



DukeNUS
Medical School



Centre of
Regulatory Excellence

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 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

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	CoRE Education Team
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	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	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	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 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 <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	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 <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	CoRE Education Team
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	Presentation and Discussion Topic-Green Pharma: Building Sustainable Strategies for the Future	Experts: Mr. Brett Marshall Former Vice President, Zuellig Pharma Quality Assurance, HSSE Dr. Bess Ng Associate Principal, Sustainability Business, Schneider Electric
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	