



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

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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	Mr. Jaineet Arora Education Associate II 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	Mr Thean Soo (TS) LO Regulatory Affairs Management Consultant TS Consulting
11.30am	Quality Evaluation for Biotherapeutics • Why biologics require distinct CMC requirements • Difference in assessment: Pharmaceuticals vs Biotherapeutics • Manufacturing and Process Validation requirements • Key components in characterization and biological activity	CoRE Education Team
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	Ms. Yean Yean Yip Regulatory Consultant Therapeutic Products Branch Health Products Regulation group Health Sciences Authority (HSA) Singapore
2.30pm	Case discussion 1 – Impurities Identify the impurities to be monitored in a DS and their acceptable limits.	Ms. Yean Yean Yip Health Sciences Authority (HSA) Singapore and CoRE Education Team
3.30 pm	Refreshment Break	
3.45pm	Networking	CoRE Education Team
4.15pm	Nitrosamine Impurities: Assessment, Control, Analytical Strategies and Regulatory Expectations - Nitrosamine sources, acceptable limits - Nitrosamine drug substance-related impurities (NDSRIs) - Risk Assessment, Controls & Analytical strategies - Regulatory expectations & CMC submissions	Mr. Amit Mukherjee Senior Manager Scientific Affairs United States Pharmacopeia (USP) India
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	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 Dr. Rathi Saravanan and CoRE Education Team
10.15am	Refreshment Break	
10.30am	Case discussion 3 – Viral Clearance (Cont'd)	CoRE Education Team
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	CoRE Education Team
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 Dr. Rathi Saravanan and CoRE Education Team
3.00pm	Refreshment Break	
3.15pm	Practicum I (cont'd)	CoRE Education Team
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	Dr. Crystal Lau Senior Director CMC (APAC Lead) MSD Singapore
10.30am	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 Singapore
12.00noon	Lunch	
1.00pm	Case discussion 4 – Stability Requirements Country-specific requirements for DP stability data	Dr. Crystal Lau MSD Singapore and 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	Ms. Xinqiao Wang Senior Regulatory Specialist GMP Unit Audit & Licensing Division Health Products Regulation group Health Sciences Authority (HSA) Singapore
4.15pm	Case discussion 5 – GMP Compliance	Ms. Xinqiao Wang Senior Regulatory Specialist Health Sciences Authority (HSA) Singapore and CoRE Education Team
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	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 Dr. Rathi Saravanan and 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 <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	Mr. Jeff Poh Senior Manager, Regulatory Affairs CMC Gilead Sciences Singapore Pte Ltd
2.00pm	Case Discussion 6 – Post-approval changes Identify CMC changes that require prior approval notification or if reporting is required	Dr. Rathi Saravanan and CoRE Education Team
3.30 pm	Refreshment Break	
3.45 pm	Understanding Pharmacopeia: Transfer, Validation and Verification of Analytical Procedures	Dr. Safa Abu Gharbia Senior Scientific Affairs Manager (Middle East, Africa and CAC countries) United States Pharmacopeia (USP), Jordan
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	Overview of Process Development and Manufacturing of Biologics • Complexity of biologics and manufacturing • Biosimilar Development – Unique Challenges • Managing Process Changes • ICH and FDA guidance's for industry on process development	Mr. Yusdy Pan Executive Director, Process Development Amgen Singapore Manufacturing
11.45am	Pharmaceutical quality and risk management • Principles and key aspects of ICH Q9(R1) • Potential applications • Risk assessment tools	Dr Rathi Saravanan Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
12.45pm	Lunch	
1.45pm	Implementation of a pharmaceutical quality system • Scope and objectives ICHQ10 • Principles and key aspects of ICH Q10 • Enablers of ICH Q10 • Potential opportunities for risk-based approaches	Mr. Howard Yu Quality Director, Hilleman Laboratories, Singapore
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	Mr. Ehab Taqieddin Head of APAC International Regulatory Senior Regulatory Group Director Roche Singapore
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	