GRADUATE CERTIFICATE IN PHARMACEUTICAL REGULATION

GMS5003: Fundamentals of Health Products Regulation

15 – 19 September 2025

Venue: Training Room 5C (Level 5),

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

Please note that the venue will be relocated to Room 3D (Level 3, Duke-NUS Medical School) only for 16 September 2025 (Tuesday).

WORKSHOP PROGRAMME

Learning outcomes

- 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 – 15 September 2025, Mon

	Topic	Speaker/ Organisation
Session 1: Overview of Pharmaceutical Development, Regulations & Commercialisation Strategies		
8.30 am	**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	**Prof John Skerritt** Former Deputy Secretary Health Products Regulation, Australian Department of Health and Aged Care Enterprise Professor in Health Research Impact, University of Melbourne, Australia Adjunct Professor, Faculty of Medicine and Health, University of Sydney, Australia
9.15 am	**Welcome Graduate Certificate Students**	**Dr Rathi Saravanan** Lead Education Associate Lead, Graduate Certificate Programme Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
9.45 am	**Workshop Briefing**	**Dr Uttara Soumyanarayanan** Senior Education Associate CoRE, Duke-NUS Medical School
10.00 am	**Brightspace and Assessment Familiarization**	**Mr. Osman Bin Mohamad** Senior Education Associate CoRE, Duke-NUS Medical School
10.40 am	**Photo-taking with Participants & Faculty**	**CoRE Education Team**
10.45 am	**Refreshment Break**	
11.00 am	**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	**TBD**
12.30 pm	**Lunch**	
1.30 pm	**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** Associate Director, Asia Pacific Regulatory Policy & Intelligence Lead, The Janssen Pharmaceutical Companies of Johnson & Johnson
2.15 pm	**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	**Mr Thean Soo (TS) LO** Independent Consultant TS Consulting
3.00 pm	**Refreshment Break**	
3.15 pm	**Commercialization strategies for pharmaceutical products** • Significance of TPP in product development and market entry • Regulatory activities in the context of	**Mr. Andy Li** Senior Executive NUS Enterprise National University of Singapore (NUS)

	commercialization and ensuring regulatory compliance in tech transfer • Assessing the commercial potential of innovations and inventions • Case examples	
Session 2: Ensuring Quality, Safety and Efficacy of Pharmaceutical Products		
4.15 pm	**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
5.15 pm	**Debrief and Announcements**	**CoRE Education Team**
5.30pm	**End of Day 1**	

Day 2 – 16 September 2025, Tue

Please note that the venue will be relocated to Room 3D (Level 3, Duke-NUS Medical School) only for Tuesday, 16 September 2025.

	Topic	Speaker/ Organisation
8.30 am	**Good Manufacturing Practices (GMP): Main Concepts** • Failures in GMP • GMP history • Basic GMP requirements including definition and quality management	**Ms Smitha Kenchath** Consultant Seer Pharma (Singapore) Pte Ltd
9.30 am	**Networking Session**	**Mr. Osman Bin Mohamad** CoRE, Duke-NUS Medical School
10.00 am	**Break**	
10.45 am	**Overview of Nonclinical requirements for pharmaceuticals** • Types of Nonclinical studies • Data for FIH studies	**TBD**
11.45 am	**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	**Dr Yeo Jing Ping** Vice President, Clinical Operations & Head, Asia Pacific Precision for Medicine
12.30 pm	**Lunch**	
1.30 pm	**Overview of pharmaceuticals clinical development** • Phases of Clinical Trials • Design of CT: inclusion exclusion criteria, endpoints	**Dr Yeo Jing Ping** Precision for Medicine
2.30 pm	**Practicum I** Clinical development of pharmaceuticals	**Dr Yeo Jing Ping** Precision for Medicine
3.00 pm	**Refreshment Break**	
3.15 pm	**Practicum I Continued**	
5.15 pm	**Debrief and Announcements**	CoRE Education Team
5.30 pm	**End of Day 2**	

