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
Course syllabus valid from	Spring 2011

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

COURSE GOALS The course deals with the process of product development in the biomedical industry, i.e. pharma, biotech, medical technology and health care. Special emphasis is put on the legal and regulatory frameworks. This includes patents and other forms of protection of intellectual property rights (IPR) and the national and international regulatory frameworks for assuring product quality and patient safety. LEARNING OBJECTIVES After completing this course, the students will: - Describe and be able to reason about the unique features and requirements of product development for the health care sector - Understand and show insight into the product development processes and phases, including the long time scales - Understand and be able to analyse interactions in the product development value chain/web in the different life science sectors - Understand, discuss and be able to analyse the process of

patenting and other methods for protection of intellectual property rights - Analyse and discuss how patent strategies and patent portfolios are used as a strategic assets when building companies and their value - User acquired knowledge to analyse when to and when not to patent based on novelty, cost and competition - Clearly describe the role of regulatory bodies in influencing product development Clearly describe the interplay between development and quality control systems (e.g. ISO) - Express insight into how regulatory authorities and reimbursement systems influence the development process and the path to market - Independently perform a problem detection study (PDS) - Develop a description of a target product profile relevant for the pharmaceutical, biotechnology and medical device areas - Be able to apply "Health technology assessments (HTA)" in the medical device sector

Content

The course will contain the following themes Controlling and driving factors in product development a. The drivers behind product development in the health care sector b. Legal issues in product development The product development process a. Drug discovery and drug development b. Biotechnology tools, systems and strategies c. Medical technology

Teaching methods

The course consists of lectures and seminars as well as individual case exercises. These cases may be oral as well as written. Literature seminars where both textbook content and journal articles are discussed will be included.

Examination

The examination is based on a minor written exam, submitted assignments, performance at seminars and a final exam. The different parts wil be assessed according to the following: Written minor exam: pass/fail written assigments: fail/pass/pass with distinction (50% of final grade) case seminars: pass/fail Written final exam: fail(pass/pass with distinction (50% of final grade) 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. Limitation of number of occasions to write the exam: A student who does not pass the examination on the first occasion is offered a maximum of five additional opportunities to sit the examination. If a student has not passed the examination after a total of four attempts then it is recommended that the student retake the whole course at the next opportunity. Following this the student is permitted to sit the examination on another two occasions. A student who fails the examination on six occasions is not permitted to sit the examination again or to retake the course. 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 there will be at least 6 opportunities to sit the examination within a two-years period.

Other directives

The course language is English.

Literature and other teaching aids

Charmasson, Henri

Patents, Copyrights & Trademarks for Dummies with CDROM

Henri, Buchaca

0002 : John Wiley & Sons, 2008 - 368
ISBN:0470339454

Library search

Ng, Rick

Drugs from discovery to approval

0002 : John Wiley & Sons, 2008 - 472
ISBN:047019510X

Library search