# Design of Biotechnical Process and Production Systems, Project Course

Programme course

6 credits

Projektkurs i design av biotekniska process- och produktionssystem

TFTB32

Valid from: 2020 Spring semester

**Determined by**
Board of Studies for Chemistry, Biology and Biotechnology

**Date determined**
2019-09-23

**Offered for the last time**
Spring semester 2023

**Replaced by**
TFTB52

## Main field of study
Engineering Biology

## Course level
Second cycle

## Advancement level
A1X

## Course offered for
- Chemical Biology, M Sc in Engineering
- Engineering Biology, M Sc in Engineering

## Entry requirements
Note: Admission requirements for non-programme students usually also include admission requirements for the programme and threshold requirements for progression within the programme, or corresponding.

## Prerequisites
Industrial biotechnology course is a prerequisite. It is also a prerequisite to attend the following courses that are given in parallel with the course; Biotechnical Production Systems; Biotechnical Manufacturing; Drug Discovery and Pharmaceutical Development; Quality Management.

# Intended learning outcomes

Obtain engineering skills to analyze and perform design of industrial biotech tools, process and production systems, as well as assess and evaluate production and process economy conditions. After the course, the student must be able to:

- Demonstrate the ability to work result-oriented in a project group with production and process technical tasks, that are consistent with requirements and working methods in an advanced biotechnical industry.
- Present an overall development plan for a design assignment, based on an intention document (order) from a company. Document overall target specifications, conditions, design alternatives and boundaries for the assignment.
- Obtain and evaluate information that is relevant for the design and operation of an industrial biotechnological process and production system. Based on this information, perform calculations for operations of the process, prioritize between alternatives, verify relevance and credibility in claims, and criticize the information.
- Use Biomechatronic methods to assess the conditions for an industrial biotechnological production system, and draw conclusions regarding its functional design.
- Provide realistic technical solutions for the production system for a biotechnological product, including the biotechnological process steps to meet regulatory requirements and quality management systems.
- Analyze the economic and operational conditions of the biotechnological production system.

# Course content

Project work
• Phase 1: The introductory part is led by the examiner.
• Phase 2: Key activities, project / resource planning and project contracts are carried out within the project group. Active project work and training in project management.
• Supervision of the project work takes place through a sequence of project meetings and workshops leading the project work from start to finish.

The client company
• Mapping and analyzing the customer company needs, as they are expressed in the order, and its organization (reported at a seminar)

Overall development plan for design work (UPG1)
• The project's goal description
o Specify the product and quantify the production of the end product
o Requirements imposed on the product "for its intended use"
o Requirements imposed on the production process
o The customer's expressed wishes in the order
• System solution (initial analysis):
o Alternative cultivation processes
o Functional analysis of the downstream process unit operations

o Process integration: Analysis of technical functions that take place in sequence
o Critical parameters: PAT (CPP, CCP, CQA) and QbD
o Regulatory conditions
o Quality assurance and risks
• The design options in summary
o Presentation of two alternative solutions to be compared through an iterative design work
• Overall development plan for the design work (includes analysis: CPM / PERT diagram)

Design of operational solution (PRA2)
• Summary and recommendations
• Ordered assignment
• The product and its manufacture
o Complete production schedule for the production of the ordered product according to the assignment, verified with calculations (operations are scheduled and resourced "hour by hour").
o Clarification of uncertainties in the described process (e.g. need for pilot scale verification).
• Economy and resources
o Estimates of investment and operating costs for all operations within the framework of the assignment.
o The sensitivity analysis specifies when individual costs may deviate significantly from the calculated ones.
• Quality Management
o The need for quality assurance and control. Needs are reported at an operational level, e.g. which process analytical efforts are needed at the control level and how they contribute to establishing quality (PAT / TQM / QbD), and at system level, i.e. how the work on quality development should be organized to ensure that the process's performance and that the product meets regulatory requirements (e.g. QA / QC and GMP).
The final report comprises about 17 pages; excluding notes, references and appendices. See the guideline for detailed instructions.

Quality Assurance
Analyze the contents of your own draft final report, as well as another project group's draft, with the aim of training the ability to assess and communicate about how the work progresses before the compilation of the final reports. Ensure that an industrial quality perspective enters the final phase of the work.

