GRADUATE CERTIFICATE IN HEALTH PRODUCTS REGULATION

GMS5011: Fundamentals of Pharmaceutical Regulation

7 December 2020 – 11 December 2020

Venue: Zoom

WORKSHOP PROGRAMME

Learning outcomes

- Explain the health products regulatory landscape, the interaction among the regulatory stakeholders and the implication on regulatory decision-making
- Describe the importance of quality manufacturing in the product development and quality control of health products
- Describe the stakeholders and processes involved in the marketing authorization application of health products
- Articulate the importance of regulatory strategy
- List current and future trends in health products regulations

Graduate Certificate in Health Products Regulation

GMS5011: Fundamentals of Pharmaceutical Regulation

7 – 11 December 2020

Day 1 – 7 December, Mon

	Topic	Speaker/ Organisation
8.00am	**Zoom Briefing**	**Mr Osman Bin Mohamad** Senior Associate Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
8.30am	**Workshop Briefing / Ice-breaker / Goalsetting**	**Dr How Yew Meng** Senior Associate CoRE, Duke-NUS Medical School
8.50am	**Welcome Graduate Certificate Students**	**Prof John Lim** Executive Director Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
Session 1: Health Products Regulatory Overview and Role of Regulatory Professional		
9.00am	**Health products regulatory landscape (Recording)** • Provide broad overview of how regulations are evolving in the context of changing global landscape	**Dr Murray Lumpkin** Deputy Director – Integrated Development Lead for Global Regulatory Systems Initiatives Bill and Melinda Gates Foundation
10.00am	**Refreshment Break**	
10.15am	**Introduction to pharmaceutical regulations (Recording)** • To understand the purpose of regulatory framework in ensuring pharmaceutical product SEQ • Regulatory decision-making across PLC	**Dr Murray Lumpkin** Deputy Director – Integrated Development Lead for Global Regulatory Systems Initiatives Bill and Melinda Gates Foundation
11.15am	**Pharmaceutical regulations in the context of healthcare (Recording)** • To understand the role of pharmaceutical regulations and its contribution to the healthcare environment.	**Dr Murray Lumpkin** Deputy Director – Integrated Development Lead for Global Regulatory Systems Initiatives Bill and Melinda Gates Foundation
12.15pm	**Q&A with Dr Murray Lumpkin**	
12.30pm	**Lunch**	
2.00pm	**Introduction to medical device regulations** • Overview of MD regulations • US FDA 510(k) • EU CE-mark • ASEAN	**Dr Adelheid Schneider** Head Quality and Regulatory Affairs Asia Pacific Roche Diagnostics Asia Pacific
2.45pm	**Medical device regulations in the context of healthcare** • To understand the role of medical device regulations and its contribution to the healthcare environment.	**Mr Michael Gropp** Advisory Board Member and Visiting Expert CoRE, Duke-NUS Medical School Former Chair RAPS Global Advisory Council
3.30pm	**Refreshment Break**	
4.00pm	**Good Regulatory Practice and the Role of regulatory professionals** • Role of regulatory professional in the current landscape • Good Regulatory Practice (GRP)	**Dr How Yew Meng** Senior Associate CoRE, Duke-NUS Medical School
5.00pm	**End**	

Day 2 – 8 December, Tue

	Topic	Speaker/ Organisation
8.30am	**Individual and Group assessment I**	
Session 2:	**Health Products Processes: Ensuring Quality, Safety, Efficacy**	
9.30am	**Clinical trials for pharmaceutical products and medical devices: Similarities and differences** • Understand the basis for differences in CT requirements between pharm and MD	**Ms Geraldine Seow** Director, Global Program Leader Medical Affairs Operation, Asia Pacific Global Development, Janssen R&D The Janssen Pharmaceutical Companies of Johnson & Johnson
10.15am	**Refreshment Break**	
10.45am	**Manufacturing and inspection process pharmaceutical products** • Introduction to regulatory control on quality • Introduction to ICH Module 3 Quality section (commonly known as CMC section) - Based on ICH M4Q, explain the sections and sub sections in Module 3. In addition, explain what data is required with highlights on the key ICH quality guidelines	**Dr Sannie Chong** Asia Pacific Technical Regulatory Policy Global Regulatory Policy Group Roche Singapore Technical Operations Pte Ltd
11.15am	**Manufacturing and inspection process MD - ISO 13485 (Recording)** • Introduction to QMS for MD • Relevance of ISO 13485 to regulations	**Ms Bernice Lau** Medical Device Lead Auditor TUV SUD PSB Pte Ltd
12.00pm	**Lunch**	
1.00pm	**WHO Quality Management System Requirements**	**Mr Vimal Sachdeva** Technical Officer – Senior Inspector Inspection Services Group, Prequalification Team (PQT) Regulation of Medicines and other Health Technologies (RHT) World Health Organization (WHO)
2.00pm	**Practicum Briefing**	**Dr How Yew Meng** Senior Associate CoRE, Duke-NUS Medical School
2.15pm	**Practicum 1a**	
3.45pm	**Refreshment Break**	
4.00pm	**Practicum 1b**	
5.30pm	**End**	

