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	Programnämnd 7
Last revision	2012-03-30
Course syllabus valid from	Autumn 2012

Specific entry requirements

Bachelor´s degree or vocational degree worth at least 180 ECTS credits in biomedicine, biotechnology, cellular and molecular biology, medicine or equivalent. 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.

Upon completion of the course, the student will be able to:
- explain the basics of product development in the life science sector
- clearly describe and argue the role of regulatory bodies in influencing product development
- account for the quality control systems used in product development
- analyse and discuss cases, including arguing and defending the chosen solution

- assess and compare different types of intellectual property (IP) and patent strategies as well as perform basic IP analyses

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 (IPR) and the national and international regulatory frameworks assuring product quality and patient safety.

The course will be divided into two themes:

Product development, 6 hp - Introduction to product development
- IPR
- Case based learning **The product development process, 6 hp** - In biotechnology
- In pharmaceutical
- In medtech

Teaching methods

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

Examination

The examination is based on a written exam, a case essay, a project work and the opposition on another groups project,

Product development 6.0 hp
- Case essay (Pass/Fail)

The product development process 6.0 hp
- Project work including the opposition on another groups project (Pass with distinction/Pass/Fail)
- Written exam (Pass with distinction/Pass/Fail)

To get a “pass” on the entire course, the student need 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 project work as well as the written exam.

Attendance at seminars, work shops and presentations is mandatory. 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 numbers of examinations
Students who have not passed the regular examination are entitled to participate in a maximum of five more examinations. If the student has not passed the examination after four attempts, he/she is recommended to retake the course at the next regular course date, and may, after that, participate in two 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

After each course occasion there will be at least five opportunities to re-take the examination within a

2-year period from the end of the course.

Other directives

The course language is English.
A course evaluation will be conducted according to guidelines decided by the Board of Higher Education.

Literature and other teaching aids