HKU Med LKS Faculty of Medicine
The University of Hong Kong
香港大學李嘉誠醫學院

MAPH7330 Regulatory Affairs – Hong Kong and Beyond
(Semester 2, 2024-25)

Course Coordinator(s)	Ms. Porsha Lam, Pharmacist, Department of Pharmacology and Pharmacy (Email: porshacy@hku.hk) Mr. Donald Chong, Honorary Lecturer, Department of Pharmacology and Pharmacy (Email: chong1@hku.hk)
Course Description	Regulatory Affairs plays an integral part for the pharmaceutical company nowadays as they are involved in the applications of law and regulations affecting the pharmacy practice and the registration of medicinal products in every corner of the world. In recent years, this area of regulatory affairs is also commonly known as "regulatory science". That implies a global trend of an increasing recognition of knowledge in regulatory affairs to be highly associated with science of drugs, their mechanisms and even the overall drug profiles. Due to the myriad impacts the regulatory science could potentially bring, this course has embedded three major elements – the regulatory knowledge rendering a successful registration of drugs in Hong Kong, the various development worldwide and the various documents needed with its rationale. This course aims to provide students with the working knowledge to understand the local regulatory enforcements that apply to Pharmaceutical Products, Food Supplements, Medical Devices, and Advanced Therapy Products. This course also focuses on the regulatory systems in different regions including China, Asia Pacific, and Europe with a view to deliver students an overview of regulatory framework from countries around the world.
Tentative Topics	• Regulatory affairs in Hong Kong, Asia Pacific Region, China, EU • Managing changes in health supplement regulatory environment • Variation change of registered particulars (CORP), wholesale dealer license (WDL), manufacturing, secondary packaging, import and export • Advertising and regulating pharmaceutical products • Global regulatory affairs • Global harmonization and regulatory dossier • Global supply chain • Audit preparation and inspections • Chemistry, manufacturing and control - process of dossier submissions and approvals • Product development process • Pharmaceutical labelling • Electronic prescribing information and switch projects • Regulatory intelligence • Lifecycle management - agency commitments, renewals, variations and more • Regulatory affairs in advanced therapy products and medical devices

	• Accelerated and priority review • Post-marketing approval
Mode	F2F, Zoom live, Pre-recorded
HKU Credits	6 credits
Assessment (tentative)	Online Assessments – 30% Written Assignments – 40% Forum Activities – 30%
Lecture Date and Time (Tentative as of Nov 7, 2024)	Friday Evenings in 2025 – Feb 7, Feb 21, Mar 7, Mar 21, Apr 11, May 2, May 16, May 30 3 Interactive Forums on Saturday Afternoons in 2025 – Feb 15, Mar 15, Apr 5
Cost	HK$13800