# Teaching and working methods

The students receive "orders" that concern real development work that a company must carry out in its actual development phase. The orders are based on real companies and the work that takes place in that company (at the present).

In project groups of five to seven people, they will develop a proposal for the design of a production process of a biotechnological product. The work begins with familiarizing yourself with the company's needs and organization. The needs

are made concrete in an overall development plan for a design assignment. The design work is primarily carried out during period 2.

In the project, the students will use knowledge acquired in the courses: Industrial Biotechnology (TFYA32), Biotechnical Production Systems (TMMT03), Biotechnology Manufacturing (TFTB39), Drug Discovery and Pharmaceutical Development (NKED20) and Quality Management (TMQU46).

The project group's work is based on development work taking place at an R&D department at a major biotechnology company, or a consulting company that is commissioned to deliver a technical solution to an external or internal customer. It is organized around the CDIO project model. C represents the work of developing the concept for the design assignment and is presented with an overall development plan for a design assignment (UPG1). The design work contains analyzes and calculations (modeling / simulation) for verification of the production process's functions. The basic methodology is based on Biomechatronic methods (see reference literature). Implementation means that all operations to be performed within the framework of the production process are studied in detail. Prerequisites for the operation are mapped and documented in the final report. It refers, for example, to selection of appliances, possibilities for automation and determining the need for human resources, production economy and productivity, and scheduling of process operations. The work is done within the framework of the demands made on the biotechnological manufacture of the products. That is; within the framework of the regulations and quality systems that apply to industrial manufacturing and requirements set for the products in its intended use. The final report describes process design for Operations and is reported in the final report (PRA1).

Note that the courses TMMT03 Biotechnical Production Systems and TFTB39 Biotechnology Manufacturing should be read in parallel with TFTB32, i.e. during the same term.

A very close collaboration takes place with the courses Industrial Biotechnology (TFYA32) and Biotechnical Manufacturing (TFTB39). Teachings on manufacturing and cultivation processes are covered theoretically and exemplified in the laboratory.

Corresponding work is supervised and practiced in the CDIO course with input from relevant literature for the process being studied (within the framework of commissioned assignments). Most of the calculation work (modeling / simulation for process verification) around the upstream process is included in the course TFTB39, while definition of objectives, process design and the result of the work are examined in the final report for TTFB32.

# Examination

| | | | |
|---|---|---|---|
| PRA2 | Project | 4 credits | U, G |
| UPG1 | Production concept | 2 credits | U, G |

Grades are given as ’Fail’ or ’Pass.

# Grades

Two grade scale, older version, U, G

# Course literature

UPG1 Report: Overall development plan for design work, 2p
PRA2 Report: Design of operational solution, 4p

# Other information

Course language is Swedish and the bulk of the literature is in English.

### About teaching and examination language

The teaching language is presented in the Overview tab for each course. The examination language relates to the teaching language as follows:

- If teaching language is Swedish, the course as a whole or in large parts, is taught in Swedish. Please note that although teaching language is Swedish, parts of the course could be given in English. Examination language is Swedish.
- If teaching language is Swedish/English, the course as a whole will be taught in English if students without prior knowledge of the Swedish language participate. Examination language is Swedish or English (depending on teaching language).
- If teaching language is English, the course as a whole is taught in English. Examination language is English.

### Other

The course is conducted in a manner where both men's and women's experience and knowledge are made visible and developed.

The planning and implementation of a course should correspond to the course syllabus. The course evaluation should therefore be conducted with the course syllabus as a starting point.

# Department

Institutionen för fysik, kemi och biologi

# Director of Studies or equivalent

Magnus Boman

# Examiner

Carl-Fredrik Mandenius

# Education components

Preliminary scheduled hours: 44 h
Recommended self-study hours: 116 h

# Course literature

### Compendia

Gunnar Hörnsten, Guideline TFTB32 Design av biotekniska process- och produktionssystem

### Other

In English:
Literature from the following courses: Industrial Biotechnology (TFYA32), Biotechnical Production Systems (TMMT03), Biotechnology Manufacturing (TFTB39), Drug Discovery and Pharmaceutical Development (NKED20) and Quality Management (TMQU46).

