GRADUATE CERTIFICATE IN PHARMACEUTICAL REGULATION

GMS5004: Regulation of Pharmaceutical Manufacturing

27 – 31 October 2025

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

WORKSHOP PROGRAMME

Learning outcomes

At the end of this workshop, participants should be able to

- 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

Target Audience

- Early to mid-career professionals: regulatory affairs professionals in pharmaceutical companies, healthcare professionals, academic researchers in life sciences and regulators in national (health/drug) regulatory authorities.

Graduate Certificate in Pharmaceutical Regulation

GMS5004: Regulation of Pharmaceutical Manufacturing

27 – 31 October 2025

Day 1 – 27th October, Monday

	Topic	Speaker/ Organisation
8.00am	**Registration**	
8.30am	**Welcome**	**Dr Rathi Saravanan** Lead Education Associate Lead, Graduate Certificate Programmes Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
8.45am	**Workshop Briefing**	**Dr Rathi Saravanan** Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
9.00am	**Brightspace Briefing** • Team Introductions • Goal Setting • Bright Space Familiarization	**Dr. Uttara Soumyanarayanan** Senior Education Associate Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
9.25am	**Role of Chemistry Manufacturing and Control (CMC) in pharmaceutical product lifecycle** • CMC: scope • ICH guidelines on CMC • Product lifecycle management	**Dr Rathi Saravanan** CoRE
10.10 am	**Photo-taking Session: Faculty & Participants**	**Education Team, CoRE**
10.15am	**Refreshment Break**	
10.30am	**Critical Role of CMC Dossier in Regulatory Submissions** • ICH CTD: Quality module sections • Challenges in CMC Data collection • Strategies for Effective CMC Dossier Preparation • Best Practices for successful CMC Dossier submission	**Dr. Xiaoping Cao, PhD MBA** Founder & CEO IntelliScope PharmaSolutions Pte Ltd Singapore
Session 1: Pre-market CMC Requirements: Control of Impurities		
11.30am	**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	**TBC**
12.30pm	**Lunch**	

1.30pm	**Case discussion 1 – Impurities** • Identify the impurities to be monitored in a DS and their acceptable limits.	**Ms. Weilu Dai** Senior Regulatory Specialist (CMC) Health Products Regulation Group Health Sciences Authority (HSA) Singapore & **Education Team, CoRE**
2.30pm	**ICH Q3D Elemental Impurities** • Principles of the Risk Assessment of elemental impurities • Elements to be considered in a risk assessment of small molecule and biologic products • Control of elemental impurities • Determination of PDE for the common administration routes	**Dr Bruno Rubrecht** Former QC Transfer Head, Vaccines MSAT GSK Vaccines
3.15pm	**Refreshment Break**	
3.30pm	**Case discussion 2 – 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	**Ms. Weilu Dai** Senior Regulatory Specialist (CMC) Health Products Regulation Group Health Sciences Authority (HSA) Singapore & **Education Team, CoRE**
4.45pm	**Networking**	**Education Team, CoRE**
5.30pm	**End of Day 1**	

Day 2 – 28th October, Tuesday

	Topic	Speaker/ Organisation
8.00am	**Registration**	
Session 1:	**Pre-market 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	**Mr. Jeff Poh** Senior Manager, Regulatory Affairs CMC Gilead Sciences Singapore Pte. Ltd.
9.30am	**Case discussion 3 – Viral Clearance** • Identify appropriate approaches to optimise viral clearance	**Mr. Jeff Poh** Senior Manager, Regulatory Affairs CMC Gilead Sciences Singapore Pte. Ltd. & **Education Team, CoRE**
10.15am	**Refreshment Break**	
10.30am	**Case discussion 3 – Viral Clearance (Cont'd)**	
Session 2:	**Pre-market CMC Requirements: Specifications**	
11.00am	**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	**TBC**
12 noon	**Lunch**	
1.00pm	**Quality control for biotherapeutic: Specifications for DS and DP** • Requirements according to ICH Q6B • Analytical consideration	**Mr. Jeff Poh** Senior Manager, Regulatory Affairs CMC Gilead Sciences Singapore Pte. Ltd.
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	**Mr. Jeff Poh** Senior Manager, Regulatory Affairs CMC Gilead Sciences Singapore Pte. Ltd. & **Education Team, CoRE**
3.00pm	**Refreshment Break**	
3.15pm	**Practicum I (cont'd)**	
5.30pm	**End of Day 2**	

