



DukeNUS
Medical School



Centre of
Regulatory Excellence

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 a 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

26 – 30 October 2026

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	Role of Chemistry Manufacturing and Control (CMC) in pharmaceutical product lifecycle - CMC: scope - ICH guidelines on CMC - Product lifecycle management	Dr Rathi Saravanan CoRE
10.10am	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	
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	
12.30pm	Lunch	



1.30pm	Case discussion 1 – Impurities Identify the impurities to be monitored in a DS and their acceptable limits.	
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	CoRE Education Team
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	
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	
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	
12 noon	Lunch	
1.00pm	Quality control for biotherapeutic: Specifications for DS and DP - Requirements according to ICH Q6B - Analytical consideration	
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	
10.30am	Refreshment Break	
10.45am	Stability Requirements for Biotechnological Products - ICHQ5C - ICH Q5E - Challenges in demonstrating stability requirements	
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	
4.15pm	Understanding Certification of suitability (CEP) procedures	
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	
9.30am	Practicum II • 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 • 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 – 30th October 2026, 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 <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 • 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 Head, Health Products and Regulatory Science Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
5.30pm	End of Workshop	