# GRADUATE CERTIFICATE IN PHARMACEUTICAL REGULATION

## GMS5004: Regulation of Pharmaceutical Manufacturing

12 October – 16 October 2026

Venue: TBC

## WORKSHOP PROGRAMME

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### 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.

## Day 1 – 12 October, Monday

| | Topic | Speaker/ Organisation |
|---|---|---|
| **8.00am** | **Registration** | |
| **8.30am** | **Welcome** | **Dr Rathi Saravanan**<br>Lead Education Associate<br>Lead, Graduate Certificate Programmes<br>Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School |
| **8.45am** | **Workshop Briefing** | **Dr Rathi Saravanan**<br>CoRE |
| **9.00am** | **Brightspace Briefing**<br>• Team Introductions<br>• Goal Setting<br>• Bright Space Familiarization | **Dr. Uttara Soumyanarayanan**<br>CoRE |
| **9.25am** | **Role of Chemistry Manufacturing and Control (CMC) in pharmaceutical product lifecycle**<br>• CMC: scope<br>• ICH guidelines on CMC<br>• Product lifecycle management | **Dr Rathi Saravanan**<br>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**<br>• ICH CTD: Quality module sections<br>• Challenges in CMC Data collection<br>• Strategies for Effective CMC Dossier Preparation<br>• 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)**<br>• Concerns during manufacturing, batch release and/or stability testing<br>• Degradation products<br>• Process-related impurities and residual solvents<br>• Mutagenic impurities | |
| **12.30pm** | **Lunch** | |

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| **1.30pm** | **Case discussion 1 – Impurities**<br>• Identify the impurities to be monitored in a DS and their acceptable limits. | |
| **2.30pm** | **ICH Q3D Elemental Impurities**<br>• Principles of the Risk Assessment of elemental impurities<br>• Elements to be considered in a risk assessment of small molecule and biologic products<br>• Control of elemental impurities<br>• Determination of PDE for the common administration routes | **CoRE Education Team** |
| **3.15pm** | **Refreshment Break** | |
| **3.30pm** | **Case discussion 2 – Managing elemental impurities**<br>• Identify the elemental impurities that should be considered in the risk assessment of a pharmaceutical product<br>• Understand the different options for converting PDEs to concentration limits | |
| **4.45pm** | **Networking** | **CoRE Education Team** |
| **5.30pm** | **End of Day 1** | |

## Day 2 – 13 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**<br>• Analysis of expression construct and cell bank system<br>• Viral safety evaluation | |
| **9.30am** | **Case discussion 3 – Viral Clearance**<br>• 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**<br>• General requirements<br>• Dosage form or administration route specific requirements<br>• The appropriate specifications limits<br>• Role of Pharmacopoeias, as appropriate | |
| **12 noon** | **Lunch** | |
| **1.00pm** | **Quality control for biotherapeutic: Specifications for DS and DP**<br>• Requirements according to ICH Q6B<br>• Analytical consideration | |
| **2.00pm** | **Practicum I**<br>• Identify the critical specifications to be controlled in a DP<br>• 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 – 14 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**<br>• Minimum data requirements at regulatory submission and post-approval commitments<br>• Bracketing and matricing<br>• Extrapolation to extend retest period or shelf life<br>• Zone IVb stability data for ASEAN regulatory submission | |
| 10.30 am | **Refreshment Break** | |
| 10.45am | **Stability Requirements for Biotechnological Products**<br>• ICHQ5C - ICH Q5E<br>• Challenges in demonstrating stability requirements | |
| 12.00noon | **Lunch** | |
| 1.00pm | **Case discussion 4 – Stability Requirements**<br>• 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**<br>• Pre-approval inspection process<br>• common GMP compliance gaps<br>• PIC/S GMP guide for GMP compliance<br>• Responsibilities of manufacturers | |
| 4.15pm | **Understanding Certification of suitability (CEP) procedures** | |
| 5.30pm | **End of Day 3** | |

## Day 4 – 15 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**<br>• Compliance to cGMP requirement<br>• Traditional versus continuous process validation<br>• Manufacturing Process Validation report | |
| **9.30am** | **Practicum II**<br>• Identify the critical process parameters and manufacturing process validation steps<br>• 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**<br>• Current *versus* ICH Q12 approaches<br>• Key aspects of ICH Q12 and current progress<br>• Identification of established conditions (ECs) and categorization of post-approval CMC changes<br>• Management of post-approval changes associated with product or process CMC deviations | |
| **2.00pm** | **Case Discussion 5 – Post-approval changes**<br>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 – 16 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**<br>• Principles and key aspects of ICH Q8 (annex)<br>• Traditional *versus* enhanced approach in DS/DP development<br>• Real time release testing<br>• Role of multivariate models in regulatory submissions<br>• 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**<br>• Principles and key aspects of ICH Q10<br>• Potential applications<br>• Differences between a pharmaceutical quality system and a quality (management) system | |
| **2.30pm** | **Reflection/ Peer Sharing** | **Dr Rathi Saravanan**<br>CoRE |
| **3.30pm** | **Break** | |
| **3.45pm** | **Panel Discussion**<br><br>**TBC** | **Experts: TBC** |
| **5.00pm** | **Graduate Certificate Workshop Conclusion** | **Asst Prof James Leong**<br>CoRE |
| **5.30pm** | **End of Workshop** | |