GRADUATE CERTIFICATE IN HEALTH PRODUCTS REGULATION

GMS5011: CHEMISTRY, MANUFACTURING AND CONTROLS

12 – 16 April 2021

Venue: Zoom

WORKSHOP PROGRAMME

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Overall objectives of the workshop

- Build and enhance capability in the regulatory science of Chemistry, Manufacturing and Controls (CMC) to promote and facilitate the accessibility of medical products, through quality submissions and effective regulatory assessment.

- Promote regulatory convergence and cooperation/reliance on globally recognized CMC regulations.

Learning outcomes

- Explain the CMC requirements at different stages of a medical product lifecycle, i.e. pre-market regulatory submission/review, commercialization and post-approval changes.

- Demonstrate how CMC requirements are interlinked with safety, commercial manufacturing and quality aspects

- Understand the harmonized CMC-related guidelines. To enable practical and appropriate implementation of these guidelines in regulatory submission or review, with the aim of facilitating registration of medical products of the required quality standards and their post-marketing quality control.

- Identify the regional CMC requirements according to the ASEAN regulatory frameworks and the opportunities for regulatory convergence.

- Review the upcoming trends in CMC regulatory landscapes and the impact to the strategic planning and development of new medical products.

Graduate Certificate in Health Products Regulation

GMS5012: Chemistry, Manufacturing and Controls

12 April – 16 April 2021

Day 1 – 12 April, Mon

	Topic	Speaker/ Organisation
8.30am	**Zoom Briefing**	**Mr Osman Bin Mohamad** Senior Associate Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
9.00am	**Workshop Briefing / Ice-breaker / Goalsetting**	**Dr How Yew Meng** Senior Associate CoRE, Duke-NUS Medical School
9.20am	**Welcome Graduate Certificate Students**	**Prof John Lim** Executive Director Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
9.30am	**Overview of CMC for pharmaceutical products** • Scope of coverage • Product lifecycle management • ICH guidelines on CMC • Format of regulatory submission for pre-market approval: • ICH Common Technical Dossier (CTD) module 3 and ASEAN CTD (ACTD) part II • Drug Master File (DMF)	**Dr How Yew Meng** CoRE
10.30am	**Refreshment Break**	
Session 1: CMC Requirements for Pre-market Regulatory Controls – Part I		
10.15am	**Quality control for small molecule pharmaceutical:** Impurities in drug substance (DS) and drug product (DP) • Concerns during manufacturing, batch release and/or stability testing • Degradation products • Process-related impurities • Residual solvents • Mutagenic impurities	**Dr Gaelle Richer** Adjunct Lecturer National University of Singapore
12.00pm	**Lunch**	
1.00pm	**Quality control for biotherapeutic: ICH Q5A viral safety** • Analysis of expression construct and cell bank system • Viral safety evaluation	**Dr Rachel Specht** Scientist Genentech, a member of the Roche Group
2.00pm	**Case Discussion 1** • Identify the impurities to be monitored in a DS and their acceptable limits. • Identify the potential gaps where additional data may be required	**Dr Gaelle Richer** National University of Singapore
3.15pm	**Refreshment Break**	
3.45pm	**Case discussion 1 (continuation)**	**Dr Rachel Specht** Roche
5.00pm	**End**	

Day 2 – 13 April, Tue

	Topic	Speaker/ Organisation
8.30am	**Individual and Group assessment I**	
Session 2:	**CMC Requirements for Pre-market Regulatory Controls – Part II**	
9.30am	**Quality control for biotherapeutic: Specifications for DS and DP (Recording)** • Requirements according to ICH Q6B • Analytical consideration	**Dr Wassim Nashabeh** Vice President Global Head Policy and International Operations Roche
10.30am	**Refreshment Break**	
11.00 am	**Quality control for small molecule pharmaceutical: Specifications for DS and DP** • General requirements • Dosage form or administration route specific requirements • The appropriate specifications limits • Role of Pharmacopoeias, as appropriate	**Ms Pakhi Rusia** Head of Regulatory Affairs, APAC Glenmark Pharmaceutical Private Limited, Singapore
12.00pm	**Lunch**	
1.00 pm	**ICH Q3D elemental impurities** • Elements to be considered in a risk assessment of small molecule and biologic products • Determination of PDE for the common administration routes, including administration routes not established in ICH Q3D	**Dr Bruno Rubrecht** Head Product Quality Strategy & Lifecycle - Incoming Materials/Secondary GSK Vaccines
2.00 pm	**Case discussion** • Identify the elemental impurities that should be considered in the risk assessment of a pharmaceutical product • Understand the different options for converting PDEs to concentration limits	**Dr Bruno Rubrecht** GSK Vaccines
3.00pm	**Break**	
3.30pm	**Practicum I:** • Identify the critical specifications to be controlled in a DP • Determine the robustness of the scientific rationale for the proposed specification limits.	**Ms Pakhi Rusia** **CoRE Team Education team**
5.30pm	**End**	

