RADUATE CERTIFICATE IN PHARMACEUTICAL REGULATION

GMS5011 Fundamentals of Pharmaceutical Regulation

2 to 6 September 2019

Venue: Grand Copthorne Waterfront Hotel, Singapore

WORKSHOP PROGRAMME

Learning outcomes

- Describe the design and operational attributes of different phases of clinical trials
- Apply relevant regulatory guidelines in marketing authorization of pharmaceutical products
- Explain basic principles of pharmacokinetic and statistical analyses as relevant to assessing benefit-risk ratio and regulatory decision-making for approval of pharmaceutical products.
- Explain the ethical, legal and regulatory aspects of design and conduct of clinical trials.
- Distinguish clinical trial design and statistical analysis between multi-regional clinical trials and domestic clinical trials.

Graduate Certificate in Pharmaceutical Regulation
GMS5011: Fundamentals of Pharmaceutical Regulation
2 – 6 September 2019

Day 1 – 2 Sep, Mon

	Topic	
8.30am	**Registration**	
9.00am	**Opening of Graduate Certificate Programme**	**Prof John Lim** Executive Director Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
9.10am	**Workshop Briefing**	**Asst Prof James Leong** Head, Pharmaceutical Regulatory Science Programme, CoRE Duke-NUS Medical School
9.30am	**Introduction to Pharmaceutical Regulation** - Role of regulatory agencies in the past, present and the future. - Regulators as "gate keeper" but also an "enabler"	**Dr Tomas Salmonson** Partner Consilium Salmonson & Hemmings; Former Chair Committee for Medicinal Products for Human Use (CHMP), European Medicines Agency
10.15am	**Break**	
10.45am	**Regulatory Landscape** - International collaboration, including ICH and the development within EU over the last 30-40 years and looking forward - New innovations (e.g. gene therapies) challenging the "standard" way of product development (RCT vs single arm trials, real world data etc).	**Dr Tomas Salmonson**
11.30am	**Regulatory Requirements in the Non-clinical Development**	**Adj A/Prof Cynthia Sung** Visiting Expert, CoRE Duke-NUS Medical School
12.30pm	**Lunch**	
1.30pm	**Conduct of Clinical Trials and Good Clinical Practice**	**Dr Yeo Jing Ping** Director Research Integrity, Compliance and Ethics Singapore Health Services Ptd Ltd (SingHealth)
2.15pm	**Regulatory Requirements in the Early-phase Development**	**Adj A/Prof Cynthia Sung** Visiting Expert, CoRE Duke-NUS Medical School
3.00pm	**Break**	
3.30pm	**Manufacturing and Inspection Processes**	**Mr Ehab Taqieddin** Head, APAC International Operations Roche Singapore Pte Ltd

4.30pm	**Pharmaceutical Regulation in the Healthcare Context** *(remote presentation)*	**Dr Murray Lumpkin** Deputy Director Integrated Development & Lead for Global Regulatory Systems Initiatives Bill & Melinda Gates Foundation
5.15pm	Q&A	
5.45pm	**End**	

Day 2 – 3 Sep, Tue

	Topic	
8.30am	**Individual and Group Assessment 1**	
9.30am	**Introduction to Practicum**	**Dr Andrew Green**
10.00am	**Practicum 1: Non-clinical & Early-phase Development** • CTD (Mod 2 & 4) - Identify the types of non-clinical studies for a given drug candidate and discuss their purpose and design. Justify why these studies essential. • To find guidelines and related resources • Peer review of task by different teams	
10.30am	**Break**	
11.00am	**Practicum 1: Cont'd**	
1.00pm	**Lunch**	
2.00pm	**Regulatory Requirements in the Late-phase Development**	**Asst Prof James Leong** Head, Pharmaceutical Regulatory Science Programme, CoRE Duke-NUS Medical School
2.45pm	**Marketing Authorisation Application**	**Asst Prof James Leong** Head, Pharmaceutical Regulatory Science Programme, CoRE Duke-NUS Medical School
3.30pm	**Break**	
4.00pm	**Good Reliance Practice**	**Dr Lim Sok Bee** Senior Associate, CoRE Duke-NUS Medical School
5.00pm	**End**	

Day 3 – 4 Sep, Wed

	Topic	
8.30am	**Individual and Group Assessment 2**	
9.30am	**Practicum 2: Late-phase Development** • CTD (Mod 2, 3, 5) - Design a phase II/III registrational clinical trial for a specific pharmaceutical product and determine the various evaluation parameters (primary and secondary endpoints, markers) for the desired clinical uses/ indications • Peer review of task by different teams	
10.30am	**Break**	
11.00am	**Practicum 2: Cont'd**	
1.00pm	**Lunch**	
2.00pm	**Pharmaceutical Post-Approval Requirements**	**Dr Cecilia Chia** GPS Regional Head of APAC Global Patient Safety, Biopharma Merck Pte Ltd
2.45pm	**Post-Market Activities and Compliance**	**Mr Ramesh Raj** Regional Manager, Asia Pacific Pharmaceutical Security Institute, Singapore
3.30pm	**Break**	
4.00pm	**Advertisement and Promotion of Pharmaceuticals**	**Ms Ng Ying Lu** Senior Regulatory Specialist Medical Advertisements and Compliance Vigilance & Compliance Branch Health Sciences Authority, Singapore
5.00pm	**End**	

Day 4 – 5 Sep, Thurs

	Topic	
8.30am	**Individual and Group Assessment 3**	
9.30am	**Practicum 3: Marketing Authorisation & Post-approval Activities** • CTD (Mod 2, 3, 4, 5) – from the previous Practicums to determine outcome of marketing authorisation application	
10.30am	**Break**	
11.00am	**Practicum 3: Cont'd**	
1.00pm	**Lunch**	
2.00pm	**Pharmaceutical Marketing of New Products**	**Mr Arun Mishra** Executive Vice-President Regulatory Affairs GSK Consumer Healthcare India
2.45pm	**Case Studies in Pharmaceutical Marketing: Generics and Biosimilars**	**Mr Fabio La Mola** Partner and Executive Director Asia-Pacific Life Sciences Centre of Excellence L.E.K. Consulting, Singapore
3.30pm	**Break**	
4.00pm	**The Role of the Regulator/Regulatory Affairs Manager**	**Mr Wong Kum Cheun** Head, Asia Pacific Regulatory & Development Policy, Novartis Asia Pacific Pharmaceuticals Pte Ltd
4.30pm	**Q&A**	
5.00pm	**End**	

Day 5 – 6 Sep, Fri

	Topic	
8.30am	**Preparation for assessment**	
9.30am	**End-of-Module Assessment**	
10.30am	**Break**	
11.00am	**Q&A**	
12.00pm	**Global and Regional Regulatory Platforms**	**Mr Neo Cherng Yeu** Associate Director, Strategic Engagement, CoRE Duke-NUS Medical School
12.30pm	**Good Regulatory Management and Professional Development**	**Asst Prof James Leong** Head, Pharmaceutical Regulatory Science Programme, CoRE Duke-NUS Medical School
1.00pm	**Lunch**	
2.00pm	**Current Trends in Pharmaceutical Regulation**	**Mr Arun Mishra** Executive Vice-President Regulatory Affairs GSK Consumer Healthcare India
2.45pm	**Regulatory Excellence**	**Prof John Lim** Executive Director Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
3.30pm	**Break**	
4.00pm	**Closing Remarks**	**Prof John Lim** Executive Director Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
5.00pm	**End**	