Day 3 – 17 September 2025, Wed

	Topic	Speaker/ Organisation
8.30 am	**Individual and Group assessment I**	
Session 4:	**Regulatory Processes for Pharmaceutical Products**	
9.30 am	**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
10.30 am	**Refreshment Break**	
10.45 am	**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
12.00 pm	**Lunch**	
1.00 pm	**Practicum II** Benefit-Risk Assessment of Pharmaceutical Products	**Expert Faculty:** Asst/Prof James Leong
3.30 pm	**Refreshment Break**	
3.45 pm	**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
4.30 pm	**Good Registration Management (GRM)** • WHO GRevP (Good Review Practices) • GSubP (Good Submission Practices)	**Mr Thean Soo (TS) LO** TS Consulting
5.20 pm	**Debrief and Announcements**	**CoRE Education Team**
5.30pm	**End of Day 3**	

Day 4 – 18 September 2025, Thurs

	Topic	Speaker/ Organisation
Session 5: Post-approval processes and product lifecycle management		
8.30 am	**Managing post-approval quality changes** • Risk based approach to post-approval changes • Reliance practices in post-approval CMC changes	**Ms Jacinta Watt,** Director, Pharmaceutical Chemistry Variations Section, Therapeutics Goods Administration Australia
9.30 am	**GMP compliance, Audit and Inspections** • Types of GMP inspections • Common GMP Inspection Findings • GMP Audit Deficiencies	**Ms Smitha Kenchath** Seer Pharma (Singapore) Pte Ltd
10.30 am	**Refreshment Break**	
10.45 am	**Overview of Pharmacovigilance for Pharmaceutical Products** • Introduction to pharmacovigilance • Appreciation of the pharmacovigilance framework • Risk management plans and post-marketing activities	**Dr Han Phey Yen** Regulatory Consultant Vigilance & Compliance Branch Health Sciences Authority, Singapore
12.00 pm	**Lunch**	
1.00 pm	**Case Discussion I** • Risk management plans for pharmaceutical products	**Expert Faculty: Dr Han Phey Yen**
2:45 pm	**Refreshment Break**	
3.00 pm	**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
4.00 pm	**Case Discussion II** • Product deviations & levels of recall	**Expert Faculty: Asst/Prof James Leong**
5.15 pm	**Debrief and Announcements**	
5.30pm	**End of Day 4**	

Day 5 – 19 September 2025, Fri

	Topic	Speaker/ Organisation
9.00 am	**End-of-Module (EOM) Assessment**	**CoRE Education Team**
10.00 am	**Refreshment Break**	
10.15 am	**Review of EOM Questions**	**CoRE Education Team**
Session 6: Trends in Health Products Development and Regulations		
11.00 am	**Introduction to Precision Health and Medicine** • Significance of biomarkers • Strategies integrating drug & diagnostic development • Challenges in the diagnostic development process	**Ms Valerie Mbella** Director Global Regulatory Affairs Diagnostics, Johnson & Johnson Innovative Medicine
11.45 am	**Introduction to Health Technology Assessment** • HTA principles & process • Technology evaluation & decision-making • Examples	**Mr Mohamed Ismail ABDUL AZIZ** Agency for Care Effectiveness
12.30 pm	**Lunch**	
1.30 pm	**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
2.15 pm	**Gallery Walk: Target Product Profiling** • Development of TPP for different therapeutic areas • Peer Evaluation	**Mr. Andy Li** NUS Enterprise
3.45 pm	**Break**	
4.00 pm	**Reflection and Peer Sharing**	**Dr. Rathi Saravanan** CoRE
5.00 pm	**Graduate Certificate Workshop Conclusion**	**Prof Silke Vogel** Deputy Director, CoRE Senior Associate Dean Graduate Studies Duke-NUS Medical School
5.30 pm	**End of Workshop**	