The Hebrew University of Jerusalem

Syllabus

Drug Development - 64874

Last update 02-05-2024

HU Credits: 2

Degree/Cycle: 2nd degree (Master)

Responsible Department: School of Pharmacy

Academic year: 0

Semester: 2nd Semester

Teaching Languages: English

Campus: Ein Karem

Course/Module Coordinator: Katy Margulis

Coordinator Email: katy.margulis@mail.huji.ac.il

Coordinator Office Hours:

Teaching Staff:

Dr. Katy Margulis

Course/Module description:

The course will cover the main aspects of the drug development process and will expose students to the essential activities of drug development, from discovery, through to preclinical development, clinical development, manufacturing, and regulation.

Course/Module aims:

Learning outcomes - On successful completion of this module, students should be able to:

At the end of the course, the students will be familiar with the terminology and main stages in drug development in an industry setting.

Attendance requirements(%):

80%

Teaching arrangement and method of instruction:

Course/Module Content:

1. Introduction to Drug Development: introduction to the drug development process from planning to execution and probability of success; introduction to the functions/teams involved at different stages of drug development; overview for the rest of the course in which we will dive deeper into each of the stages;
2. Preclinical pharmacology: the role of preclinical research in drug development in industry and its importance for the clinical development stages and for the regulatory requirements; understanding the therapeutic potential of a therapy in development, examples of experiments and the relevance of animal models.
3. Early-stage drug discovery: bioassay development and high throughput screening: early stages of drug discovery, methods to investigate biological activity, and approaches for high throughput screening.
4. The role of medicinal chemistry in drug discovery and development: characteristics of molecules with medicinal potential; selection and optimization processes; natural molecules as a source of new drug candidates.
5. Preclinical safety: introduction to the main topics in toxicology and ADME (absorption, distribution, metabolism, and excretion); objectives of the toxicology

studies, the stages, the regulatory and clinical requirements; emphasis will be put on studies that cannot be performed in humans (for example, carcinogenicity, reproductive toxicology); learn the relevant terminology, such as Good Laboratory Practice (GLP).
6. Planning a clinical trial: familiarity with terms such as clinical development plan (CDP), target product plan (TPP), planning clinical trials in advanced phases (2-4), biomarkers, protocols and regulatory approvals, the placebo effect, criteria for participation in a clinical trial.
7. Clinical pharmacology: pharmacokinetics and pharmacodynamics; the regulatory requirements for a clinical pharmacology program and examples.
8. Intellectual property (IP) in the pharmaceutical industry. What is a patent, why is it needed, different types of patents and basic concepts of patent law, patent infringement, and patentability issues.
9. Introduction to development of biologics and biosimilars: the stages involved in developing a biologic as compared to a small molecule drug; comparison of the processes for developing biologics as compared to biosimilars; the stages and challenges in developing biosimilars.
10. Computational Biology: The lecture will cover the two major approaches in the computer-aided drug design field, structure- and ligand- based, using data on protein structure and on the properties of bound ligands, respectively. Introduction to computational methods in these approaches: comparative modeling, docking, pharmacophore modeling, etc.
11. Analytics and big data: introduction to the role of technology, big data and analytics for drug development and clinical monitoring; use of sensors and wearables; digital biomarkers and predictive models.
12. Chemistry Manufacturing and Control (CMC): CMC main principles; how do physico-chemical properties of a drug substance (DS) influence its formulation into drug product (DP); process development for DS and DP; analytical method development and quality control; clinical and regulatory requirements, CMC in generic medicine development.
13. Tour of the Teva site in Kfar Saba and of the BLAVATNIK CENTER for Drug Discovery at Tel Aviv University: (dates to be determined, limited number of places)

<u>Required Reading:</u>
Guide to Drug Development: A Comprehensive Review & Assessment - Bert Spilker

• FDA Guidance for Industry - Oversight of Clinical Investigations — A Risk-Based Approach to Monitoring, August 2013
Introduction to nonclinical safety testing:
• ICH M3(R2) guideline. 11 June 2009.
• Principles of Toxicology by David L. Eaton and Curtis D. Klaassen. In: Casarett & Doull's Toxicology: The Basic Science of Poisons, Eighth Edition. Unit 1: Editor: Curtis D. Klaassen. Chapter 2, pages 13-48. Publisher: McGraw-Hill Professional

Publishing, 2013.

Additional Reading Material:

- *Communication from the Commission 2010/C 82/01 — Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial (CT-1), March 2010*
- *US Code Title 21, Part 312, Investigational New Drug Application, April 2012*
- *FDA Guidance for Industry: Formal Meetings Between the FDA and Sponsors or Applicants, May 2009*
- *European Commission: Notice to Applicants Vol. 2A: Procedures for marketing authorisation, June 2013*
- *European Commission. (2008, May). Volume 2B: Notice to Applicants: Medicinal products for human use. Presentation and format of the dossier: Common Technical Document (CTD).*
- *U.S. Food and Drug Administration: New Drug Application, May 2012*
- *The CDER Handbook, produced by the Department of Health and Human Services, Food and Drug Administration, March 1998*
- *CDER 21st Century Review Process, Desk Reference Guide, produced by the Department of Health and Human Services, Food and Drug Administration, September 2014*
- *Beishon M., Approval rating: how do the EMA and FDA compare?, 12 I CancerWorld I January-February 2014*
- *Navigating the Regulatory Landscape for Healthcare Product Development: Key principles and best practices, MaRS Discovery District, October 2012*

Grading Scheme:

Written / Oral / Practical Exam 100 %

Additional information: