Course syllabus for

Product Development in Life Sciences, 11 credits

Produktutveckling inom life science, 11 hp
This course syllabus is valid from spring 2022.
Please note that the course syllabus is available in the following versions:
Spring2021 , Spring2022 , Spring2023 , Spring2024 , Spring2025

Course code	4BP044
Course name	Product Development in Life Sciences
Credits	11 credits
Form of Education	Higher Education, study regulation 2007
Main field of study	Bioentrepreneurship
Level	AV - Second cycle
Grading scale	Pass with distinction, Pass, Fail
Department	Department of Learning, Informatics, Management and Ethics
Decided by	Utbildningsnämnden LIME
Decision date	2020-10-20
Revised by	Education committee LIME
Last revision	2021-10-20
Course syllabus valid from	Spring 2022

Specific entry requirements

A Bachelor's degree or a professional degree equivalent to a Swedish Bachelor's degree of at least 180 credits in health care, biomedicine, biology, cellular and molecular biology, pharmaceutics, chemistry, medicine, biotechnology, or the equivalent. And proficiency in English equivalent to English B/English 6.

At least the grade Pass for the courses "Theory in Bioentrepreneurship" and "Communication in Bioentrepreneurship 1" within the Master's programme in Bioentrepreneurship.

Objectives

This course aims to introduce the students to the product development process in the life science sector.

Upon completion of the course the student should be able to:

Regarding knowledge and understanding

- explain the basics of product development in the life science sector,
- relate product innovations to economic and technological aspects,

- account for the quality for systems and standards used in product development,
- account for different reimbursment systems' importance for pricing and the importance of acknowledging these aspects at early phases of product planning,

Regarding skills and ability

- analyse how the product development process differs between large and small molecular pharmaceuticals and medical devices,
- carry out advanced tasks within specified time limits,

Regarding judgement and approach

- evaluate product related risks and clearly describe and argue for the role of regulatory bodies in influencing product development,
- assess and compare different types of intellectual property and patent strategies as well as perform basic IP analyses,
- account for the ethical issues that might arise during the product development process.

Content

This course deals with the process of product development in the life science sector. Emphasis is put on the legal and regulatory frameworks of product development. This includes patents and other forms of protection of intellectual property rights and the national and international regulatory frameworks assuring product quality and patient safety.

Context of product development, 5.0 hp

Grading scale: VU

The component will among other things cover the following content:

- The product development process for both large and small molecular pharmaceuticals
- Cost-effectiveness requirements, evidence and reimbursement in relation to product development
- Regulatory requirements in relation to the product development process
- Ethical considerations in product development

Product Development Project, 6.0 hp

Grading scale: VU

This component will among other thinngs cover the following content:

- Introduction to product development
- The product development process in selected fields of medtech
- Intellectual Property Rights
- Regulatory process for medical devices
- Relationship to digital health & service design
- Medical devices business models

Teaching methods

The course will consist of lectures, seminars and workshops as well as case and project work. Literature seminars will also be included.

The course is given at the master's level, where the students are assumed to be familiar with the most common study methods in higher education. The fundamental pedagogical view is based on

entrepreneurial learning and requires an active student participation.

Compulsary participation
Participation at seminars, work shops and presentations is compulsory. The examiner assesses if and, in that case, how absence from compulsory parts can be compensated. Before the student has participated in all compulsory parts or compensated absence in accordance with the examiner's instructions, the student's results for respective part will not be registered. Absence from a compulsory activity may result in that the student cannot compensate the absence until the next time the course is given.

Examination

The examination of Component 1 (Context for product development) consists of

- a case essay (Fail/Pass),
- a written examination (Fail/Pass/Pass with distinction)

The examination of Component 2 (Product development project) consists of

- a project report from a group work (Fail/Pass),
- opposition on another groups project (Fail/Pass),
- an individual reflection (Fail/Pass/Pass with distinction),

To get the grade "Pass" on the entire course, the student needs to get the grade "Pass" on all examinations in both components. To get a "Pass with distinction" on the entire course, the student needs to get the grade "Pass with distinction" on the written exam in component 1 as well as on the individual reflection in component 2, and the grade "Pass" on all other examinations. Submission of written examinations after the deadline will result in the student missing the chance to get the grade "Pass with distinction".

Limited number of examinations
Students who have not passed the regular examination are entitled to participate in five more examinations. If the student has not passed the exam after four participations, the student is encouraged to visit the study advisor. If the student has failed six examinations/tests, no additional examination or new admission is provided.

The number of times that the student has participated in one and the same examination is regarded as an examination session.
Submission of blank exam is regarded as an examination session. An examination for which the student registered but not participated in, will not be counted as an examination.

If there are special grounds, or a need for adaptation for a student with a disability, the examiner may decide to deviate from the syllabus's regulations on the examination form, the number of examination opportunities, the possibility of supplementation or exemptions from the compulsory section/s of the course etc. Content and learning outcomes as well as the level of expected skills, knowledge and abilities may not be changed, removed or reduced.

Transitional provisions

Examination will be provided during a time of two years after a possible cancellation of the course. Examination can take place according to an earlier literature list during a time of one year after the date when a major renewal of the literature list has been made.

Other directives

Course evaluation is carried out according to the guidelines that are established by The Committee for Higher Education.

The course is given in English.

Literature and other teaching aids

Mandatory literature

Hill, Raymond; Rang, Humphrey Peter
Drug discovery and development : technology in transition

2nd ed. : Edinburgh : Elsevier, 2013. - xiv, 345 p.
ISBN:9780702042997 LIBRIS-ID:13912416
Library search

Yock, Paul G.
Biodesign : the process of innovating medical technologies

Second edition : Cambridge : Cambridge University Press, 2015. - xiii, 839 p.
ISBN:9781107087354 (hardback) LIBRIS-ID:18269103
Library search

Recommended literature