GRADUATE CERTIFICATE IN PHARMACEUTICAL REGULATION

GMS5003: Fundamentals of Health Products Regulation

7 – 11 September 2026

Venue: Whitespace (Academia, SGH),

Duke-NUS Medical School, 8 College Rd, Singapore 169857

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**	
10.00am	**Brightspace and Assessment Familiarization**	**Dr Rathi Saravanan** CoRE Duke-NUS Medical School
8.30am	**Introduction to Pharmaceutical Regulations- A Regulator's Perspective** • Purposes & Scope of regulation • Role of regulation in healthcare systems • Evolution of regulatory frameworks • Regulatory convergence • Regulatory cooperation/ reliance HTA and patient perspectives	
10.40am	**Photo-taking with Participants & Faculty**	**CoRE Education Team**
10.45am	**Refreshment Break**	
11.00am	**Regulatory Processes Across Pharmaceutical Products Lifecycle – Industry Perspective** • Role of industry in supporting product life cycle management • Different regulatory pathways across market • Country-specific requirements • Novel health products • Optimising engagement with regulators • Challenges for industry	
12.30pm	**Lunch**	
1.30pm	**Regulatory landscape in ASEAN region** • 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)	
2.15pm	**Role of stakeholder interactions for effective regulatory decision making** • Pre-consultations in guiding development • Importance of stakeholder interactions in ensuring SEQ of pharmaceutical products • Role of regulatory professionals	
3.00pm	**Refreshment Break**	
3.15pm	**Commercialization strategies for pharmaceutical products** • Significance of TPP in product development and market entry • Regulatory activities in the context of commercialization and ensuring regulatory compliance in tech transfer • Assessing the commercial potential of innovations and inventions	

	• Case examples	
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** • 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	
9.30am	**Good Manufacturing Practices (GMP): Main Concepts** • Failures in GMP • GMP history • Basic GMP requirements including definition and quality management	
10.30am	**Break**	
10.45am	**Overview of Nonclinical requirements for pharmaceuticals** • Types of Nonclinical studies • Data for FIH studies	
11.30am	**Overview of Good Clinical Practice (GCP) requirements and clinical trial application (CTA) for pharmaceuticals** • Principles of GCP • Key GCP guidelines (WHO/ICH/HSA) • CTA vs CTN	
12.30pm	**Lunch**	
1.30pm	**Overview of Pharmaceuticals Clinical Development** • Phases of Clinical Trials • Design of CT: inclusion exclusion criteria, endpoints	
2.30pm	**Practicum I** Clinical development of pharmaceuticals	
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** • Requirements for MAA submission and review in select countries • ICH CTD submission requirements	
10.30am	Refreshment Break	
10.45am	**Regulatory Requirements for Regulatory Decision-Making: Benefit-risk analysis** • Benefit-risk assessment for regulatory decision making	
12.00pm	Lunch	
1.00pm	**Practicum II** Benefit-Risk Assessment of Pharmaceutical Products	
3.30pm	Refreshment Break	
3.45pm	**Facilitated Regulatory Pathways with Case Examples** • Expedited pathways, accelerated • Designations: Orphan, breakthrough • Regulatory Cooperation • Regulatory Agility • Case Examples	
4.30pm	**Good Registration Management (GRM)** • WHO GRevP (Good Review Practices) • GSubP (Good Submission Practices)	
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** • Risk based approach to post-approval changes • Reliance practices in post-approval CMC changes	
9.30am	**GMP compliance, Audit and Inspections** • Types of GMP inspections • Common GMP Inspection Findings • GMP Audit Deficiencies	
10.30am	**Refreshment Break**	
10.45am	**Overview of Pharmacovigilance for Pharmaceutical Products** • Introduction to pharmacovigilance • Appreciation of the pharmacovigilance framework • Risk management plans and post-marketing activities	
12.00pm	**Lunch**	
1.00pm	**Case Discussion I** • Risk management plans for pharmaceutical products	
2:45pm	**Refreshment Break**	
3.00pm	**Total Product Lifecycle (TPLC) management** • Potential issues during pre-market activities • Potential issues during post-market activities • Quality deviations & regulatory actions • Assessing clinical impact	
4.00pm	**Case Discussion II** • 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	**Introduction to Precision Health and Medicine** • Significance of biomarkers • Strategies integrating drug & diagnostic development • Challenges in the diagnostic development process	
11.45am	**Introduction to Health Technology Assessment (HTA)** • HTA principles & process • Technology evaluation & decision-making • Case Examples	
12.30pm	**Lunch**	
1.30pm	**Introduction to Healthcare Services Regulation** • Trending areas in healthcare landscape • Service models and technologies in gene therapies • AI in healthcare	
2.15pm	**Gallery Walk: Target Product Profiling** • Development of TPP for different therapeutic areas • Peer Evaluation	
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**	