GRADUATE CERTIFICATE IN HEALTH PRODUCTS REGULATION

GMS5104: Biotherapeutics and Biosimilars

2 November 2020 – 6 November 2020

Venue: Zoom

WORKSHOP PROGRAMME

Learning outcomes

- Explain the principles underlying the current regulatory guidelines as applicable to the development and evaluation of biologics.
- Identify the quality and CMC attributes critical for characterization of biotherapeutics and comparability of biosimilars.
- Describe the key regulatory requirements in the nonclinical and clinical development of biosimilars and evaluate the adequacy of data as applicable to marketing authorization application.
- Identify the common areas of concerns in the regulation of biotherapeutics and biosimilars, in the context of pharmacovigilance and product life cycle management.
- Explain the importance of the recent trends in biologics that play an important role in the access of these products to patients.

Graduate Certificate in Health Products Regulation

GMS5104: Biotherapeutics and Biosimilars

2 – 6 November 2020

Day 1 – 2 November, Mon

	Topic	Speaker/ Organisation
9.00am	**Zoom Briefing**	**Mr Osman Bin Mohamad** Senior Associate Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
9.20am	**Welcome Graduate Certificate Students**	**Prof John Lim** Executive Director CoRE, Duke-NUS Medical School
9.35am	**Workshop Briefing**	**Dr Uttara Soumyanarayanan** Associate II CoRE, Duke-NUS Medical School
Session 1: Regulation of Biologics		
10.00am	**Overview of Biologics** • Types of Biologics • Examples of approved products	**Dr Uttara Soumyanarayanan** Associate II CoRE, Duke-NUS Medical School
10.30am	**Refreshment Break**	
11.00am	**Regulatory Requirements for Biotherapeutics** • Overview of the major global guidelines • Key principles in regulation of biotherapeutics • Highlight some best practices within the major regulatory authorities	**Dr Sannie Chong** Head, APAC Technical Regulatory Policy Roche
11.45am	**Regulatory Requirements for Biosimilars** • Overview of the major global guidelines • Key principles in regulation of biosimilars • Highlight some best practices within the major regulatory authorities • EMA's product specific biosimilar guidelines	**Ms Inger Mollerup** Regulatory Consultant, Inger Mollerup Regulatory Consulting Denmark
12.30pm	**Lunch Break**	
Session 2: Quality Requirements for biologics		
1.30pm	**Process Development and manufacturing for Biologics** • Complexity of biologics and their manufacturing • Biosimilar Development – A unique challenge • Managing process lifecycle and changes	**Dr Yusdy Pan** Director of Process Development Amgen Singapore Manufacturing (ASM)
2.30pm	**Quality evaluation for biotherapeutics** • Overview of CMC requirements and scope for biotherapeutics • Key components in characterisation and of biotherapeutics	**Dr Anne Cook** Biologicals Quality Assessor, Licensing Division, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom
3.15pm	**Refreshment Break**	
3.45pm	**Quality evaluation for biosimilars** • Key components in characterisation and comparability of biosimilars • Biosimilar product development	**Dr Anne Cook** MHRA

	• Reference medicinal product • Assessment of similarities/differences in biosimilar and RMP • Shift in QTPP during product lifecycle	
4.15pm	**Case Study I: CMC assessment of biosimilars** • CMC assessment of biosimilars ○ Considerations in the choice of a reference medicinal product • Comparison of the critical quality attributes between the biosimilar product and the reference product	**Dr Anne Cook** MHRA
5.30pm	**End of Day 1**	

Day 2 – 3 November, Tue

	Topic	Speaker/ Organisation
8.30am	**Individual and Group assessment I**	
Session 3:	**Nonclinical and clinical requirements for biologics**	
9.30am	**Non-clinical studies for biotherapeutics** • Overview of non-clinical considerations when evaluating biotherapeutics • Key non-clinical aspect: Pharmacokinetics/ pharmacodynamics • Sharing of case examples	**A/Prof Cynthia Sung** Adjunct Faculty, CoRE Portfolio & Platform Lead Translational Sciences Bill & Melinda Gates Medical Research Institute Greater Seattle Area, USA
10.30am	**Refreshment Break**	
11.00am	**Clinical studies for biotherapeutics** • Overview of clinical considerations when evaluating biotherapeutics • Overview of clinical study design • Key clinical aspect: Immunogenicity • Sharing of case examples	**Dr Julia Katharina Maier** Clinical Assessor Paul-Ehrlich-Institut (PEI), Federal Institute for Vaccines and Biomedicines Langen, Germany
12.00pm	**Lunch**	

1.00pm	**Clinical studies for biosimilars**
	• Key clinical considerations when evaluating biosimilars
	• Clinical comparability of biosimilars
	  ○ Study designs and approaches – Stepwise and Totality-of-evidence
	  ○ Justification of endpoints
	  ○ Requirements for interchangeability, substitution and switching
		Dr Julia Katharina Maier
		PEI

