



MAPH7330 Regulatory Affairs – Hong Kong and Beyond

(Semester 2, 2023-24)

Course Coordinator(s)	Dr. Aviva Chow, Assistant Professor, Department of Pharmacology and Pharmacy (Email: asfchow@hku.hk) Mr. Donald Chong, Honorary Lecturer, Department of Pharmacology and Pharmacy (Email: donald.x.chong@haleon.com)
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, would be included. This course aims to provide students with the working knowledge to understand the local regulatory enforcements that apply to Pharmaceutical Products, Food Supplement, Medical Devices, and Advanced Therapy Products. Besides, 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.
Mode	Pre-recorded Lectures, Face-to-face Lectures and Interactive Forums
HKU Credits	6 credits
Assessment	Online Multiple-Choice Questions - 45% Forum Activities - 15% Reflection - 15% Essay - 25%
Lecture Date and Time	Weekday evening: 18 Jan, 23 Jan, 25 Jan, 27 Feb, 19 Mar Forums on Saturday afternoon – 3 Feb, 2 Mar, 23 Mar 2024
Cost	13120 HKD