Faculty of Medicine

BIMM04, Biomedicine: Drug Development and Clinical Trials, 7.5 credits

Biomedicin: Läkemedelsutveckling och kliniska prövningar, 7,5 högskolepoäng

Second Cycle / Avancerad nivå

Details of approval

The syllabus was approved by The Master's Programmes Board on 2021-03-16 to be valid from 2021-03-24, autumn semester 2021.

General Information

The course is compulsory in the industrial research path in *the specialisation in industrial biomedical research* and is included in semester 3 of the Master's Programme in Biomedicine.

Language of instruction: English

Main field of studies	*Depth of study relative to the degree requirements*
Biomedicine	A1F, Second cycle, has second-cycle course/s as entry requirements

Learning outcomes

Knowledge and understanding

On completion of the course, the students shall be able to

- give an account of drug development from discovery to registration of a new drug and describe commonly occurring methods associated with drug development
- give an account of important breakpoints in the drug development process
- give an account of different types of patents that occur in drug development
- describe the laws and rules that control the development of a new drug in the pre-clinical and clinical phase
- describe the different phases of the clinical development

- give an account of different possibilities for funding drug development in the pre-clinical and clinical phase

Competence and skills

On completion of the course, the students shall be able to

- plan and summarise in writing a delimited project in drug development and present it orally
- participate in teamwork to provide theoretical and practical solutions for assignments related to drug development and clinical trials
- behave with a professional approach, respect others' opinions in discussions of drug development and clinical trials and meet set deadlines

Judgement and approach

On completion of the course, the students shall be able to

- reflect on ethical considerations during the drug development process
- reflect on different strategies to achieve scientific, market-related and regulatory goals during drug development

Course content

The course covers the general process for development of a new drug from pre-clinical discovery via pre-clinical development and clinical trials. The course will address scientific, strategic and regulatory challenges from discovery to approval of a new drug and also includes key methods and terminology. It also covers the importance of the professional groups that are involved in the different phases of the development of a new drug This course will prepare the students for subsequent degree projects and future work in the pharmaceutical industry as well as work in academia regarding innovations, early drug development and entrepreneurship.

Course design

The working methods in the course mostly involve active learning, requiring the students to prepare before each teaching component. The students are expected to behave professionally and, just as in a future work situation, participate constructively in the working group to enable the group to achieve progress together. In the course, a group assignment is carried out in which the students write a project plan for the development of a new drug from pre-clinical discovery to registration. The group assignment is compiled in writing and presented orally for an expert panel and the other students. Written and oral feedback is given on each others' group assignments.

Assessment

Assessment consists of two different components:

1. Course portfolio 5 credits (Fail/Pass/Pass with Distinction)
2. Multiple-choice questions 2.5 credits (Fail/Pass)

The course portfolio includes group assignment, written group assignment in which individual contributions are to be clearly evident, oral presentation of the assignment and critical review and feedback on other group assignments. Multiple-choice questions test learning outcomes for knowledge and understanding.

If there are special reasons, other forms of assessment may apply.

The examiner, in consultation with Disability Support Services, may deviate from the regular form of examination in order to provide a permanently disabled student with a form of examination equivalent to that of a student without a disability.

Subcourses that are part of this course can be found in an appendix at the end of this document.

Grades

Marking scale: Fail, Pass, Pass with distinction.
To achieve the grade of Pass as a final grade, the grade of Pass is required on all components. To achieve the grade of Pass with Distinction as a final grade, the grade of Pass with Distinction is required on the course portfolio.

Entry requirements

Passed examinations and course components in semester 1 of the Master's Programme (30 credits) and at least 15 credits from semester 2 and completion of BIMM03 (Innovation and Entrepreneurship).

Further information

The course is preparatory for BIMM80 (Research Project in the Life Science Industry, 45 credits).

Subcourses in BIMM04, Biomedicine: Drug Development and Clinical Trials

Applies from H21

2101 Course portfolio, 5,0 hp
Grading scale: Fail, Pass, Pass with distinction
2102 Multiple-choice questions, 2,5 hp
Grading scale: Fail, Pass