2.00pm	**Defining and handling non-comparable biologics** • Highlight definitive differences between NCBs and biosimilars – WHO guidelines • Implications of NCBs in current regulatory processes for biotherapeutics, including post-approval monitoring • Example of products approved in specific regions or countries (e.g., Korea, India, etc)	**Ms Inger Mollerup** Inger Mollerup Regulatory Consulting
3.00pm	**Refreshment Break**	
3.30pm	**Practicum I: Quality Evaluation of Biosimilars**	**Dr Anne Cook** MHRA

	• Control specification • Acceptability of biosimilar, comparable to reference biotherapeutic product	
5.30pm	**End of Day 2**	

Day 3 – 4 November, Wed

	Topic	Speaker/ Organisation
8.30am	**Individual and Group assessment II**	
9.30am	**Practicum II: Non-Clinical Evaluation of Biologics** • Biologics specificity • Toxicity and safety studies	**A/Prof Cynthia Sung** Adjunct Faculty, CoRE Bill & Melinda Gates Medical Research Institute
10.30	**Refreshment Break**	
11.00am	Practicum II continued	
12.00pm	**Lunch Break**	
1.00pm	**Practicum III: Clinical Evaluation of Biosimilars** • PK/PD • Efficacy	**Dr Julia Katharina Maier** PEI
3.30pm	**Refreshment Break**	
4.00pm	**Extrapolation of therapeutic indications** • Overview of current regulatory requirements for extension of clinical data • Common issues encountered in justifying for adequacy of clinical data	**Ms Inger Mollerup** Inger Mollerup Regulatory Consulting
5.00pm	**End of Day 3**	

Day 4 – 5 November, Thurs

	Topic	Speaker/ Organisation
8.45am	**Networking Session Activity**	**CoRE Staff**
Session 4: Post Market Activities for Biotherapeutics and Biosimilars		
9.30am	**Pharmacovigilance for strengthening approaches to regulation of Biologics** • Overview of PV framework • Specific safety considerations for biotherapeutics and biosimilars • Risk Management Plan components	**Dr Vidhya Hariraj** **Senior Principal Assistant Director** Centre of Compliance and Quality Control Pharmacovigilance Section National Pharmaceutical Regulatory Agency (NPRA), Malaysia
10.15am	**Refreshment Break**	
10.45am	**Case study II:** Post-market activities for Biotherapeutics and Biosimilars	**Asst Prof James Leong** Head of Pharmaceutical Regulatory Science Programme CoRE, Duke-NUS Medical School
11.45am	**Post-approval variations for reference products and biosimilars** • Concerns related to drift between originator and biosimilar across multiple variations and product evolution • Potential approaches to ensure similarity along product life cycle	**Dr Martin Schiestl** Head Regulatory Affairs Policy & Intelligence Sandoz Biopharmaceuticals, Austria
12.30pm	**Lunch Break**	
Session 5: Development of Vaccines		

1.30pm	**Overview of vaccine development** • Phases of vaccine development • How is the evaluation of vaccines different from biologics	**Dr Andrew Green** Head of Medical Affairs Takeda
2.30pm	**COVID-19 vaccine: new developments in vaccinology** • Nonclinical and clinical development	**Prof Ooi Eng Eong** Deputy Director, Emerging Infectious Diseases Programme Duke-NUS Medical School
3.30pm	**Refreshment Break**	
4.00pm	**Case study III: Post-market activities for vaccines** • RMP framework	**Asst Prof James Leong** CoRE, Duke-NUS Medical School
5.00pm	**End**	

Day 5 – 6 November, Fri

	Topic	Speaker/ Organisation
09:00am	**End of the Module (EoM) Assessment**	**CoRE Staff**
10.00am	**Refreshment Break**	
10.30am	**EoM Assessment Clarifications**	**CoRE Staff**
Session 6: Trends in Biologics		
11.00am	**A Clinician's perspective on the use of biosimilars**	**Prof William Hwang** Medical Director National Cancer Centre Singapore Senior Consultant, Department of Haematology Singapore General Hospital
12.00pm	**Lunch Break**	
1.00pm	**Utility of Real-world Data** • Case Example of Biologic	**Dr Chris L. Pashos** Independent Consultant (RWE/HEOR) Cambridge, Massachusetts
2.00pm	**Health Technology Assessment of Biologics** • Role of HTA in access • Case Study: A UK perspective • Intellectual Property considerations	**Mr Paul Ranson** Consultant Morgan Lewis Stamford LLC **Mr Todd Esker** Legal Partner Morgan Lewis Stamford LLC **Ms Jacqueline R. Berman** Legal Partner Morgan Lewis Stamford LLC
3.00pm	**Pre-panel Activity**	**CoRE/Panelists**
3.30pm	**Refreshment Break**	
4.00pm	**Panel Session** **Title:** Adoption of Biosimilars	**Moderator:** Ms Inger Mollerup **Panelists:** • Dr Martin Schiestl • Prof William Hwang
4.45pm	**Conclusion of Graduate Certificate Workshop**	**A/Prof Silke Vogel** Deputy Director, CoRE Senior Associate Dean Graduate Studies Duke-NUS Medical School
5.00pm	**End**	