

**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)

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**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:**

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

**Required Texts and Materials**

Not applicable.