GRADUATE CERTIFICATE IN PHARMACEUTICAL REGULATION

GMS5004: Regulation of Pharmaceutical Manufacturing

26 – 30 October 2026

Venue: Coriander (Level 2),
Shaw Foundation Alumni House, National University of Singapore,
11 Kent Ridge Dr, #01-02, 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 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

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Day 1 – 26th October 2026, 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	**Photo-taking Session: Faculty & Participants**	**Education Team, CoRE**
Session 1: Overview of Pharmaceutical Quality Regulations		
9.30am	**Role of Chemistry Manufacturing and Control (CMC) in pharmaceutical product lifecycle** • CMC: scope • ICH guidelines on CMC • Product lifecycle management	**Dr Rathi Saravanan** CoRE
10.15am	**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	**TBC**
11.30am	**Quality Evaluation of Biologics and Biosimilars** • Why biologics require distinct CMC requirements • Key components in characterization and comparability • Reference medicinal product (RMP) • Assessment of similarities/differences in biosimilar and RMP	**TBC**
12.30pm	**Lunch**	

Session 2: Pre-market CMC Requirements: Control of Impurities		
1.30pm	**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**
2.30pm	**Case discussion 1 – Impurities** • Identify the impurities to be monitored in a DS and their acceptable limits.	**CoRE Education Team**
3.30 pm	**Refreshment Break**	
3.45pm	**Nitrosamine Impurities: Control, Analytical Strategies and Regulatory Expectations** • Nitrosamine sources, acceptable limits • Nitrosamine drug substance-related impurities (NDSRIs) • Controls & Analytical strategies • Regulatory expectations & CMC submissions	**TBC**
4.45pm	**Networking**	**CoRE Education Team**
5.30pm	**End of Day 1**	

Day 2 – 27th October 2026, 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	**TBC**
9.30am	**Case discussion 3 – Viral Clearance** • 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** • 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	**TBC**
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	**CoRE Education Team**
3.00pm	**Refreshment Break**	
3.15pm	**Practicum I (cont'd)**	
5.30pm	**End of Day 2**	

Day 3 – 28th October 2026, 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** • 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	**TBC**
10.30am	**Refreshment Break**	
10.45am	**Stability Requirements for Biotechnological Products** • ICHQ5C - ICH Q5E • Challenges in demonstrating stability requirements	**TBC**
12.00noon	**Lunch**	
1.00pm	**Case discussion 4 – Stability Requirements** • 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** • Pre-approval inspection process • common GMP compliance gaps • PIC/S GMP guide for GMP compliance • Responsibilities of manufacturers	**TBC**
4.15pm	**Case discussion 5 – GMP Compliance**	
5.30pm	**End of Day 3**	

Day 4 – 29th October 2026, 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	**TBC**
9.30am	**Practicum II** • Identify the critical process parameters and manufacturing process validation steps • Identify common gaps in process validation report	**CoRE Education Team**
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	**TBC**
2.00pm	**Case Discussion 6 – 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**	**TBC**
5.00pm	**Preparation for EOM & Debrief**	
5.30pm	**End of Day 4**	

Day 5 – 30th October 2026, Friday

	Topic	Speaker/ Organisation
8.30am	**Registration**	
9.00am	**End-of-Module (EOM) Assessment**	
10.00am	**Refreshment Break**	
10.15am	**Review of EOM Questions**	**CoRE Education Team**
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	**TBC**
11.45am	**Pharmaceutical quality and risk management** • Principles and key aspects of ICH Q9(R1) • Potential applications • Risk assessment tools	**TBC**
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	**TBC**
2.45pm	**AI in pharmaceutical quality: Applications, Risks and Regulatory expectations** • Applications of AI across pharmaceutical quality and CMC • Regulatory expectations for AI-enabled systems • AI in CMC and regulatory submissions	**TBC**
3.45pm	**Break**	
4.00pm	**Reflection/ Peer Sharing**	**Dr Rathi Saravanan** CoRE
5.00pm	**Graduate Certificate Workshop Conclusion**	**Asst Prof James Leong** Head, Health Products and Regulatory Science Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
5.30pm	**End of Workshop**	