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

Graduate Certificate in Pharmaceutical Regulation
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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** • 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** • Role of industry in supporting product life cycle management • Different regulatory pathways across market • Optimising engagement with regulators • Challenges for industry	**Dr Karin Markgraf** Head of Regulatory Affairs Asia Pacific Merck Group
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)	**Ms Sandy Chan** Director, Global Regulatory Policy & Intelligence Lead for AP, The Janssen Pharmaceutical Companies of Johnson & Johnson
2.15pm	**Regulatory Policy Development and Strategic Engagement** • 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** • Significance of TPP in product development and market entry • Regulatory activities in the context of	**Dr Tan Wee Kiat** Founder & CEO Stealth Venture **Consulting Lead**

	commercialization and ensuring regulatory compliance in tech transfer • Assessing the commercial potential of innovations and inventions • Case examples	Biotech Connection Singapore
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	**Dr Rathi Saravanan** CoRE, Duke-NUS Medical School
9.30am	**Good Manufacturing Practices (GMP): Main Concepts** • 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** • Types of Nonclinical studies • Data for FIH studies	**Dr Xiaofeng (Maple) Wu** Regulatory Consultant
11.30am	**Overview of GCP and CTA Requirements for Pharmaceuticals** • 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** • 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** • 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** • 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** • 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	**Regulatory Submissions and Lifecycle Management** • Submission strategy and planning • Building a submission-ready dossier: eCTD structure, completeness checks and internal "mock review" before filing • Managing the query–response cycle • The global dossier challenge: one product, many divergent "as-approved" versions across markets	**Ms Por Suat Gnoh** Regulatory Program Director, International Roche Singapore
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	**Mr Jeff Webb** Principal Evaluator Pharmaceutical Chemistry Variations Section, Therapeutics Goods Administration Australia
9.30am	**GMP Compliance, Audit and Inspections** • 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** • 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** • Risk Management Plans for Pharmaceutical Products	**Expert Faculty: Ms Leng Xue Zhen**
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	**Asst/Prof James Leong** CoRE, Duke-NUS Medical School
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	**Radiopharmaceuticals and Their Regulatory Landscape** • 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 Boon Tay Kiat (Joel)** QA and RA Lead Clinical Imaging Research Centre National University of Singapore
11.45am	**Introduction to Health Technology Assessment (HTA)** • 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** • 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** • Development of TPP for different therapeutic areas • Peer Evaluation	**Dr Tan Wee Kiat** Stealth Venture
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**	