Course syllabus for

Development of products in the biomedical industry, 12 credits

Produktutveckling inom den biomedicinska industrin, 12 hp
This course has been cancelled, for further information see Transitional provisions in the last version of the syllabus.
Please note that the course syllabus is available in the following versions:
Spring2011 , Autumn2012 , Autumn2013 , Autumn2014 , Autumn2015 , Autumn2016 , Autumn2018 , Autumn2019

Course code	4BP019
Course name	Development of products in the biomedical industry
Credits	12 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	Programnämnd 7
Decision date	2010-10-26
Revised by	Education committee LIME
Last revision	2021-10-20
Course syllabus valid from	Autumn 2019

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 or biotechnology. English language skills equivalent to English B at Swedish upper secondary school.

Objectives

This course aims to introduce the students to the product development process in the life science sector, that is biotechnology, pharmaceuticals and medtech.

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.

The course will cover the following themes:

- Introduction to product development
- Intellectual Property Rights
- The product development process for both large and small molecular pharmaceuticals
- The product development process in selected fields of medtech
- Cost-effectiveness requirements, evidence and reimbursement in relation to product development
- Regulatory requirements in relation to the product development process

Teaching methods

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

Examination

The examination consists of

- a case essay (Fail/Pass),
- a project report from the group work (Fail/Pass),
- an individiual reflection (Fail/Pass/Pass with distinction),
- opposition on another groups project (Fail/Pass),
- a written examination (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.

To get a pass with distinction on the entire course, the student needs to get the grade pass with distinction on the written exam as well as on the individual reflection, 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.

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.

Compulsary participation
Participation at seminars, work shops and presentations is compulsory. The course director assesses if and, in that case, how absence can be compensated. Before the student has participated in all compulsory parts or compensated absence in accordance with the course director's instructions, the student's results for respective part will not be registered in LADOK.

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

Participation in an examination is defined as an occasion on which a student attends an examination, even if the student submits a blank examination paper. If a student has registered to sit an examination, but does not attend the examination, this is not defined as participation in the examination.

Transitional provisions

The course has been cancelled.

Other directives

The course language is 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