

GRADUATE CERTIFICATE IN PHARMACEUTICAL REGULATION

GMS5004: Regulation of Pharmaceutical Manufacturing

26 October – 30 October 2026

Venue: Shaw Foundation Alumni House
11 Kent Ridge Drive, Singapore 119244

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 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.

Day 1 – 26 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 CoRE
9.00am	Brightspace Briefing <ul style="list-style-type: none"> • Team Introductions • Goal Setting • Bright Space Familiarization 	Dr Uttara Soumyanarayanan CoRE
9.25am	Role of Chemistry Manufacturing and Control (CMC) in pharmaceutical product lifecycle <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • ICH CTD: Quality module sections • Challenges in CMC Data collection • Strategies for Effective CMC Dossier Preparation • Best Practices for successful CMC Dossier submission 	
Session 1: Pre-market CMC Requirements: Control of Impurities		
11.30am	Qualitycontrol for small molecule pharmaceutical: Impurities in drug substance (DS) and drug product (DP) <ul style="list-style-type: none"> • Concerns during manufacturing, batch release and/or stability testing • Degradation products • Process-related impurities and residual solvents • Mutagenic impurities 	
12.30pm Lunch		

1.30pm	Case discussion 1 – Impurities <ul style="list-style-type: none"> Identify the impurities to be monitored in a DS and their acceptable limits. 	
2.30pm	ICH Q3D Elemental Impurities <ul style="list-style-type: none"> 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 	CoRE Education Team
3.15pm	Refreshment Break	
3.30pm	Case discussion 2 – Managing elemental impurities <ul style="list-style-type: none"> 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 	
4.45pm	Networking	CoRE Education Team
5.30pm	End of Day 1	

Day 2 – 27 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 <ul style="list-style-type: none"> • Analysis of expression construct and cell bank system • Viral safety evaluation 	
9.30am	Case discussion 3 – Viral Clearance <ul style="list-style-type: none"> • Identify appropriate approaches to optimise viral clearance 	CoRE Education Team
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 <ul style="list-style-type: none"> • General requirements • Dosage form or administration route specific requirements • The appropriate specifications limits • Role of Pharmacopoeias, as appropriate 	
12 noon	Lunch	
1.00pm	Quality control for biotherapeutic: Specifications for DS and DP <ul style="list-style-type: none"> • Requirements according to ICH Q6B • Analytical consideration 	
2.00pm	Practicum I <ul style="list-style-type: none"> • Identify the critical specifications to be controlled in a DP • Determine the robustness of the scientific rationale for the proposed specification limits 	CoRE Education Team
3.00pm	Refreshment Break	
3.15pm	Practicum I (cont'd)	
5.30pm	End of Day 2	

Day 3 – 28 October, Wednesday

Topic	Speaker/ Organisation
8.00am Registration	
8.30am Individual and Group Readiness Assessment	CoRE Education Team
Session 3: Pre-market CMC Requirements: Stability	
9.30am Stability requirements for small molecule DS and DP <ul style="list-style-type: none"> • 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 	
10.30 am Refreshment Break	
10.45am Stability Requirements for Biotechnological Products <ul style="list-style-type: none"> • ICH Q5C - ICH Q5E • Challenges in demonstrating stability requirements 	
12.00noon Lunch	
1.00pm Case discussion 4 – Stability Requirements <ul style="list-style-type: none"> • Country-specific requirements for DP stability data 	CoRE Education Team
3.00pm Refreshment Break	
Session 4: Quality compliance: Best Practices	
3.15pm Good Manufacturing Practice in ensuring quality compliance <ul style="list-style-type: none"> • Pre-approval inspection process • common GMP compliance gaps • PIC/S GMP guide for GMP compliance • Responsibilities of manufacturers 	
4.15pm Understanding Certification of suitability (CEP) procedures	
5.30pm End of Day 3	

Day 4 – 29 October, 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 <ul style="list-style-type: none"> Compliance to GMP requirement Traditional versus continuous process validation Manufacturing Process Validation report 	
9.30am Practicum II <ul style="list-style-type: none"> Identify the critical process parameters and manufacturing process validation steps Identify common gaps in process validation report 	
10.30am Refreshment Break	
10.45am Practicum II (continued)	
12.00 pm Lunch	
1.00pm Post-approval CMC controls on marketed products <ul style="list-style-type: none"> Current <i>versus</i> 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 	
2.00pm Case Discussion 5 – Post-approval changes Identify CMC changes that require prior approval notification or if reporting is required	CoRE Education Team
3.30 pm Refreshment Break	
3.45 pm Understanding Pharmacopeia: Transfer, Validation and Verification of Analytical Procedures	
5.00pm Pre-Panel Preparation & Debrief	
5.30pm End of Day 4	

Day 5 – 30 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 <ul style="list-style-type: none"> Principles and key aspects of ICH Q8 (annex) Traditional <i>versus</i> enhanced approach in DS/DP development Real time release testing Role of multivariate models in regulatory submissions Principles and key aspects of ICH Q11 	
11.45am	Pharmaceutical quality and risk management	
12.45pm	Lunch	
1.45pm	Implementation of a pharmaceutical quality system <ul style="list-style-type: none"> Principles and key aspects of ICH Q10 Potential applications Differences between a pharmaceutical quality system and a quality (management) system 	
2.30pm	Reflection/ Peer Sharing	Dr Rathi Saravanan CoRE
3.30pm	Break	
3.45pm	Panel Discussion TBC	Experts: TBC
5.00pm	Graduate Certificate Workshop Conclusion	Asst Prof James Leong CoRE
5.30pm	End of Workshop	