Gilliam**
5.20 pm	**Debrief and Announcements**	CoRE Education Team
5.30 pm	**End of Day 2**	

Day 3 – 11 September 2024, Wed

	Topic	Speaker/ Organisation
8.30 am	**Individual and Group assessment I**	
Session 4:	**Regulatory Processes for Pharmaceutical Products**	
9.30 am	**Market authorisation application (Pharmaceutical Products)** • Requirements for MAA submission and review in select countries • ICH CTD submission requirements	**Asst/Prof James Leong** Head Pharmaceutical Regulatory Science Programme CoRE, Duke-NUS Medical School
10.30 am	**Refreshment Break**	
10.45 am	**Regulatory requirements for regulatory decision making: Benefit-risk analysis** • Benefit-risk assessment for regulatory decision making	**Asst/Prof James Leong** CoRE, Duke-NUS Medical School
12.00 pm	**Lunch**	
1.00 pm	**Practicum II** Benefit-Risk Assessment of Pharmaceutical Products	**Expert Faculty: Asst/Prof James Leong**
3.30 pm	**Refreshment Break**	
3.45 pm	**Good Submission Practices (GSubP) in supporting efficient therapeutics registration in ASEAN**	**Dr Sannie Chong** Senior Director, APAC Regulatory Policy MSD
4.30 pm	**Good Review Practices (GRevP) and Regulatory cooperation** • WHO GRevP guideline • Principles of a Good Review • Managing the Review	**Asst/Prof James Leong** CoRE Duke-NUS Medical School
5.20 pm	**Debrief and Announcements**	**CoRE Education Team**
5.30pm	**End of Day 3**	

Day 4 – 12 September 2024, Thurs

	Topic	Speaker/ Organisation
Session 5: Post-approval processes and product lifecycle management		
8.30 am	**Managing post- approval quality changes** • Risk based approach to post-approval changes • Reliance practices in post-approval CMC changes	**Dr. Jeremy Shonberg** Regional Senior Regulatory Scientist TGA Australia
9.30 am	**GMP compliance, audit and inspections**	**Dr Smitha Kenchath** Consultant Seer Pharma (Singapore) Pte Ltd
10.30 am	**Refreshment Break**	
10.45 am	**Total Product Lifecycle (TPLC) management**	**Asst/Prof James Leong** CoRE Duke-NUS Medical School
12.00 pm	**Lunch**	
1.00 pm	**Global trends in pharmacovigilance**	**Asst. Prof Tan-Koi Wei Chuen** Assistant Professor, Advisory Lead CoRE Duke-NUS Medical School
1.45 pm	**Overview of pharmacovigilance for pharmaceutical products** • Introduction to pharmacovigilance • Appreciation of the pharmacovigilance framework • Risk management plans and post-marketing activities	**Dr Han Phey Yen** Regulatory Consultant Vigilance & Compliance Branch Health Sciences Authority, Singapore
2.30 pm	**Practicum III** Risk management plans for pharmaceutical products	**Expert Faculty: Dr Han Phey Yen**
3.00 pm	**Refreshment Break**	
3.15 pm	**Practicum III** Continued and Discussions	
5.30pm	**End of Day 4**	

Day 5 – 13 September 2024, Fri

	Topic	Speaker/ Organisation
9.00 am	**End-of-Module (EOM) Assessment**	**CoRE Education Team**
10.00 am	**Refreshment Break**	
10.15 am	**Review of EOM Questions**	**CoRE Education Team**
Session 6: Trends in Health Products Development and Regulations		
11.00 am	**Introduction to Precision Health and Medicine** • Overview of landscape • National and Regional programs in Precision Medicine	**Valerie Mbella** Director Global Regulatory Affairs Diagnostics, Johnson & Johnson Innovative Medicine
12.00 pm	**Development and use of standards in supporting product development**	**Dr. Fan / Siow Kay** CoRE SDO
11.30 am	**Patient engagement, Coalition to Accelerate Patient Engagement in Asia-Pacific (CAPE)** • Importance of patient involvement • Patient engagement in product lifecycle • Real world examples	**Dr Khoo Yoong Khean** Scientific Officer Global Health Policy CoRE Duke-NUS Medical School
12.00 pm	**Lunch**	
1.00 pm	**Gallery Walk**	**CoRE Education Team**
3.00 pm	**Introduction to Healthcare Services Regulation** • Trending areas in healthcare landscape • Service models and technologies in Gene therapies	**Asst. Prof. Kavitha Palaniappan** Assistant Professor, Lead, Healthcare Services Regulation Group (HRG) CoRE Duke-NUS Medical School
3.45 pm	**Break**	
4.00 pm	**Reflection and Peer Sharing**	**Dr. Rathi Saravanan** CoRE
5.15 pm	**Graduate Certificate Workshop Conclusion**	**Prof Silke Vogel** Deputy Director, CoRE Senior Associate Dean Graduate Studies Duke-NUS Medical School
5.30pm	**End of Workshop**	