



GRADUATE CERTIFICATE IN PHARMACEUTICAL REGULATION

GMS5003: Fundamentals of Health Products Regulation

7 – 11 September 2026

Venue: Whitespace (Academia, SGH),

White Space Room (Level 2), Academia, 20 College Rd, Singapore 169856

WORKSHOP PROGRAMME

Learning outcomes

At the end of this workshop, participants should be able to

- Explain the foundational basis of regulatory management and decision-making for health products
- Explain the essential principles in managing pharmaceuticals across their life cycles
- Describe the regulatory requirements for the different product development phases
- Relate to the real-life settings in regulatory decision-making through hands-on practical sessions
- Recognize the major regulatory organisations steering the innovation of regulatory processes and focus

Day 1 – 7 September 2026, Monday

Topic		Speaker/ Organisation
Session 1: Overview of Pharmaceutical Development, Regulations & Commercialisation Strategies		
8.30am	Welcome Graduate Certificate Students	Dr Rathi Saravanan Lead Education Associate Lead, Graduate Certificate Programme Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
8.50am	Workshop Briefing	CoRE Education Team
9.00am	Brightspace and Assessment Familiarization	Dr Rathi Saravanan CoRE, Duke-NUS Medical School
9.30am	Introduction to Pharmaceutical Regulations- A Regulator's Perspective <ul style="list-style-type: none"> • Purposes & Scope of regulation • Role of regulation in healthcare systems • Evolution of regulatory frameworks • Regulatory cooperation/ reliance • HTA and patient perspectives 	Mr Foo Yang Tong Senior Regulatory Consultant Health Sciences Authority (HSA) Singapore
10.40am	Photo-taking with Participants & Faculty	CoRE Education Team
10.45am	Refreshment Break	
11.00am	Regulatory Processes Across Pharmaceutical Products Lifecycle – Industry Perspective <ul style="list-style-type: none"> • Role of industry in supporting product life cycle management • Different regulatory pathways across market • Country-specific requirements • Challenges for industry 	TBD
12.30pm	Lunch	
1.30pm	Regulatory Landscape in ASEAN Region <ul style="list-style-type: none"> • Broad overview of ASEAN NRAs and their scope of regulation: focus on HSA, NPRA, BPOM • Initiatives like ASEAN PPWG, Joint Assessment, Pharmaceutical Regulatory Framework (APRF) 	Ms Sandy Chan Director, Asia Pacific Regulatory Policy & Intelligence Lead, The Janssen Pharmaceutical Companies of Johnson & Johnson
2.15pm	Regulatory Policy Development and Strategic Engagement <ul style="list-style-type: none"> • Role of regulatory professionals in policy development and implementation • Importance of stakeholder interactions in shaping regulatory policy • Regulatory intelligence and horizon scanning 	Dr Sandra Lim Vice President, Head of Regulatory Affairs-Asia Pacific Bayer, Singapore
3.00pm	Refreshment Break	
3.15pm	Commercialization Strategies for Pharmaceutical Products <ul style="list-style-type: none"> • Significance of TPP in product development and market entry • Regulatory activities in the context of commercialization and ensuring regulatory compliance in tech transfer • Case examples 	TBD
4.30am	Networking Session	CoRE Education Team
5.30pm	End of Day 1	

Day 2 – 8 September 2026, Tuesday

	Topic	Speaker/ Organisation
Session 2: Ensuring Quality, Safety and Efficacy of Pharmaceutical Products		
8.30am	Overview of Chemistry, Manufacturing and Controls <ul style="list-style-type: none"> • Concept of pharmaceutical quality (PQ/CMC) • Importance and impact of pharmaceutical quality on patient safety • Pharmaceutical quality initiatives • Key regulatory guidelines and requirements • General practices in the industry providing quality assurance 	Dr Rathi Saravanan CoRE, Duke-NUS Medical School
9.30am	Good Manufacturing Practices (GMP): Main Concepts <ul style="list-style-type: none"> • Failures in GMP • GMP history • Basic GMP requirements including definition and quality management 	Ms Smitha Kenchath (Virtual) Consultant Seer Pharma (Singapore) Pte Ltd
10.30am	Break	
10.45am	Overview of Nonclinical Requirements for Pharmaceuticals <ul style="list-style-type: none"> • Types of Nonclinical studies • Data for FIH studies 	Dr Xiaofeng (Maple) Wu Regulatory Consultant
11.30am	Overview of GCP and CTA Requirements for Pharmaceuticals <ul style="list-style-type: none"> • Principles of GCP • Key GCP guidelines (WHO/ICH/HSA) • CTA vs CTN 	Dr Yeo Jing Ping Vice President, Clinical Operations & Head, Asia Pacific Precision for Medicine
12.30pm	Lunch	
1.30pm	Overview of Pharmaceuticals Clinical Development <ul style="list-style-type: none"> • Phases of Clinical Trials • Design of CT: inclusion exclusion criteria, endpoints 	Dr Yeo Jing Ping Precision for Medicine
2.30pm	Practicum I Clinical development of pharmaceuticals	Dr Yeo Jing Ping Precision for Medicine
3.00pm	Refreshment Break	
3.15pm	Practicum I Continued	
5.15pm	Debrief and Announcements	CoRE Education Team
5.30pm	End of Day 2	

