



FBB3650 Animal Cell Technology 7.5 credits

Animalcellsteknologi

This is a translation of the Swedish, legally binding, course syllabus.

Establishment

Course syllabus for FBB3650 valid from Spring 2018

Grading scale

G

Education cycle

Third cycle

Specific prerequisites

The KTH course
BB1120 Cultivation technology **or**
BB2080 Bioprocess Technology **or** equivalent.

Language of instruction

The language of instruction is specified in the course offering information in the course catalogue.

Intended learning outcomes

The students will learn how to design a cultivation process to produce a biopharmaceutical drug protein. In particular, after the course, they will be able to

- design a cultivation process flow sheet of operations
- select an appropriate cell line
- choose an expression system
- design a cultivation process fit for industrial purpose, i.e. integrating scale-up constraints, Good Manufacturing Practice (GMP), manufacturing operation
- select the level of safety required for the patients and design a process accordingly
- be able to design a strategy to develop a cultivation process

Course contents

- Introduction to processes for the manufacturing of biopharmaceuticals.
- Introduction to animal cell based cultivation process and relations/interactions between cultivation and other steps of the biopharmaceutical process.
- Usage of stable expression systems and description of the existing systems, e.g. cell lines.
- Review of cell metabolism relevant for the animal cell cultivation and application to process design. Scale-up aspects.
- Issues of commercial production, e.g. requirements of patient safety and compliance to regulatory constraints.
- Integration of the different course materials into development and design of a cultivation process.
- Cells as product
- Basic techniques for mammalian cell culture in shake flask, and small-scale fed-batch bioreactor operations

Disposition

- 12 lectures (2 x 45 min) accompanied by peer review and discussion of home assignments of other students
 - 12 home assignments (e.g. literature searching and reading). Efforts with home assignments will be about 5 hours/week.
 - Practical training of sterile techniques to culture mammalian cells in shake flask (5 days) and performance of a fed-batch bioreactor culture as demonstrator in groups (5 days)
- Lectures are given during daytime at KTH. Total weekly attendance is 4 x 45 min. Total course duration is 8 weeks. The course includes a final report.

Course literature

- Handout material
- Butler M ed. (2007) "Cell Culture and Upstream Processing" Taylor and Francis ISBN 0-415-39969-6
- Ozturk S and Hu W-S (2006) "Cell Culture Technology for Pharmaceutical and Cell-based Therapies" Taylor and Francis ISBN 0-8247-5334-8

Examination

Based on recommendation from KTH's coordinator for disabilities, the examiner will decide how to adapt an examination for students with documented disability.

The examiner may apply another examination format when re-examining individual students.

If the course is discontinued, students may request to be examined during the following two academic years.

Other requirements for final grade

- (1) > 50 % attendance at lectures, **and**
- (2) Score > 60 % of max points at written examination, **and**
- (3) > 80 % of home assignments approved

Ethical approach

- All members of a group are responsible for the group's work.
- In any assessment, every student shall honestly disclose any help received and sources used.
- In an oral assessment, every student shall be able to present and answer questions about the entire assignment and solution.