

GRADUATE CERTIFICATE IN HEALTH PRODUCTS REGULATION

GMS5003: Fundamentals of Health Products Regulation

8 November 2021 – 12 November 2021

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

GMS5003: Fundamentals of Health Products Regulation

8 – 12 November 2021

Day 1 – 8 November, Mon

	Topic	Speaker/ Organisation
8.15am	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 Uttara Soumyanarayanan Associate II CoRE, Duke-NUS Medical School
8.45am	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		
9.15am	Introduction to Pharmaceutical Regulation in the Context of Health Care in Resource Endowed and Resource Constrained Settings	Dr Murray Lumpkin Deputy Director – Integrated Development Lead for Global Regulatory Systems Initiatives Bill and Melinda Gates Foundation
10.30am	Refreshment Break	
11.00am	Introduction to Pharmaceutical Regulation in the Context of Health Care in Resource Endowed and Resource Constrained Settings (Continued)	Dr Murray Lumpkin Bill and Melinda Gates Foundation
12.30pm	Lunch	
2.00pm	Medical device regulations in the context of healthcare <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • 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
3.30pm	Refreshment Break	
4.00pm	Role of regulatory professionals <ul style="list-style-type: none"> • Role of regulatory professional in the current landscape • Good Regulatory Practice (GRP) 	Dr Uttara Soumyanarayanan CoRE, Duke-NUS Medical School
4:45pm	Practicum Briefing	Dr Uttara Soumyanarayanan CoRE, Duke-NUS Medical School
5.00pm	End	

Day 2 – 9 November, Tue

	Topic	Speaker/ Organisation
8.30am	Individual and Group assessment I	CoRE Education Team
Session 2: Health Products Processes: Ensuring Quality, Safety, Efficacy		
9.30am	Manufacturing and inspection process of pharmaceutical products <ul style="list-style-type: none"> • Introduction to regulatory control on quality • Introduction to ICH Module 3 Quality section (commonly known as CMC section) <ul style="list-style-type: none"> - 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
10.15am	Refreshment Break	
10.45am	Quality Management System – an overview with case studies <ul style="list-style-type: none"> • ISO 13485 general requirements • Distribution vs manufacturing • Manufacturing process 	Mr Jason Lim CEO & Co-founder Stendard Mr Nichol Lim QA/RA Consultant Stendard
11.30am	WHO Quality Management System Requirements for <i>in-vitro</i> diagnostics	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)
12.15pm	Lunch	
1.15pm	Clinical trials for pharmaceutical products and medical devices: Similarities and differences <ul style="list-style-type: none"> • 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
2.00pm	Practicum 1a Clinical Development of Pharmaceuticals	CoRE Education Team
3.45pm	Refreshment Break	
4.00pm	Practicum 1b Clinical Studies for Medical Devices	CoRE Education Team
5.30pm	End	

Day 3 – 10 November, Wed

	Topic	Speaker/ Organisation
8.30am	Individual and Group assessment II	
Session 3: Health Products Regulatory Process		
9.30am	Market authorisation application (pharmaceutical) <ul style="list-style-type: none"> 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) <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> 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 Benefit-Risk Assessment of Pharmaceuticals	Expert Faculty: Asst / Prof James Leong
3.30pm	Refreshment Break	
4.00pm	Practicum 2b Marketing Authorisation of Medical Devices	Expert Faculty: Mr Sharad Shukla
5.30pm	End	

Day 4 – 11 November, Thurs

	Topic	Speaker/ Organisation
8.30am	Individual and Group Assessment III	
9.30am	Vigilance and Post-marketing for pharmaceutical products <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • Adverse event reporting • Field Safety Corrective Actions 	Mr Nishith Desai Vice-President of QA and RA, APAC Medtronic
12.00pm	Lunch	
1.00pm	Practicum 3b Adverse Event Reporting of Medical Devices	Expert Faculty: Mr Nishith Desai
2.30pm	Practicum 3a Risk Management Plans for Pharmaceuticals	Expert Faculty: Asst / Prof James Leong
3.30pm	Refreshment Break	
Session 4: Health Products Commercialisation Strategy		
3.45pm	Commercialisation strategy of pharmaceutical products <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • Understand regulatory activities in the context of commercialization of Medical Devices. 	Dr John Thornback Senior Advisor Diagnostics Development Hub (DxD Hub)
5.15pm	End	

Day 5 – 12 November, Fri

	Topic	Speaker/ Organisation
8.30am	End-of-Module (EOM) Assessment	
9.30am	Review of EOM Questions	CoRE Education Team
10.00am	Panel Discussion Preparation	CoRE Education Team
10.30am	Break	
Session 5: Trends in Health Product Development and Regulations		
11.00am	Good Regulatory Management and Professional Development <ul style="list-style-type: none"> 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 Regulation¹ <ul style="list-style-type: none"> Digitalization, wearables, combination products, robotics, AI, 3D printing 	Mr Yu Liang Associate Director, Regulatory Affairs CMC APAC, MSD
12.30pm	Lunch	
1.30pm	Trends in Pharmaceutical Development and Regulation² <ul style="list-style-type: none"> 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 Platforms³ <ul style="list-style-type: none"> Regulatory reliance, convergence, harmonization, work-sharing 	Ibu Lucky Slamet Visiting Expert CoRE, Duke-NUS Medical School
3.10pm	Break	
3.30pm	Panel Session: Accelerating innovative developments of therapeutic technologies 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
4.30pm	Graduate Certificate Workshop Conclusion	A/Prof Silke Vogel Deputy Director, CoRE Senior Associate Dean Graduate Studies Duke-NUS Medical School
5.00 pm	End of Workshop	