LIFS 4888: Development and Registration of Pharmaceutical Products (Spring 2024)

Lecturers:	Prof. Karl Tsim	Rm 5456	X-7332	botsim@ust.hk
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Teaching Assistant: Dr. Ka Wing Leung

Time: Tuesday/Thursday, 9 am to 10:20 am, Room 4579, Lift 27-28

Recommended Book:

Biotechnology Operations	Centanni and Roy, 2017	CRC Press

Course Description:

An introduction of the development and registration of pharmaceutical products in Hong Kong and the Mainland markets. Registration of pharmaceutical products (drugs, medical devices, food supplements) is a comparatively new biotechnology-business model, which has evolved from governmental regulations to public health through the assurance of safety and efficacy of pharmaceutical products.

This course emphasizes the essential components of pharmaceutical development; discusses the key stages and decision points in the process; and gives a detailed analysis on the quality control and regulatory requirements. The technological and financial requirements of the development of pharmaceutical products are also covered. Professional training in these disciplines, lacking in Hong Kong and the Greater Bay Area, is crucial for students who plan to pursue further studies or develop their career in the biotechnology sectors.

Intended Learning Outcome:

1. Explain the procedure of development for pharmaceutical products.
2. Summarize the governmental requirements of registration of pharmaceutical products.
3. Exemplify and differentiate the characteristics of pharmaceutical industries in Hong Kong and Mainland.
4. Apply the knowledge in the development and registration of pharmaceutical products and evaluate the procedure.
5. Construct essential connections between market and industries.

GRADING:

Individual Drug Research Writing & Presentation:	40%
Team Consent Decree Writing & Presentation:	60%

No.	Date	Topics	Lecturers
1	2/1	Regulatory Agencies: FDA, EMA, and ICH	TAM
2	2/6	Regulatory Agencies: NMPA, CMPR and others	Richard Ko / TAM
3	2/8	Pharmaceutical Development: Preclinical & GLP	TAM
4	2/15	Pharmaceutical Development: Preclinical & IND registration	TAM
5	2/20	Pharmaceutical Development: Clinical Studies & GCP	Peng, Bin / TAM
6	2/22	Pharmaceutical Development: GMP & QA/QC	Paul Partovi / TAM
7	2/27	Pharmaceutical Development: NDA registration	TAM
8	2/29	Pharmaceutical Development: Pharmacovigilance	Bao, Jing / TAM
9	3/5	Nutraceutical Development & Registration	TSIM
10	3/7	Nutraceutical Development & Registration	TSIM
11	3/12	Nutraceutical Development & Registration	TSIM
12	3/14	Nutraceutical Development & Registration	TSIM
13	3/19	*Midterm Project: Individual research summary*	Students
14	3/21	*Midterm Project: Individual research summary*	Students
15	3/26	Medical Device: Classifications & dossier	TAM
16	4/9	Medical Device: 510K & PMA registration	Walter Carney / TAM
17	4/11	Medical Device: NMPA	TAM
18	4/16	Product Case Study	TBA
19	4/18	Product Case Study	Li - F
20	4/23	Product Case Study	Venice Choi
21	4/25	Product Case Study	Chi Ming Lee
22	4/30	Product Case Study: The Genzyme Story	TAM
23	5/2	*Team Consent Decree Presentations*	Students
24	5/7	*Team Consent Decree Presentations*	Students
25	5/9	*Team Consent Decree Presentations*	Students

Weekly planner could be updated, as needed !