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

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
8.30 am	**Welcome Graduate Certificate Students**	**Professor John C W Lim** Executive Director Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
9.00 am	**Workshop Briefing**	**Dr Rathi Saravanan** Lead Education Associate CoRE, Duke-NUS Medical School
9.15 am	**Brightspace and Assessment Familiarization**	**Mr. Osman Bin Mohamad** Senior Education Associate CoRE, Duke-NUS Medical School
Session 1: Health Products Regulatory Overview and Role of Regulatory Professionals		
9.45 am	**Introduction to pharmaceutical regulation in the context of healthcare in resource endowed and resource constrained settings** • Provide broad overview of how regulations are evolving in the context of changing global landscape	
11.00 am	**Refreshment Break**	
11.20 am	**To understand the role of regulation – and different approaches to regulation – in each phase of the product lifecycle** • The role of pharmaceutical regulations and its contribution to the healthcare environment	
12.30 pm	**Lunch**	
1.30 pm	**Role of regulatory professionals** • Role of regulatory professionals • Professional development frameworks	
2.15 pm	**Health Products Regulation: Role of stakeholder interactions for effective regulatory decision making** • Pre-consultations in guiding development • Importance of stakeholder interactions in ensuring SEQ of pharmaceutical products	
3.00 pm	**Refreshment Break**	
3.15 pm	**Target Product Profiling (TPP) in product development** • Use of TPP significance in product development and market entry	
4.15 pm	**Commercialisation strategies for pharmaceutical products** • Regulatory activities in the context of commercialization and ensuring regulatory compliance in tech transfer • Assessing the commercial potential of innovations and inventions • Case examples	
5.20 pm	**Debrief and Announcements**	**CoRE Education Team**
5.30pm	**End of Day 1**	

Day 2 – 16 September 2025, Tue

	Topic	Speaker/ Organisation
Session 3:	**Ensuring Quality, Safety and Efficacy of Pharmaceutical Products**	
8.30 am	**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	
9.30 am	**Manufacturing of pharmaceutical products** • Introduction to regulatory control on quality • Introduction to ICH CTD Module 3 Quality section	
10.30 am	**Refreshment Break**	
10.45 am	**Good Manufacturing Practices (GMP): Main Concepts** • Failures in GMP • GMP history • Basic GMP requirements including definition and quality management	
11.30 am	**Overview of non-clinical requirements for pharmaceuticals** • Types of nonclinical studies • Data for FIH studies	
12.30 pm	**Lunch**	
1.30 pm	**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	
2.00 pm	**Overview of pharmaceuticals clinical development** • Phases of Clinical Trials • Design of CT: inclusion exclusion criteria, endpoints	
3.00 pm	**Refreshment Break**	
3.15 pm	**Practicum I** Clinical development of pharmaceuticals	**Expert Faculty:**
5.20 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 (Pharmaceutical Products)** • Requirements for MAA submission and review in select countries • ICH CTD submission requirements	
10.30 am	**Refreshment Break**	
10.45 am	**Regulatory requirements for regulatory decision making: Benefit-risk analysis** • Benefit-risk assessment for regulatory decision making	
12.00 pm	**Lunch**	
1.00 pm	**Practicum II** Benefit-Risk Assessment of Pharmaceutical Products	**Expert Faculty:**
3.30 pm	**Refreshment Break**	
3.45 pm	**Good Submission Practices (GSubP) in supporting efficient therapeutics registration in ASEAN**	
4.30 pm	**Good Review Practices (GRevP) and Regulatory cooperation** • WHO GRevP guideline • Principles of a Good Review • Managing the Review	
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	
9.30 am	**GMP compliance, audit and inspections**	
10.30 am	**Refreshment Break**	
10.45 am	**Total Product Lifecycle (TPLC) management**	
12.00 pm	**Lunch**	
1.00 pm	**Global trends in pharmacovigilance**	
1.45 pm	**Overview of pharmacovigilance for pharmaceutical products** • Introduction to pharmacovigilance • Appreciation of the pharmacovigilance framework • Risk management plans and post-marketing activities	
2.30 pm	**Practicum III** Risk management plans for pharmaceutical products	**Expert Faculty:**
3.00 pm	**Refreshment Break**	
3.15 pm	**Practicum III** Continued and Discussions	
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** • Overview of landscape • National and Regional programs in Precision Medicine	
12.00 pm	**Development and use of standards in supporting product development**	
12.30 pm	**Lunch**	
1.30 pm	**Patient engagement, Coalition to Accelerate Patient Engagement in Asia-Pacific (CAPE)** • Importance of patient involvement • Patient engagement in product lifecycle • Real world examples	
2.00 pm	**Gallery Walk: Target Product Profiling**	
3.00 pm	**Introduction to Healthcare Services Regulation** • Trending areas in healthcare landscape • Service models and technologies in Gene therapies	
3.45 pm	**Break**	
4.00 pm	**Reflection and Peer Sharing**	**Dr. Rathi Saravanan** CoRE
5.15 pm	**Graduate Certificate Workshop Conclusion**	**Prof Silke Vogel** Deputy Director, CoRE Senior Associate Dean Graduate Studies Duke-NUS Medical School
5.30pm	**End of Workshop**	