

The Hong Kong University of Science and Technology

UG Course Syllabus

Course Title: Regulatory Affairs in the Healthcare Industry

Course Code: BIEN 4110

Course Credits: 3 credits

Prerequisites: None

Course Coordinator: Mr. Donald Chong (additional support will be provided by Prof. Richard Lakerveld)

Email: donchong@ust.hk

Course Description

This undergraduate level course aims at introducing basic principles of regulatory science and engineering as the foundation, while familiarizing students with the medical and engineering operations in the pharmaceutical and medical device industry, as well as the associated regulatory requirements, with an emphasis on Hong Kong and the nearby region. Students will be introduced to topics such as Good Manufacturing Practice (GMP), pharmaceutical product/ medical device registration, pharmacovigilance, and clinical trials. The course should prepare students for a career in both the pharmaceutical and medical device industry.

Assessments:

Assessment Task	Contribution to Overall Course grade (%)
Multiple-Choice Questions (2 x 15%)	30%
Interview	30%
Presentation	35%
Class Participation	5%

Required Texts and Materials

Not applicable.