BIO-497

Concept to early-stage Drug and MedTech products

Deplancke Bart, Ghisays Fiorella, Maitra Gautam, Pojer Florence

Cursus	Sem.	Type
Life Sciences Engineering	MA1, MA3	Opt.

Language of teaching	English
Credits	4
Withdrawal	Unauthorized
Session	Winter
Semester	Fall
Exam	During the semester
Workload	120h
Weeks	14
Hours	**4 weekly**
Courses	2 weekly
Exercises	2 weekly
Number of positions	**25**

It is not allowed to withdraw from this subject after the registration deadline.

Summary

This course covers the steps in the development and commercialization of drugs, medical devices, food and nutritional products. The aim is to educate and motivate students to explore career paths in the Life Sciences industry and bridge the acute talent gap in Switzerland.

Content

The course is designed to introduce the basic concepts to early-stage Drug and MedTech products development, as well as to provide regulatory and clinical professionalism to students having little or no exposure to industry.
In addition, it will give the "real world" knowledge and skills to develop solutions to regulatory, clinical, quality and market access challenges. *This is done with live case studies, team work and exposure, and presentations by over 13 industry speakers*
Topics covered are:

- Concepts and Strategic approach to drug and medical device development
- Regulatory affairs and the role of regulatory professionals
- Quality management system
- Market access challenges
- Project management
- Intellectual property (IP)
- Introduction to food and nutrition products development

Keywords

Industry, Drug and device development, Pre-clinical and clinical trials, Regulatory approval, Market access, Manufactor, FDA/EMA

Learning Prerequisites

Required courses

Bachelor of Sciences

Learning Outcomes

By the end of the course, the student must be able to:

- Master the major steps of the drug and device development process
- Develop skills of early-stage Project Management
- Develop tools to interact with regulators
- Understand the basics of a Quality Management System
- Present a Product Profile for a drug, device or therapy
- Feel more confident about job seeking and job interviews
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Transversal skills

- Communicate effectively with professionals from other disciplines.
- Communicate effectively, being understood, including across different languages and cultures.
- Respect relevant legal guidelines and ethical codes for the profession.

Teaching methods

Lectures, external industry speakers, group study

Expected student activities

In person mandatory, group presentation

Assessment methods

During the semester

Resources

Websites

- https://ec.europa.eu/health/documents/eudralex_en
- https://www.ich.org/home.html
- https://www.fda.gov/forpatients/approvals/drugs/ucm405622.htm
- http://www.imdrf.org/
- http://Medical devices | European Medicines Agency (europa.eu)