Day 3 – 14 April, Wed

	Topic	Speaker/ Organisation
8.30am	**Individual and Group assessment II**	
Session 3:	**CMC Requirements for Pre-market Regulatory Controls – Part III**	
9.30am	**Stability requirements for DS and DP** • Minimum data requirements at regulatory submission and post-approval commitments • Bracketing and matricing • Extrapolation to extend retest period or shelf life • Zone IVb stability data for ASEAN regulatory submission, if applicable	**Ms Chuah Su Yin Florence** Senior Principal Assistant Director New Drug Section, Centre for Product and Cosmetic Evaluation National Pharmaceutical Regulatory Division (NPRA) Ministry of Health, Malaysia
10.30am	**Refreshment Break**	
11.00am	**Case discussion** Country specific requirements on DP stability data when there are multiple DS and DP manufacturing sites.	**Ms Chuah Su Yin Florence** NPRA
12.00 pm	**Manufacturing process validation of DP (Recording)** • Compliance to cGMP requirement • Traditional versus continuous process validation • Continued process verification	**Dr Maria Bruno** Merck
1.00pm	**Lunch**	
2.00 pm	**Practicum II:** • Manufacturing Process Validation	CoRE education team
3.00pm	**Refreshment Break**	
3.30pm	**Practicum II (continued)**	CoRE education team
4.30pm	**Understanding European Pharmacopoeia and the Certification of suitability (CEP) procedures** • Assessment of the drug substance part of submissions for substances covered by the pharmacopoeia • Related risk-based inspections.	**Mr Cristian Sampaolesi** Head of the New Dossier Evaluation Section EDQM Certification of Substances Department
5.30pm	**End**	

Day 4 – 15 April, Thurs

	Topic	Speaker/ Organisation
9.00am	**Individual and Group Assessment III**	
Session 4: CMC Requirements for Post-market Quality Controls		
10.00 am	**Post-approval CMC controls on marketed products** • Current *versus* ICH Q12 approaches • Key aspects of ICH Q12 and current progress • Identification of established conditions (ECs) and categorization of post-approval CMC changes • Management of post-approval changes associated with product or process CMC deviations.	**Ms Saroj Ramdas, MSc** Director Biopharm CMC Strategy Policy and Advocacy GSK Fellow
11.00am	**Refreshment Break**	
11.30am	**Case discussion** Identify CMC changes that require prior approval, notification or no reporting is required	**Ms Saroj Ramdas, MSc** Director Biopharm CMC Strategy Policy and Advocacy GSK Fellow
12.30pm	**Lunch**	
2.00 pm	**Development of global regulatory submission strategies (focusing on emerging markets) for new drug products: CMC-related considerations.** • Common areas of CMC concerns • CMC Regulatory trends – Emerging Markets	**Mr Arun Mishra** Head Global Nutrition Regulatory Affairs and Global Health and Wellness Regulatory Affairs Unilever
3.00pm	**Refreshment Break**	
3.30pm	**Networking**	**Mr Osman Bin Mohamad** CoRE
4.15pm	**Panel Discussion Preparation**	**Dr How Yew Meng** CoRE
5.00pm	**End**	

Day 5 – 16 April, Fri

	Topic	Speaker/ Organisation
9.00am	**End-of-Module (EOM) Assessment**	
10.00am	**Break**	
10.15am	**EOM Review**	
Session 5: Trends in Health Product Development and Regulations		
11.15am	**Pharmaceutical quality supported by concepts developed in ICH** • Background and scientific basis • Linkage between the guidelines	**Dr.-Ing. Stephan Roenninger** Director Quality External Affairs – Group lead Amgen
12.15am	**Understanding quality risk management as a behaviour** • Principles of quality risk management in ICH Q9 • Risk management tools • Potential applications	**Dr.-Ing. Stephan Roenninger** Amgen
1.00pm	**Lunch**	
2.00 pm	**Implementation of a pharmaceutical quality system** • Principles and key aspects of ICH Q10 • Potential applications • Differences between a pharmaceutical quality system and a quality (management) system	**Dr Roger Nosal** Vice President Global Head CMC Pfizer
2.45pm	**Development and manufacture (DS/DP) *via* the QbD approach** • Principles and key aspects of ICH Q8 (annex) • Traditional *versus* enhanced approach in DS/DP development • Real time release testing • Role of multivariate models in regulatory submissions • Principles and key aspects of ICH Q11	**Dr Sarah Pope Miksinski** Senior Director Global Regulatory Affairs AstraZeneca
3.30pm	**Break**	
4.00pm	**Panel Session** Opportunities and challenges of new CMC trends for quality control and manufacturing technologies	**Moderator:** **Dr.-Ing. Stephan Roenninger** Amgen **Panelist:** **Dr Roger Nosal** Vice President Global Head CMC Pfizer **Dr Sarah Pope Miksinski** AstraZeneca
5.15pm	**Graduate Certificate Workshop Conclusion**	**Assoc/ Prof Silke Vogel** Deputy Director Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
5.30 pm	**End**	