GRADUATE CERTIFICATE IN HEALTH PRODUCTS REGULATION

GMS5011: Fundamentals of Pharmaceutical Regulation

7 September 2020 – 11 September 2020

Venue: Zoom

WORKSHOP PROGRAMME

Learning outcomes

- Interpret the health products regulatory landscape, the interaction among the regulatory stakeholders and the implication on regulatory decision-making
- Compare between the similarities and differences between regulations and guidelines in marketing authorization of pharmaceutical products and medical devices
- Recognize and demonstrate basic principles of assessing benefit-risk ratio and regulatory decision-making for approval of pharmaceutical products and medical devices
- Evaluate and assemble the documentation required for regulatory submission and assessment, for pharmaceutical products and medical devices
- Evaluate the importance of regulatory strategy
- Identify current and future trends in health products regulations
- Examine the role of the regulatory affairs professional

Graduate Certificate in Health Products Regulation

GMS5011: Fundamentals of Health Products Regulation

7 – 11 September 2020

Day 1 – 7 September, 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** • Provide broad overview of how regulations are evolving in the context of changing global landscape	
10.00am	**Refreshment Break**	
10.30am	**Introduction to pharmaceutical regulations** • To understand the purpose of regulatory framework in ensuring pharmaceutical product SEQ • Regulatory decision-making across PLC	
11.30am	**Pharmaceutical regulations in the context of healthcare** • To understand the role of pharmaceutical regulations and its contribution to the healthcare environment.	
12.30pm	**Lunch**	
1.30pm	**Knowledge-Check 1**	**Understanding of pharmaceutical regulations**
2.00pm	**Introduction to medical device regulations** • Overview of MD regulations • US FDA 510(k) • EU CE-mark • ASEAN	
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.	
3.30pm	**Refreshment Break**	
4.00pm	**Knowledge-Check 2**	**Understanding of MD regulations**
4.30pm	**Role of regulatory professionals** • Role of regulatory professional in the current landscape • Changing roles and skill sets	**Dr How Yew Meng** Senior Associate CoRE, Duke-NUS Medical School
5.30pm	**End**	

Day 2 – 8 September, Tue

	Topic	Speaker/ Organisation
8.30am	**Individual and Group assessment I**	
Session 2:	**Health Products: Ensuring Quality, Safety, Efficacy**	
9.30am	**Manufacturing and inspection process pharm products** • Introduction to CMC standards • Drugs + Biologics CMC differences	
10.15am	**Refreshment Break**	
10.45pm	**Manufacturing and inspection process MD (ISO 13485)** • Introduction to QMS for MD • **Relevance of ISO 13485 to regulations**	
11.30am	**Knowledge-Check 3**	**Differences in pharma and MD manufacturing**
12.00pm	**Lunch**	
1.00pm	**Non-clinical trials for pharmaceutical products and medical devices: Similarities and differences** • Understand the basis for differences in Pre/Non-CT requirements between pharm and MD	
2.00pm	**Clinical trials for pharmaceutical products and medical devices: Similarities and differences** • Understand the basis for differences in CT requirements between pharm and MD	
3.00pm	**Refreshment Break**	
3.30pm	**Practicum 1a**	
4.30pm	**Practicum 1b**	
5.30pm	**End**	

Day 3 – 9 September, 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	
10.30am	**Refreshment Break**	
11.00am	**Market authorisation application (MD)** • Requirements for MAA submission and review in select countries • ASEAN CSDT for GSP	
12.00pm	**Knowledge-check 4**	**Differences in between pharma and MD MAA process**
12.30pm	**Lunch**	
1.30pm	**Regulatory requirements for regulatory decision making: Benefit-risk analysis** • Benefit-risk assessment for regulatory decision making	
2.30pm	**Practicum 2a**	
3.30pm	**Refreshment Break**	
3.45pm	**Practicum 2a Cont'd**	
4.15pm	**Practicum 2b**	
5.30pm	**End**	

Day 4 – 25 June, Thurs

	Topic	Speaker/ Organisation
8.30am	**Individual and Group Assessment III**	
9.30am	**Vigilance and Post-marketing for pharmaceutical products** • Regulatory requirements for post-marketing activities • Introduce PV, RMP, enforcement, surveillance •	
10.30am	**Refreshment Break**	
11.00am	**Vigilance and Post-marketing for medical devices** • MD post-marketing activities under the context of Risk management MD (ISO 14971)	
12.00pm	**Knowledge-check 5**	**Differences between pharma and MD post-marketing activities**
12.30pm	**Lunch**	
Session 4: Health Products Strategy		
1.30pm	**Commercialization strategy of pharmaceutical products** • Regulatory activities in the context of commercialization of pharmaceutical product	
2.30pm	**Commercialization strategy of medical devices** • Understand regulatory activities in the context of commercialization of Medical Devices.	
3.00pm	**Refreshment Break**	
3.30pm	**Practicum 3a**	
4.30pm	**Practicum 3b**	
5.30pm	**End**	

Day 5 – 26 June, 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 Regulations		
11.00am	**Good Regulatory Management and Professional Development** • Continuing development for regulatory professionals	
11.45am	**Trends in MD Regulation[1]** • Digitalization, wearables, combination products, robotics, AI, 3D printing	
12.30pm	Photo-taking with Faculty and Participants	**CoRE Team**
12.40pm	**Lunch**	
1.30pm	**Trends in Pharmaceutical Regulation[2]** • RWE, rolling subs, advanced therapies, digital therapies	
2.15pm	**Global and Regional Regulatory Platforms[3]** • Regulatory reliance, convergence, harmonization, work-sharing	
3.00pm	**Break**	
3.30pm	**Panel Session: Accelerating innovative developments of therapeutic technologies of health products** Q&A with Industry and Regulators	
4.30pm	**Towards Regulatory Excellence**	**Prof John Lim** Executive Director Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
5.15pm	**Graduate Certificate Workshop Conclusion**	**A/Prof Silke Vogel** Deputy Director, CoRE Senior Associate Dean Graduate Studies Duke-NUS Medical School
5.30 pm	**End**	