香港中文大學(深圳)
The Chinese University of Hong Kong, Shenzhen

Course code	PHM3006
Course title (English)	Drug Discovery, Development and Regulation
Course title (Chinese)	药物发现、开发和监管
Units	2
Language of Instruction	English
Description (English)	This course provides students with an understanding of the overall process of drug discovery and development. It covers the basic principles of how new drugs are discovered, developed, manufactured, and become medicines. Patenting, phase 1, 2, and 3 clinical trials, marketing processes, and the cooperation between basic science researchers with drug companies will be covered. Case studies of both successful and unsuccessful drug candidates will be presented, where students will learn about the entire drug discovery and development process.
Description (Chinese)	本课程让学生了解药物发现和开发的整个过程。它涵盖了新药如何被发现、开发、制造和成为药物的基本原则。并且包括专利申请、1 期、2 期和 3 期临床试、营销流程，以及基础科学研究人员与制药公司的合同协作等。本课程将介绍成功和失败的候选药物的案例研究，学生将在其中了解整个药物发现和开发过程。

Learning Outcomes

By the end of this course, each student should be able to describe and discuss:
- Examples of how new drugs are discovered
- How drugs interact with their biological target
- Fundamentals of medicinal chemistry
- Importance of preclinical studies in drug development
- The purpose of each phase in a clinical trial, and procedures used in each phase
- Steps involved in patenting a new drug
- Ways in which basic science researchers and drug companies interact
- Examples of successful and unsuccessful drug development, including all stages of the process

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Indicative Teaching Plan

Week	Lectures / Topics
1	• Drug Discovery: History of Drug Discovery and Development • Drug Discovery: Modern Drug Discovery and Development
2	• Drug Discovery: Overview of the Drug Discovery Process - I • Drug Discovery: Overview of the Drug Discovery Process - II
3	• Drug Discovery: Transforming Novel Molecules to Medicines - I • Drug Discovery: Transforming Novel Molecules to Medicines - II
4	• Drug Discovery: Safety and DMPK Considerations - I • Drug Discovery: Safety and DMPK Considerations - II
5	• Drug Discovery: From Basic Science to Clinical Trials - I • Drug Discovery: From Basic Science to Clinical Trials - II
6	• Case Study - I • Case Study - II
7	• Drug Development: Investigational New Drug Application • Drug Development: New Drug Application
8	• Drug Development: Patent Process for Drug Discovery and Development I • Drug Development: Patent Process for Drug Discovery and Development II
9	• Drug Development: Generic Drug Development and Abbreviated New Drug Application - I • Drug Development: Generic Drug Development and Abbreviated New Drug Application - II
10	• Drug Development: Current Good Manufacturing Practices and Good Laboratory Practices - I • Drug Development: Current Good Manufacturing Practices and Good Laboratory Practices - II
11	• Review Lecture