Day 3 – 9 December, Wed

	Topic	Speaker/ Organisation
8.30am	**Individual and Group assessment II**	
Session 3:	**Health Products Regulatory Process**	
9.30am	**Market authorisation application (pharmaceutical)** • Requirements for MAA submission and review in select countries • ICH CTD submission requirements	**Asst Prof James Leong** Head of Pharmaceutical Regulatory Science Programme CoRE, Duke-NUS Medical School
10.30am	**Refreshment Break**	
11.00am	**Market authorisation application (MD)** • Requirements for MAA submission and review in select countries • ASEAN CSDT for GSP	**Mr Sharad Shukla** Head Regulatory Affairs SEA (MD&D) Johnson & Johnson
12.00pm	**Lunch**	
1.00pm	**Regulatory requirements for regulatory decision making: Benefit-risk analysis** • Benefit-risk assessment for regulatory decision making	**Asst Prof James Leong** Head of Pharmaceutical Regulatory Science Programme CoRE, Duke-NUS Medical School
2.00pm	**Practicum 2a**	
3.30pm	**Refreshment Break**	
4.00pm	**Practicum 2b**	
5.30pm	**End**	

Day 4 – 10 December, Thurs

	Topic	Speaker/ Organisation
8.30am	**Individual and Group Assessment III**	
9.30am	**Vigilance and Post-marketing for pharmaceutical products (Recording)** • Overview of Pharmacovigilance for Pharmaceutical Products • Introduction to Pharmacovigilance • Appreciation of the Pharmacovigilance Framework • Risk Management Plans and Post-marketing Activities	**Ms Christine Ho** Regulatory Consultant Vigilance & Compliance Branch Health Sciences Authority
10.30am	**Refreshment Break**	
11.00am	**Vigilance and Post-marketing for medical devices** • Adverse event reporting • Field Safety Corrective Actions	**Mr Nishith Desai** Vice-President of QA and RA, APAC Medtronic
12.00pm	**Lunch**	
1.00pm	**Practicum 3a**	
2.15pm	**Practicum 3b**	
3.30pm	**Refreshment Break**	
Session 4: Health Products Commercialisation Strategy		
3.45pm	**Commercialisation strategy of pharmaceutical products** • Regulatory activities in the context of commercialization of pharmaceutical product	**Mr Arun Mishra** Head, Global Nutrition Regulatory Affairs and Global Health and Wellness Regulatory Affairs Unilever
4.30pm	**Commercialisation strategy of medical devices** • Understand regulatory activities in the context of commercialization of Medical Devices.	**Dr John Thornback** Chief Operating Officer Diagnostics Development Hub (DxD Hub)
5.15pm	**End**	

Day 5 – 11 December, Fri

	Topic	Speaker/ Organisation
8.30am	**End-of-Module (EOM) Assessment**	
9.30am	**Review of EOM Questions**	
10.30am	**Break**	
Session 5: Trends in Health Product Development and Regulations		
11.00am	**Good Regulatory Management and Professional Development** • Continuing development for regulatory professionals	**Dr Lin Hsien-Yi** Senior Reviewer Division of Medicinal Products Taiwan Food and Drug Administration
11.45am	**Trends in MD Development and Regulation** • Digitalization, wearables, combination products, robotics, AI, 3D printing	**Mr Yu Liang** Director, Regulatory Affairs Asia Pacific Medical Technology Association (APACMed)
12.30pm	**Lunch**	
1.30pm	**Trends in Pharmaceutical Development and Regulation** • RWE, rolling subs, advanced therapies, digital therapies	**Mr Arun Mishra** Head, Global Nutrition Regulatory Affairs and Global Health and Wellness Regulatory Affairs Unilever
2.15pm	**Global and Regional Regulatory Platforms** • Regulatory reliance, convergence, harmonization, work-sharing	**Ibu Lucky Slamet** Visiting Expert CoRE, Duke-NUS Medical School
3.00pm	Photo-taking with Faculty and Participants	**CoRE Team**
3.10pm	**Break**	
3.30pm	**Panel Session: Accelerating innovative developments of health products** Q&A with Industry and Regulators	**Moderator:** **Prof John Lim** **Panelists:** **Mr Michael Gropp** **Mr Yu Liang** **Mr Arun Mishra** **Ibu Lucky Slamet**
5.15pm	**Graduate Certificate Workshop Conclusion**	**A/Prof Silke Vogel** Deputy Director Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
5.30 pm	**End**	