Project Course: Biomedical Product Development

Projektkurs: Produktutveckling inom biomedicin
6.0 credits

Programme course

8BKG16

Valid from: 2020 Spring semester

Determined by	**Main field of study**	
Chairman of The Board for First and Second Cycle Programmes	Medical Biology	
Date determined	**Course level**	**Progressive specialisation**
2017-08-22	First cycle	G1X
Revised by	**Disciplinary domain**	
	Medicine	
Revision date	**Subject group**	
2018-08-24; 2021-05-03	Medical Biology	
Offered first time	**Offered for the last time**	
Autumn semester 2018		
Department	**Replaced by**	
Medicinska fakulteten		

Course offered for

- Bachelor´s Programme in Experimental and Industrial Biomedicine

Entry requirements

General entry requirements for undergraduate studies
and
English corresponding to the level of English in Swedish upper secondary education (English 6)
And
Chemistry, Mathematics and Biology corresponding to the level in Swedish upper secondary education (Chemistry 2, Mathematic 4 and Biology 2)
Exemption from Swedish 3

Intended learning outcomes

Knowledge and understanding
On completion of the course, the student shall be able to:

- Describe the principles and methods for developing a method of medical diagnostic testing
- Describe the foundations of the validation of biomedical methods
- Describe the principles of the production and quality monitoring of a method of medical diagnostic testing
- Describe regulatory issues in medical research and development
- Describe the demands placed on a method of diagnostic testing from a commercial perspective

Skills and abilities
On completion of the course, the student shall be able to:

- Develop and validate a method of medical diagnostic testing on commercial grounds
- Document and assess relevant biomedical laboratory data for subsequent quality control
- Use the project format to identify knowledge requirements, formulate a project plan, assign work and present the results in the form of a project report
- Present an informative and accurate description of a method of medical diagnostic testing orally and in writing to recipients who are not necessarily specialists in the techniques that are being applied
- Identify customer benefits and needs in the development of biomedical products
- Work in projects applying a project management method based on the three guiding parameters of quality, time and cost

Judgement ability and approach
On completion of the course, the student shall be able to:

- Acquire, critically appraise and evaluate knowledge within the field of medical product development from an academic, social and ethical perspective.
- Critically process a commercially viable diagnostic test from a social perspective and with economic awareness

Course content

The course is an introduction to project management methodology in which the student learns to develop a method of medical diagnostic testing for healthcare, the "life science" industry or research. This includes basic knowledge of medical validation, regulatory issues within good laboratory practice (GLP), good manufacturing practice (GMP) and CE marking, as well as quality management in regard to documentation. The aim is to understand the requirements placed on the development of a medical diagnostic tests for research and healthcare. The course also aims to teach the student how to work in projects in accordance with the guiding parameters of time, economics and quality.
The course also encompasses the fields medical validation, evidence-based healthcare, GLP, biomedical improvement studies, clinical biochemistry and laboratory medicine, which are integrated with project management methodology.

Teaching and working methods

At the Faculty of Medicine and Health Sciences student centred and problem based learning make up the foundation of the teaching. The student takes responsibility for, studies and researches current content of the courses and study programme. The methods of the course work challenge the students to independently formulate questions for learning, to seek knowledge and in dialogue with others judge and evaluate achieved knowledge. Students in the Bachelor's programme in Experimental and Industrial Biomedicine work together in groups based on reality based and course related biomedical issues to apply their knowledges, develop their own learning, contribute to the fellow students' learning and to practice cooperation. Throughout the study programme theory is integrated with practical modules. The course methods and integration modules stimulates and support the student's ability to apply their knowledge and professional competence.
The work methods in this course are lectures, seminars, laboratory sessions and work in project groups.

Examination

The forms of examination are a written project report and an oral presentation that is carried out as part of a group but assessed individually. In addition, active participation in compulsory course elements is required in order to pass the course. Compulsory course elements include project work, laboratory sessions, seminars, reports and written assignments.

The written project report and the oral presentation are resource-demanding forms of examination and are limited to five attempts.

If special circumstances prevail, and if it is possible with consideration of the nature of the compulsory component, the examiner may decide to replace the compulsory component with another equivalent component.

Application for examination

Instructions on how to apply for examinations are given prior to the beginning of each course.

Re-examination

The date for re-examination should normally be announced by the date of the regular examination at latest; in which case the scope must be the same as at the regular examination.

Examination for students with disabilities

If the LiU coordinator for students with disabilities has granted a student the right to an adapted examination for a written examination in an examination hall, the student has the right to it.

If the coordinator has recommended for the student an adapted examination or alternative form of examination, the examiner may grant this if the examiner assesses that it is possible, based on consideration of the course objectives.

An examiner may also decide that an adapted examination or alternative form of examination if the examiner assessed that special circumstances prevail, and the examiner assesses that it is possible while maintaining the objectives of the course.

Nomination of another examiner

A student who has taken two examinations in a course or a part of a course without obtaining a pass grade is entitled to the nomination of another examiner, unless there are special reasons to the contrary.

Grades

Two grade scale, older version, U, G

Course literature

A literature reference list must be set no later than two months before the course begins by the programme committee for the Bachelor's Programme in Experimental and Industrial Biomedicine. There is no compulsory course literature.

Other information

Planning and implementation of the course is to be based on the wordings in the course syllabus. A course evaluation is compulsory for each course and should include how the course is in agreement with the course syllabus. The course coordinator will analyse the course evaluation and propose appropriate development of the course. The analysis and proposal will be returned to the students, the Director of Studies, and as needed to the Education Board, if related to general development and improvement.

The course is conducted in such a way that there are equal opportunities with regard to sex, transgender identity or expression, ethnicity, religion or other belief, disability, sexual orientation and age.

If the course is cancelled or undergoes major changes, examination is normally offered under this course syllabus, at a total of three occasions, within/in connection to the two following semesters, of which one in close proximity to the first examination.

If special circumstances prevail, the vice-chancellor may in a special decision specify the preconditions for temporary deviations from this course syllabus, and delegate the right to take such decisions.