Day 3 – 9 September 2026, Wednesday

	Topic	Speaker/ Organisation
8.30am	Individual and Group assessment I	
Session 3: Regulatory Processes for Pharmaceutical Products		
9.30am	Market Authorisation Application <ul style="list-style-type: none"> Requirements for MAA submission and review in select countries ICH CTD submission requirements 	Asst/Prof James Leong Head Health Products & Regulatory Science CoRE, Duke-NUS Medical School
10.30am	Refreshment Break	
10.45am	Regulatory Requirements for Regulatory Decision-Making: Benefit-risk analysis <ul style="list-style-type: none"> Benefit-risk assessment for regulatory decision making 	Asst/Prof James Leong CoRE, Duke-NUS Medical School
12.00pm	Lunch	
1.00pm	Practicum II Benefit-Risk Assessment of Pharmaceutical Products	Expert Faculty: Asst/Prof James Leong
3.30pm	Refreshment Break	
3.45pm	Facilitated Regulatory Pathways with Case Examples <ul style="list-style-type: none"> Expedited pathways, accelerated Designations: Orphan, breakthrough Regulatory Cooperation Regulatory Agility Case Examples 	Prof Lawrence Liberti USC Mann School of Pharmacy and Pharmaceutical Sciences Director, The DK Kim International Center for Regulatory Science Associate Professor, Department of Regulatory and Quality Sciences
4.30pm	GRM in Practice: Navigating Submissions <ul style="list-style-type: none"> Principles of good submission practices The submission framework: screening, evaluation HSA review common deficiencies in submissions Document integrity and consistency: GMP, Clinical docs Promoting submission excellence 	TBD
5.20pm	Debrief and Announcements	CoRE Education Team
5.30pm	End of Day 3	

Day 4 – 10 September 2026, Thursday

	Topic	Speaker/ Organisation
Session 4: Post-approval Processes and Product Lifecycle Management		
8.30am	Managing Post-Approval Quality Changes <ul style="list-style-type: none"> Risk based approach to post-approval changes Reliance practices in post-approval CMC changes 	TBD Pharmaceutical Chemistry Variations Section, Therapeutics Goods Administration Australia
9.30am	GMP Compliance, Audit and Inspections <ul style="list-style-type: none"> Types of GMP inspections Common GMP Inspection Findings GMP Audit Deficiencies 	Ms Smitha Kenchath (In person) Seer Pharma (Singapore) Pte Ltd
10.30am	Refreshment Break	
10.45am	Overview of Pharmacovigilance for Pharmaceutical Products <ul style="list-style-type: none"> Introduction to pharmacovigilance Appreciation of the pharmacovigilance framework Risk management plans and post-marketing activities 	Ms Leng Xue Zhen Senior Regulatory Specialist Vigilance and Compliance Branch Health Sciences Authority (HSA), Singapore
12.00pm	Lunch	
1.00pm	Case Discussion I <ul style="list-style-type: none"> Risk Management Plans for Pharmaceutical Products 	Expert Faculty: Ms Leng Xue Zhen
2:45pm	Refreshment Break	
3.00pm	Total Product Lifecycle (TPLC) Management <ul style="list-style-type: none"> Potential issues during pre-market activities Potential issues during post-market activities Quality deviations & regulatory actions Assessing clinical impact 	Asst/Prof James Leong CoRE, Duke-NUS Medical School
4.00pm	Case Discussion II <ul style="list-style-type: none"> Product Deviations & Levels of Recall 	Expert Faculty: Asst/Prof James Leong
5.15pm	Debrief and Announcements	
5.30pm	End of Day 4	

Day 5 – 11 September 2026, Friday

	Topic	Speaker/ Organisation
9.00am	End-of-Module (EOM) Assessment	CoRE Education Team
10.00am	Refreshment Break	
10.15am	Review of EOM Questions	CoRE Education Team
Session 5: Trends in Health Products Development and Regulations		
11.00am	Radiopharmaceuticals and Their Regulatory Landscape <ul style="list-style-type: none"> Definition and unique dual-function nature: diagnostic vs. therapeutics, examples Development and manufacturing considerations Global and regional regulatory frameworks 	Dr. Svetlana Selivanova Senior Scientist, Head, Radiochemistry and Medical Applications Section Canadian Nuclear Laboratories Mr Joel Senior Laboratory Executive National University of Singapore
11.45am	Introduction to Health Technology Assessment (HTA) <ul style="list-style-type: none"> HTA principles & process Technology evaluation & decision-making Case Examples 	Mr Mohamed Ismail Abdul Aziz Senior Lead Specialist Agency for Care Effectiveness (ACE)
12.30pm	Lunch	
1.30pm	Introduction to Healthcare Services Regulation <ul style="list-style-type: none"> Trending areas in healthcare landscape Service models and technologies in gene therapies AI in healthcare 	Asst. Prof. Kavitha Palaniappan Assistant Professor, Lead, Healthcare Services Regulation Group (HRG) CoRE, Duke-NUS Medical School
2.15pm	Gallery Walk: Target Product Profiling <ul style="list-style-type: none"> Development of TPP for different therapeutic areas Peer Evaluation 	TBD
3.45pm	Break	
4.00pm	Reflection and Peer Sharing	Dr. Rathi Saravanan CoRE
5.00pm	Graduate Certificate Workshop Conclusion	Asst/Prof James Leong CoRE, Duke-NUS Medical School
5.30 pm	End of Workshop	