GRADUATE CERTIFICATE IN PHARMACEUTICAL REGULATION

GMS5105: Generic Medicines

13 July – 17 July 2020

Venue: Zoom

WORKSHOP PROGRAMME

Overall objectives of the workshop

- Build and enhance capability for the key activities and roles essential for effective regulation of generic medicines
- Promote opportunities for optimisation of regulatory cooperation and networking within ASEAN region

Learning outcomes

- Explain the principles and regulatory requirements for a generic medicinal product and the differences from an innovator product
- Describe the fundamental principles for evaluating quality and clinical aspects of a generic medicine
- Describe contemporary approaches and considerations for assessing bioequivalence of different dosage forms
- List the initiatives that are promoting efficiency and effectiveness through regulatory cooperation

Graduate Certificate in Pharmaceutical Regulation

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Day 1 – 13 July, Mon

	Topic	Speaker/ Organisation
8.00am	**Registration**	
Session 1: Regulatory Management of Generic Medicines		
9.00am	**Welcome Graduate Certificate Students**	**Prof John Lim** Executive Director Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
9.15am	**Workshop Briefing**	**Asst Prof James Leong** Head of Pharmaceutical Science Progarmme Centre of Regulatory Excellence Duke-NUS Medical School
9.30am	**Regulatory Frameworks for Generics** • Overview of the regulatory requirements of major regulators and Asia Pacific region	**Dr Jin Shun** Head, Regulatory Affairs APMA Sandoz
10.30am	**Refreshment Break**	
11.00am	**Regulatory Guidelines for Generics** • Key references for submission and evaluation of generics	**Dr Henrike Potthast** Biopharmaceutics Expert Pharmacokinetics Federal Institute for Drugs and Medical Devices (BfArM) Germany
11.45am	**Dossier Requirements for Generics** • ICH CTD and ACTD • ASEAN Technical Guidelines	
12.30pm	**Lunch**	
1.30pm	**Case Discussion** • Identify differences in regulatory requirements among major regulators and ASEAN regulators	
3.00pm	**Refreshment Break**	
3.30pm	**Contemporary Issues in Generic Medicines Development** • Patent enforcement and Intellectual Property • Trends in generics product developments	**Dr Stefanie Amend-Mall** Head Global Project Management Office PD (Product Development) Sandoz
4.15pm	**Challenges in Regulatory Management of Generics** • Different dosage forms • Divergence in requirements • Infringement of patents and IP	
5.00pm	**End**	

Day 2 – 14 July, Tue

	Topic	Speaker/ Organisation
8.30am	**Individual and Group assessment I**	
10.00am	**Refreshment Break**	
Session 2:	**Quality Requirements and Assessment of Generics**	
10.30am	**Guidelines and Regulatory Requirements for Quality Aspects of Generics**	
11.15am	**Standards and Use of Pharmacopeia in the Regulatory Management of Generics**	**Dr Sharad Mankumare** Director RSL and Verification Programs The United States Pharmacopeia (USP) India
11.45am	**In-Vitro Dissolution Studies** • Utility of dissolution studies for assessment of generics • Design and dissolution procedures	
12.30pm	**Lunch**	
1.30pm	**In-Vitro Dissolution Studies (cont'd)** • Dissolution conditions for various dosage forms, including modified release	
2.15pm	**Briefing for Practicum 1**	
2.30pm	**Refreshment Break**	
3.00pm	**Practicum 1** • Evaluation of quality data for regulatory approval	
4.30pm	**Group presentation and Discussion for Practicum 1**	
5.00pm	**End**	

Day 3 – 15 July, Wed

	Topic	Speaker/ Organisation
8.30am	**Individual and Group assessment II**	
10.00am	**Refreshment Break**	
Session 3:	**Clinical Requirements and Assessment of Generics**	
10.30am	**Guidelines and Regulatory Requirements for Clinical Aspects of Generics**	**Dr Jan Welink** Chair Pharmacokinetics Working Party European Medicines Agency Senior Clinical Assessor Medicines Evaluation Board (MEB)
11.00am	**Assessing Bioavailability and Bioequivalence (BABE)** • Study Designs • Evaluation of BABE, including modified release dosage forms	**Dr Jan Welink** MEB
12.30pm	**Lunch**	
1.00pm	**Bioanalytical Studies for Assessing BABE** • Standards, calibration and controls • Methods and Validation	**Dr Jan Welink** MEB
2.15pm	**Briefing for Practicum 2**	
2.30pm	**Refreshment Break**	
3.30pm	**Practicum 2** • Assessment of BABE data for regulatory approval	**Dr Jan Welink** MEB
4.30pm	**Group Presentation and Discussion for Practicum 2**	
5.00pm	**End**	

Day 4 – 16 July, Thurs

	Topic	Speaker/ Organisation
8.30am	**Individual and Group assessment III**	
10.30am	**Refreshment Break**	
Session 4:	**Advanced Approaches and Different Dosage Forms**	
10.30am	**Overview of Dosage Forms in Generic Medicines Development**	**Dr Henrike Potthast** BfArM
11.00am	**Approaches and challenges for different dosage forms** • Orodispersible tablets • Transdermal patches and topicals • Inhalers and nasal sprays • Depot injections	**Dr Henrike Potthast** BfArM
12.30pm	**Lunch**	
1.30pm	**BCS-based Biowaivers** • Guidelines and recommendations • Technical and documentary requirements • (differentiate IVIVCs)	**Dr Henrike Potthast** BfArM
2.15pm	**Briefing for Practicum 3**	
2.30pm	**Refreshment Break**	
3.00pm	**Practicum 3** • BCS waivers to support regulatory decisions	**Dr Henrike Potthast** BfArM
4.30pm	**Group presentation and Discussion for Practicum 3**	
5.00pm	**End**	

Day 5 – 17 July, Fri

	Topic	Speaker/ Organisation
9.00am	**End of Module Assessment**	
10.00am	**Discussion**	
10.30am	**Refreshment Break**	
Session 5:	**Improving the Regulatory Management of Generics**	
11.00am	**Ensuring Quality Control for Generics** • GMP compliance • Quality Management System	**Mr Lakshmana Murthy** Director Quality Assurance United States Pharmacopeia (USP) India
11.45am	**Lunch**	
1.00pm	**Regulatory Cooperation: Work-sharing Initiatives for Generics in ASEAN**	
1.30pm	**ACSS – Generics**	
2.00pm	**Tea Break**	
2.30pm	**Panel Discussion - Post-Market Activities for Generics** • Alignment of post-market commitments of innovator products • Pharmacovigilance of generics • Concerns in interchangeability	
3.45pm	**Business and Regulatory Strategy for Developing Generics**	
4.30pm	**Q&A**	
4.45pm	**Graduate Certificate Workshop Conclusion**	**A/Prof Silke Vogel** Deputy Director, CoRE Senior Associate Dean Graduate Studies Duke-NUS Medical School
5.00 pm	**End**	