Literature acquired through Searches in databases is essential in the development of the projects.
Reference literature; Biomechatronic Design in Biotechnology. Carl-Fredrik Mandenius and Mats Björkman. Wiley 2011.
Basic Biotechnology. Colin Ratledge and Björn Kristiansen. 3d edition. Cambridge University Press 2006.
Bioseparations Science and Engineering. Second Edition. Roger G. Harrison, Paul W. Todd, Scott R. Rudge, and Demetri P. Petrides. Oxford University Press 2015.
Quality by design for biopharmaceuticals: principles and case studies. Edited by Anurag S. Rathore and Rohin Mhatre. Wiley 2009.

# Common rules

## Course syllabus

A syllabus must be established for each course. The syllabus specifies the aim and contents of the course, and the prior knowledge that a student must have in order to be able to benefit from the course.

## Timetabling

Courses are timetabled after a decision has been made for this course concerning its assignment to a timetable module.

## Interrupting a course

The vice-chancellor's decision concerning regulations for registration, deregistration and reporting results (Dnr LiU-2015-01241) states that interruptions in study are to be recorded in Ladok. Thus, all students who do not participate in a course for which they have registered must record the interruption, such that the registration on the course can be removed. Deregistration from a course is carried out using a web-based form: https://www.lith.liu.se/for-studenter/kurskomplettering?l=en.

## Cancelled courses

Courses with few participants (fewer than 10) may be cancelled or organised in a manner that differs from that stated in the course syllabus. The Dean is to deliberate and decide whether a course is to be cancelled or changed from the course syllabus.

## Guidelines relating to examinations and examiners

For details, see Guidelines for education and examination for first-cycle and second-cycle education at Linköping University, http://styrdokument.liu.se/Regelsamling/VisaBeslut/917592.

An examiner must be employed as a teacher at LiU according to the LiU Regulations for Appointments (https://styrdokument.liu.se/Regelsamling/VisaBeslut/622784). For courses in second-cycle, the following teachers can be appointed as examiner: Professor (including Adjunct and Visiting Professor), Associate Professor (including Adjunct), Senior Lecturer (including Adjunct and Visiting Senior Lecturer), Research Fellow, or Postdoc. For courses in first-cycle, Assistant Lecturer (including Adjunct and Visiting Assistant Lecturer) can also be appointed as examiner in addition to those listed for second-cycle courses. In exceptional cases, a Part-time Lecturer can also be appointed as an examiner at both first- and second cycle, see Delegation of authority for the Board of Faculty of Science and Engineering.

## Forms of examination

### Examination

Written and oral examinations are held at least three times a year: once immediately after the end of the course, once in August, and once (usually) in one of the re-examination periods. Examinations held at other times are to follow a decision of the board of studies.

Principles for examination scheduling for courses that follow the study periods:

- courses given in VT1 are examined for the first time in March, with re-examination in June and August
- courses given in VT2 are examined for the first time in May, with re-examination in August and October
- courses given in HT1 are examined for the first time in October, with re-examination in January and August
- courses given in HT2 are examined for the first time in January, with re-examination in March and in August.

The examination schedule is based on the structure of timetable modules, but there may be deviations from this, mainly in the case of courses that are studied and examined for several programmes and in lower grades (i.e. 1 and 2).

Examinations for courses that the board of studies has decided are to be held in alternate years are held three times during the school year in which the course is given according to the principles stated above.

Examinations for courses that are cancelled or rescheduled such that they are not given in one or several years are held three times during the year that immediately follows the course, with examination scheduling that corresponds to the scheduling that was in force before the course was cancelled or rescheduled.

When a course is given for the last time, the regular examination and two re-examinations will be offered. Thereafter, examinations are phased out by offering three examinations during the following academic year at the same times as the examinations in any substitute course. If there is no substitute course, three examinations will be offered during re-examination periods during the following academic year. Other examination times are decided by the board of studies. In all cases above, the examination is also offered one more time during the academic year after the following, unless the board of studies decides otherwise.

If a course is given during several periods of the year (for programmes, or on different occasions for different programmes) the board or boards of studies determine together the scheduling and frequency of re-examination occasions.

