



**Karolinska  
Institutet**

Course syllabus for

## **Product Development in Life Sciences, 11 credits**

Produktutveckling inom life science, 11 hp

This course syllabus is valid from spring 2025.

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	2024-09-30
Course syllabus valid from	Spring 2025

## **Specific entry requirements**

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 where 'product' refers to technologies included within pharmaceuticals/biotechnology, medical technology and digital health.

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

- demonstrate the basics of product development in the life science sector,
- relate product innovations to economic, ethical and technological aspects,
- account for the quality of systems and standards used in product development,
- analyse how the product development process differs between pharmaceuticals and medical devices,
- carry out advanced tasks within specified time limits,

- evaluate product-related risks and clearly describe and argue for the role of national as well as international regulatory bodies in influencing product development,
- assess and compare different types of intellectual property and patent strategies as well as perform basic intellectual property 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 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 pharmaceuticals and medical devices
- Technological tools and methods used in Life Science product development
- Cost-effectiveness and evidence requirements in relation to product development
- Regulatory requirements in relation to the product development process

### Product development project, 6.0 hp

Grading scale: GU

This component will among other things cover the following content:

- Demonstration of product development
- The Stanford Biodesign process
- The product development process in selected fields of the Life Science sector
- Intellectual Property Rights
- The regulatory process within the life science sector
- Business Model Canvas

## Teaching methods

The course will consist of lectures, workshops and project work.

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 active student participation.

## Examination

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

- a report (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 teamwork (Fail/Pass),

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, 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".

### **Compulsory participation**

The examiner assesses if and how absence from compulsory parts can be compensated. Before the student has participated in compulsory parts or compensated absence in accordance with the course examiner's the student's course results will not be reported. Absence from a compulsory part may result in the student having to wait to compensate until the next time the course is given.

### **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 a blank examination 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**

*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](#)

#### **Drug discovery and development : technology in transition**

*Hill, Raymond G.; Richards, Duncan B.*

Third edition : Amsterdam : Elsevier, [2022] - 373 pages

ISBN:9780702078040 LIBRIS-ID:r596b43kp01xgcw2

[Library search](#)