GRADUATE CERTIFICATE IN HEALTH PRODUCTS REGULATION

GMS5004: Regulation of Pharmaceutical Manufacturing

11 – 15 November 2024

Venue: White Space Room (Level 2), Academia, 20 College Road, Singapore 169856

WORKSHOP PROGRAMME

Learning outcomes

- Explain the importance of manufacturing and quality control for pharmaceuticals
- Describe the controls and regulatory requirements on product stability and specifications
- Assess and critique mock reviews of dossier materials
- Explain the utility of as systems approach to quality control
- Review the upcoming regulatory trends in CMC regulatory landscape

Graduate Certificate in Health Products Regulation

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Day 1 – 11 November 2024, Mon

	Topic	Speaker/ Organisation
8.00am	**Registration**	
8.30am	**Welcome**	
8.45am	**Workshop Briefing**	**Dr Rathi Saravanan** Lead Education Associate Lead, Graduate Certificate Programmes Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
9.00am	**Brightspace Briefing**	**Mr Osman Mohamad** Senior Education Associate Lead, Online Programmes Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
9.15am	**Overview of CMC for pharmaceutical products** • Scope of coverage • Product lifecycle management • ICH guidelines on CMC	**Mr Thean Soo (TS) LO** Regulatory Affairs Management Consultant TS Consulting
10.00am	**Overview of ICHQ8 – ICHQ12 guidelines** • Concepts and Principles • Tools, approaches and systems	**Dr Rathi Saravanan** CoRE
10.30am	**Refreshment Break**	
Session 1: CMC Requirements for Pre-market – Control of Impurities		
10.45am	**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** Former QC Transfer Head, Vaccines MSAT GSK Vaccines
11.15am	**Case discussion 1 – Managing elemental impurities** • 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	
12.30pm	**Lunch**	

1.30pm	**Case discussion 1 – Managing elemental impurities (cont'd)**	
2.00pm	**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 and residual solvents • Mutagenic impurities	**Ms Pakhi Rusia** Senior Regulatory Consultant
3.00pm	**Refreshment Break**	
3.15pm	**Case discussion 2 – Impurities** • Identify the impurities to be monitored in a DS and their acceptable limits. • Identify the potential gaps where additional data may be required	**Ms Pakhi Rusia** Senior Regulatory Consultant
5.30pm	**End of Day 1**	

Day 2 – 12 November 2024, Tue

	Topic	Speaker/ Organisation
8.00am	**Registration**	
Session 1:	**CMC Requirements – Control of Impurities (cont'd)**	
8.30am	**Quality control for biotherapeutic: ICH Q5A viral safety** • Analysis of expression construct and cell bank system • Viral safety evaluation	**Dr Rachel Specht** Technical Development Senior Scientist Genentech, a member of the Roche Group
9.30am	**Case discussion 3 – Viral Clearance** • Identify appropriate approaches to optimise viral clearance	
10.00am	**Refreshment Break**	
10.15am	**Case discussion 3 – Viral Clearance (Cont'd)**	
11.00am	**Quality control for biotherapeutic: Specifications for DS and DP** • Requirements according to ICH Q6B • Analytical consideration	**Dr Wassim Nashabeh** Vice President Regulatory Policy and International Operations Genentech, a member of the Roche Group
12.00pm	**Lunch**	
Session 2:	**CMC Requirements for Pre-market – Specifications**	
1.00pm	**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** Senior Regulatory Consultant
2.00pm	**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** Senior Regulatory Consultant
3.00pm	**Refreshment Break**	
3.15pm	**Practicum I (cont'd)**	**Ms Pakhi Rusia** Senior Regulatory Consultant
5.30pm	**End of Day 2**	

Day 3 – 13 November 2024, Wed

	Topic	Speaker/ Organisation
8.00am	**Registration**	
8.30am	**Individual and Group assessment**	
Session 3: CMC Requirements for Pre-market – Stability		
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	**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**	
10.45am	**Stability Requirements for Biotechnological Products** • ICHQ5C - ICH Q5E • Challenges in demonstrating stability requirements	*TBD*
Session 4: Other Manufacturing Considerations		
11.30am	**Role of Good Manufacturing Practice: Basic Principles**	**Dr Vimal Sachdeva** Technical Officer (Expert Inspector) Prequalification Team World Health Organization
12.30pm	**Lunch**	
1.30pm	**Case discussion 4 – Stability Requirements** • Country-specific requirements for DP stability data	**Dr Crystal Lau** Senior Director CMC (APAC Lead) MSD
3.30pm	**Refreshment Break**	
3.45pm	**CMC Dossier Submission** • ICH CTD and ASEAN CTD • QbD Application • Challenges	**Mr Thean Soo (TS) LO** Regulatory Affairs Management Consultant TS Consulting
4.30pm	**Networking**	**Mr Osman Mohamad** CoRE
5.30pm	**End of Day 3**	

Day 4 – 14 November 2024, Thurs

	Topic	Speaker/ Organisation
8.00am	**Registration**	
Session 5: CMC Requirements for Post-market Controls		
8.30am	**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** Vice President, CMC Amicus Therapeutics
9.30am	**Case Discussion 5 – Post-approval changes** • Identify CMC changes that require prior approval, notification or if reporting is required	**Mr Thean Soo (TS) LO** Regulatory Affairs Management Consultant TS Consulting
10.30am	**Refreshment Break**	
Session 6: Manufacturing Process Validation and Analytical Control		
10.45pm	**Case Discussion 5 – Post-approval changes (cont'd)**	
11.15am	**Manufacturing process validation of DP** • Compliance to cGMP requirement • Traditional versus continuous process validation • Continued process verification	**Dr Maria Bruno** Site Quality Head Merck
12.00pm	**Lunch**	
1.00pm	**Practicum II** • Identify the critical process parameters and manufacturing process validation • Identify common gaps in process validation report	
3.30pm	**Refreshment Break**	
3.45pm	**Transfer, Validation and Verification of Analytical Procedures**	**Dr Christian Zeine** Senior Manager Scientific Affairs, EMEA United States Pharmacopeia (USP)
5.30pm	**End of Day 4**	

Day 5 – 15 November 2024, Fri

	Topic	Speaker/ Organisation
8.30am	**Registration**	
9.00am	**End-of-Module (EOM) Assessment**	
10.00am	**Review of EOM Questions**	
10.30am	**Refreshment Break**	
Session 7: Quality Systems Approach to Pharmaceutical Manufacturing and Control		
10.45am	**Development and manufacture (DS/DP) *via* the Quality by Design (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** Executive Director CMC Global Regulatory Affairs AstraZeneca
11.45am	**Pharmaceutical quality and risk management**	**Dr Rathi Saravanan** CoRE
12.30pm	**Lunch**	
1.30pm	**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** Principal Consultant Roger Nosal PharmaCMC Regulatory Consultants
2.30pm	**Reflection/ Peer Sharing**	**Dr Rathi Saravanan** CoRE
3.30pm	**Break**	
3.45pm	**Panel Discussion** Evolving towards Sustainable Pharmaceutical Manufacturing: Barriers, Challenges and Opportunities	
5.00pm	**Graduate Certificate Workshop Conclusion**	**Prof Silke Vogel** Deputy Director, CoRE Senior Associate Dean Graduate Studies Duke-NUS Medical School
5.30pm	**End of Workshop**	