GRADUATE CERTIFICATE IN HEALTH PRODUCTS REGULATION

GMS5007 Regulation of Generic Medicines

09 May 2022 – 13 May 2022

WORKSHOP PROGRAMME

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 Health Products Regulation

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Day 1 – 09 May, Mon

	Topic	Speaker/ Organisation
9.00am	**Zoom Briefing**	**Mr Osman Bin Mohamad** Senior Associate Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
9.30am	**Workshop Briefing**	**Asst Prof James Leong** Head of Pharmaceutical Regulatory Science Programme CoRE, Duke-NUS Medical School
10.30am	**Refreshment Break**	
Session 1: Regulatory Management of Generic Medicines		
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	**Ms Tan Mui Kiat** Principal Assistant Director Generic Medicines Section National Pharmaceutical Regulatory Agency (NPRA), Malaysia
12.30pm	**Lunch**	
2.00pm	**Regulatory frameworks for generics** • Overview of the regulatory requirements of major regulators and Asia Pacific region	**Mr Jin Shun** Head, Regulatory Affairs APMA Sandoz
3.00pm	**Refreshment Break**	
3.30pm	**Challenges in regulatory management of generics** • Different dosage forms • Divergence in requirements • Infringement of patents and IP	
4.15pm	**Networking**	
5.00pm	**End**	

Day 2 – 10 May, Tue

	Topic	Speaker/ Organisation
9.00am	**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	**In-Vitro Dissolution studies** • Utility of dissolution studies for assessment of generics • Design and dissolution procedures	**Ms Leanne Cornell** Senior Evaluator Pharmaceutical Chemistry Section Scientific Evaluation Branch Medicines Regulation Division Therapeutic Goods Administration (TGA), Australia **Ms Ji Wenjie** Pharmaceutical Chemistry Section Scientific Evaluation Branch Medicines Regulation Division Therapeutic Goods Administration (TGA), Australia
12.30pm	**Lunch**	
1.30pm	**In-Vitro Dissolution studies (cont'd)** • Dissolution conditions for various dosage forms, including modified release	**Ms Leanne Cornell** **Ms Ji Wenjie** TGA
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**	
5.30pm	**End**	

Day 3 – 11 May, Wed

	Topic	Speaker/ Organisation
9.00am	**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** Senior Clinical Assessor Dutch Medicines Evaluation Board (MEB), Netherlands
11.00am	**Assessing Bioavailability and Bioequivalence (BABE)** • Study Designs • Evaluation of BABE, including modified release dosage forms	**Dr Jan Welink** MEB
12.30pm	**Lunch**	
1.30pm	**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**	
3.00pm	**Practicum 2** • Assessment of BABE data for regulatory approval	
4.30pm	**Group presentation and Discussion for Practicum 2**	
5.30pm	**End**	

Day 4 – 12 May, Thurs

	Topic	Speaker/ Organisation
9.00am	**Individual and Group Assessment III**	
10.00am	**Refreshment Break**	
Session 4:	**Advanced Approaches and Different Dosage Forms**	
10.30am	**Overview of dosage forms in generic medicines development**	**Dr Henrike Potthast** Biopharmaceutics Expert Pharmacokinetics Federal Institute for Drugs and Medical Devices (BfArM) Germany
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	**Dr Henrike Potthast** BfArM
2.15pm	**Briefing for Practicum 3**	
2.30pm	**Refreshment Break**	
3.00pm	**Practicum 3** • BCS waivers to support regulatory decisions	
4.30pm	**Group presentation and Discussion for Practicum 3**	
5.30pm	**End**	

Day 5 – 13 May, Fri

	Topic	Speaker/ Organisation
9.00am	**End-of-Module (EOM) Assessment**	
10.00am	**Review of EOM Questions**	
10.30am	**Break**	
Session 5: Improving the Regulatory Management of Generics		
11.00am	**Contemporary issues in generic medicines development** • Patent enforcement and Intellectual Property • Trends in generics product developments	**Dr Stefanie Amend-Mall** Global Program Lead, CN and APAC Sandoz Small Molecules Product Development Sandoz
11.45am	**ACSS Consortium – Regional Collaborations for Generics**	**Dr Michael Harding** Principal Evaluator Pharmaceutical Chemistry Section Scientific Evaluation Branch Medicines Regulation Division Therapeutic Goods Administration (TGA), Australia
12.30pm	**Lunch**	
1.30pm	**Case Discussion** • Considerations for Sampling	
2.30pm	**Case Discussion** • Sampling and Regulatory actions for quality deviations of generics	
3.30pm	**Break**	
4.00pm	**Business and regulatory strategy for developing generics**	**Dr Krishna Prasad** Abbott
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**	