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	Programme Committee 7
Last revision	2015-04-16
Course syllabus valid from	Autumn 2015

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:

- explain the basics of product development in the life science sector,

- relate product innovations to economic, technological and institutional aspects,
- analyse how the product development process differs between large and small molecular pharmaceuticals and medical devices,
- evaluate product related risks and clearly describe and argue the role of regulatory bodies in influencing product development,
- account for the quality control systems and standards used in product development,
- assess and compare different types of intellectual property (IP) and patent strategies as well as perform basic IP analyses,
- account for different reimbursment systems' importance for pricing and the importance of acknowledging these aspects at early phases of product planning,
- carry out advanced tasks within specified time limits.

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 cover the following themes:

- Introduction to product development
- Intellectual Property Rights
- The product development process in large molecular 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 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 in the form of a group work (Fail/Pass/Pass with distinction), an individiual reflection (Fail/Pass/Pass with distinction), opposition on another groups project (Fail/Pass), and 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 and pass with distinction on one out of the two following examinations: the project report or the individual reflection, and the grade pass on the other examinations.

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.

Transitional provisions

After each course occasion there will be at least six occasions for the examination within a two-year

period from the end of the course.

Other directives

The course language is English.

Course evaluation will be carried out in accordance with the guidelines established by the Board of Higher Education.

Oral evaluation in the form of course council meetings will be carried out during the course.

Literature and other teaching aids

Mandatory literature

Biodesign : the process of innovating medical technologies
Zenios, Stefanos A.; Makower, Josh; Yock, Paul G.

Cambridge : Cambridge University Press, 2010 - xxxv, 742 s.
ISBN:978-0-521-51742-3 (hbk.) LIBRIS-ID:11708767
Library search

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

To be provided by the courses leader:

Tillhandahålls av kursledaren:

Realizing Science-Based Medtech Innovation From Need to Successful Commercialization (Working Paper); Patrik Hidefjäll 2012.

Commercialization of Medical Device Innovation (Working Paper); Patrik Hidefjäll 2012.

Regulatoriska texter Medicintekniska direktivet etc i PDF.

Cases

Recommended literature

Ng, Rick
Drugs : from discovery to approval

2nd ed. : Hoboken, N.J. : John Wiley & Sons, c2009
ISBN:978-0-470-19510-9 (cloth) LIBRIS-ID:11283455
Library search

Charmasson, Henri.; Buchaca, John.
Patents, copyrights & trademarks for dummies

2. ed. : Hoboken, N.J. : Wiley, c2008. - xvi, 368 p.
ISBN:978-0-470-33945-9 (pbk.) LIBRIS-ID:12040742
Library search