### Registration for examination

In order to take an examination, a student must register in advance at the Student Portal during the registration period, which opens 30 days before the date of the examination and closes 10 days before it. Candidates are informed of the location of the examination by email, four days in advance. Students who have not

registered for an examination run the risk of being refused admittance to the examination, if space is not available.

Symbols used in the examination registration system:

** denotes that the examination is being given for the penultimate time.

* denotes that the examination is being given for the last time.

### Code of conduct for students during examinations

Details are given in a decision in the university's rule book: http://styrdokument.liu.se/Regelsamling/VisaBeslut/622682.

### Retakes for higher grade

Students at the Institute of Technology at LiU have the right to retake written examinations and computer-based examinations in an attempt to achieve a higher grade. This is valid for all examination components with code "TEN" and "DAT". The same right may not be exercised for other examination components, unless otherwise specified in the course syllabus.

A retake is not possible on courses that are included in an issued degree diploma.

### Retakes of other forms of examination

Regulations concerning retakes of other forms of examination than written examinations and computer-based examinations are given in the LiU guidelines for examinations and examiners, http://styrdokument.liu.se/Regelsamling/VisaBeslut/917592.

### Plagiarism

For examinations that involve the writing of reports, in cases in which it can be assumed that the student has had access to other sources (such as during project work, writing essays, etc.), the material submitted must be prepared in accordance with principles for acceptable practice when referring to sources (references or quotations for which the source is specified) when the text, images, ideas, data, etc. of other people are used. It is also to be made clear whether the author has reused his or her own text, images, ideas, data, etc. from previous examinations, such as degree projects, project reports, etc. (this is sometimes known as "self-plagiarism").

A failure to specify such sources may be regarded as attempted deception during examination.

### Attempts to cheat

In the event of a suspected attempt by a student to cheat during an examination, or when study performance is to be assessed as specified in Chapter 10 of the Higher Education Ordinance, the examiner is to report this to the disciplinary board of the university. Possible consequences for the student are suspension from study and a formal warning. More information is available at https://www.student.liu.se/studenttjanster/lagar-regler-rattigheter?l=en.

### Grades

The grades that are preferably to be used are Fail (U), Pass (3), Pass not without distinction (4) and Pass with distinction (5).

1. Grades U, 3, 4, 5 are to be awarded for courses that have written examinations.
2. Grades Fail (U) and Pass (G) may be awarded for courses with a large degree of practical components such as laboratory work, project work and group work.
3. Grades Fail (U) and Pass (G) are to be used for degree projects and other independent work.

### Examination components

1. Grades U, 3, 4, 5 are to be awarded for written examinations (TEN).
2. Examination components for which the grades Fail (U) and Pass (G) may be awarded are laboratory work (LAB), project work (PRA), preparatory written examination (KTR), oral examination (MUN), computer-based examination (DAT), home assignment (HEM), and assignment (UPG).
3. Students receive grades either Fail (U) or Pass (G) for other examination components in which the examination criteria are satisfied principally through active attendance such as other examination (ANN), tutorial group (BAS) or examination item (MOM).
4. Grades Fail (U) and Pass (G) are to be used for the examination components Opposition (OPPO) and Attendance at thesis presentation (AUSK) (i.e. part of the degree project).

For mandatory components, the following applies: 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. (In accordance with the LiU Guidelines for education and examination for first-cycle and second-cycle education at Linköping University, http://styrdokument.liu.se/Regelsamling/VisaBeslut/917592).

For written examinations, the following applies: 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 instead 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. (In accordance with the LiU Guidelines for education and examination for first-cycle and second-cycle education at Linköping University, http://styrdokument.liu.se/Regelsamling/VisaBeslut/917592).

The examination results for a student are reported at the relevant department.

## Regulations (apply to LiU in its entirety)

The university is a government agency whose operations are regulated by

legislation and ordinances, which include the Higher Education Act and the Higher Education Ordinance. In addition to legislation and ordinances, operations are subject to several policy documents. The Linköping University rule book collects currently valid decisions of a regulatory nature taken by the university board, the vice-chancellor and faculty/department boards.

LiU's rule book for education at first-cycle and second-cycle levels is available at http://styrdokument.liu.se/Regelsamling/Innehall/Utbildning_pa_grund-_och_avancerad_niva.