Day 3 – 29th October, Wednesday

	Topic	Speaker/ Organisation
8.00am	**Registration**	
8.30am	**Individual and Group Readiness assessment**	**Education Team, CoRE**
Session 3: Pre-market CMC Requirements: Stability		
9.30am	**Stability requirements for small molecule 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	**Dr Crystal Lau** Senior Director CMC (APAC Lead) MSD
10.30 am	**Refreshment Break**	
10.45am	**Stability Requirements for Biotechnological Products** • ICHQ5C - ICH Q5E • Challenges in demonstrating stability requirements	**Dr Crystal Lau** Senior Director CMC (APAC Lead) MSD
12.00noon	**Lunch**	
1.00pm	**Case discussion 4 – Stability Requirements** • Country-specific requirements for DP stability data	**Dr Crystal Lau** Senior Director CMC (APAC Lead) MSD
3.00pm	**Refreshment Break**	
Session 4: Quality compliance: Best Practices		
3.15pm	**Good Manufacturing Practice in ensuring quality compliance** • Pre-approval inspection process • common GMP compliance gaps • PIC/S GMP guide for GMP compliance • Responsibilities of manufacturers	**Dr. Ong Kang Teng** Acting Deputy Director, GMP Unit Audit & Licensing Division Health Products Regulation Group Health Sciences Authority (HSA) Singapore
4.15pm	**Understanding Certification of suitability (CEP) procedures**	**Ms. Alma Kiso** Head of New Dossier Evaluation Section 1 Certification of Substances Department European Directorate for the Quality of Medicines & HealthCare (EDQM) Council of Europe
5.30pm	**End of Day 3**	

Day 4 – 30th October 2025, Thursday

	Topic	Speaker/ Organisation
8.00am	**Registration**	
Session 5: Manufacturing Process Validation, Analytical Control and CMC Post-market Requirements		
8.30am	**Manufacturing process validation of DP** • Compliance to cGMP requirement • Traditional versus continuous process validation • Manufacturing Process Validation report	**Mr. Jeff Poh** Senior Manager, Regulatory Affairs CMC Gilead Sciences Singapore Pte. Ltd.
9.30am	**Practicum II** • Identify the critical process parameters and manufacturing process validation steps • Identify common gaps in process validation report	**Mr. Jeff Poh** Senior Manager, Regulatory Affairs CMC Gilead Sciences Singapore Pte. Ltd.
10.30am	**Refreshment Break**	
10.45am	**Practicum II (continued)**	
12.00 pm	**Lunch**	
1.00pm	**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	**Dr. Xiaoping Cao, PhD MBA** Founder & CEO IntelliScope PharmaSolutions Pte Ltd
2.00pm	**Case Discussion 5 – Post-approval changes** Identify CMC changes that require prior approval notification or if reporting is required	**Education Team, CoRE**
3.30 pm	**Refreshment Break**	
3.45 pm	**Understanding Pharmacopeia: Transfer, Validation and Verification of Analytical Procedures**	**Dr Christian Zeine** Senior Manager Scientific Affairs, EMEA United States Pharmacopeia (USP)
5.00pm	**Pre-Panel Preparation & Debrief**	
5.30pm	**End of Day 4**	

Day 5 – 31st October, Friday

	Topic	Speaker/ Organisation
8.30am	**Registration**	
9.00am	**End-of-Module (EOM) Assessment**	
10.00am	**Review of EOM Questions**	
10.30am	**Refreshment Break**	
Session 6: 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
12.45pm	**Lunch**	
1.45pm	**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** **Green Pharma: Is Sustainability the Next Compliance Metric?**	**Moderator:** **Asst. Prof. James Leong** Head, Health Products & Regulatory Science Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School **Panelists:** **Mr. Brett Marshall,** Former Vice President, Zuellig Pharma Quality Assurance, HSSE **TBC**
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**	