GRADUATE CERTIFICATE IN HEALTH PRODUCTS REGULATION

GMS5003: Fundamentals of Health Products Regulation

5 September 2022 – 9 September 2022

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 and pharmacovigilance of health products
- Explain the importance of commercialisation strategies in dictating the success of health products in the market
- List current and future trends in health products innovations and regulations

Graduate Certificate in Health Products Regulation

GMS5003: Fundamentals of Health Products Regulation

5-9 September 2022

Day 1 – 5 September, Mon

	Topic	Speaker/ Organisation
8.15am	**Zoom Briefing**	**Mr Osman Bin Mohamad** Senior Education Associate Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
8.30am	**Workshop Briefing / Ice-breaker / Goalsetting**	**Dr Uttara Soumyanarayanan** Senior Education Associate CoRE, Duke-NUS Medical School
8.40am	**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 Professionals		
9.00am	**Health products regulatory landscape** • 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
10.45am	**Refreshment Break**	
11.00am	**Introduction to pharmaceutical regulations** • 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
11.30am	**Pharmaceutical regulations in the context of healthcare** • 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
12.30pm	**Lunch**	
2.00pm	**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
2.45pm	**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
3.45pm	**Refreshment Break**	
4.00pm	**Role of regulatory professionals** • Role of regulatory professionals • Professional development frameworks	**Mr Thean Soo (TS) LO** Regulatory Affairs Management Consultant TS Consulting
5:00pm	**Practicum Briefing**	**Dr Uttara Soumyanarayanan**
5.30pm	**End**	

Day 2 – 6 September, Tue

	Topic	Speaker/ Organisation
8.30am	**Individual and Group assessment I**	
Session 2:	**Ensuring Quality, Safety and Efficacy of Health Products**	
9.30am	**Overview of Clinical Development (Pharmaceuticals)** • Phases of Clinical Trials ○ Design of CT: inclusion exclusion criteria, endpoints	**Dr Eugene Gan** Senior Director Singapore Clinical Research Institute
10.15am	**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
10.55am	**Break**	
11.00am	**Practicum 1a** Clinical Development of Pharmaceuticals	**CoRE Education Team**
12.30pm	**Lunch**	
1.30pm	**Practicum 1b** Clinical Studies for Medical Devices	**Ms Geraldine Seow** Johnson & Johnson
3.15pm	**Refreshment Break**	
3.30pm	**Manufacturing of pharmaceutical products** • Introduction to regulatory control on quality • Introduction to ICH CTD Module 3 Quality section	**Dr Sannie Chong** Senior Director, AP Regulatory Policy at MSD
4.10pm	**Good Manufacturing Practices: Main Concepts** • Failures in GMP • GMP history • Basic GMP requirements including definition and quality management • Key elements to review during GMP inspection	**Mr Vimal Sachdeva** Technical Officer – Senior Inspector Inspection Services Group, Prequalification Team (PQT), World Health Organization (WHO)
4:50pm	**Manufacturing and inspection process MD (ISO 13485)** • Introduction to QMS for MD • Relevance of ISO 13485 to regulations	**Ms Bernice Lau** Former Medical Device Lead Auditor TUV SUD
5.30pm	**End**	

Day 3 – 7 September, Wed

	Topic	Speaker/ Organisation
8.30am	**Individual and Group assessment II**	
Session 3:	**Health Products Regulatory Process**	
9.30am	**Market Authorisation Application (Pharmaceutical Products)** • 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
10.45am	**Refreshment Break**	
11.00am	**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
12.00pm	**Lunch**	
1.00pm	**Practicum 2a** Benefit-Risk Assessment of Pharmaceutical Products	**Asst/Prof James Leong** CoRE, Duke-NUS Medical School
2.30pm	**Market Authorisation Application (Medical Devices)** • Requirements for MAA submission and review in select countries • ASEAN CSDT for GSP	**Mr James Chan** RA Director, APJI Varian, a Siemens Healthineers company
3.45pm	**Refreshment Break**	
4.00pm	**Practicum 2b** Marketing Authorisation of Medical Devices	**Mr Sharad Shukla** Director Regulatory Affairs MedTech Regulatory Affairs, Southeast Asia Johnson & Johnson MedTech
5.30pm	**End**	

Day 4 – 8 September, Thurs

	Topic	Speaker/ Organisation
8.30am	**Individual and Group Assessment III**	
9.30am	**Vigilance and Post-marketing for Pharmaceutical Products** • 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
10.45am	**Refreshment Break**	
11.00am	**Practicum 3a** Risk Management Plans for Pharmaceutical Products	**Ms Christine Ho** Health Sciences Authority
12.30pm	**Lunch**	
1.30pm	**Vigilance and Post-marketing for Medical Devices** • Adverse event reporting • Field Safety Corrective Actions	**Mr Sheikh Muhammad Zulkarnein** Senior Education Associate CoRE, Duke-NUS Medical School
2.15pm	**Practicum 3b** Adverse Event Reporting of Medical Devices	**Mr Sheikh Muhammad Zulkarnein** CoRE
3.30pm	**Refreshment Break**	
Session 4: Commercialisation Strategies of Health Products		
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** Senior Advisor Diagnostics Development Hub (DxD Hub)
5.15pm	**Pre-panel Preparation**	**CoRE Education Team**
5.30pm	**End**	

Day 5 – 9 September, Fri

	Topic	Speaker/ Organisation
9.00am	**End-of-Module (EOM) Assessment**	
10.00am	**Review of EOM Questions**	CoRE Education Team
10.45am	**Break**	
Session 5: Trends in Health Product Development and Regulations		
11.00am	**Introduction to Health Technology Assessment** • HTA Principles & Process • Technology Evaluation & Decision-making • Examples	**Prof Kwong Ng** Chief HTA Officer Agency for Care Effectiveness (ACE) Ministry of Health Singapore
11.45am	**Experience from COVID-19 Pandemic: Indonesia** • Emergency Authorisation • Regulatory Agility • Products: vaccines, IVDs	**Dra Ibu Lucky Slamet** Visiting Expert CoRE, Duke-NUS Medical School
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	**Digital Health Adoption and Implementation In APAC**	**Mr Stephen Sunderland** Partner, Head of SE Asia Healthcare and Life Science L.E.K. Consulting
3.15pm	**Break**	
3.30pm	**Panel Session**: Accelerating the development and access to innovative therapeutic technologies Q&A with Industry and Regulators	**Moderator:** **Prof John Lim** **Panelists:** Mr Michael Gropp Mr Stephen Sunderland Dra Lucky Slamet
4.30pm	**Graduate Certificate Workshop Conclusion**	**Prof John Lim** Executive Director Centre of Regulatory Excellence (CoRE)
5.00 pm	**End**	