## [Kurskod]

BB2450

## [Kursens benämning på svenska]

Cellfabriken

## [Kursens benämning på engelska]

The Cell Factory

## [Kursens omfattning i högskolepoäng]

*7,5 hp*

## Betygsskala

A-F

## Utbildningsnivå

Avancerad nivå

## Lärandemål

On completion of the course (ILOs), the students should be able to:

- Describe and differentiate microorganisms and eukaryotic cellular systems, including mammalian cells, and their biochemical pathways.
- Discuss with reference to scientific literature the challenges and potential opportunities in using genetically engineered cell factories for the production of biopharmaceuticals/biomolecules/chemicals/fuels at an industry scale.
- Design a cell factory approach to the production of a given product, with reference to supporting scientific literature.
- Design a cultivation process using mammalian cell system for the production of biologics fit for industrial purpose, i.e. robust and reproducible process using appropriate mammalian cell line and expression system, integrating scale-up constraints, Good Manufacturing Practice (GMP), and awareness of patient safety, as well as describe and discuss how such a process is developed
- Design, evaluate, execute and present in written form an independent laboratory project report.

## Kursens huvudsakliga innehåll

- Prokaryotic and eukaryotic cell structure, including plant and mammalian cells, and cellular compartment functions, including sub-cellular localization of specific metabolic pathways
- Specific prokaryotic and eukaryotic pathways for the production of complex biomolecules, including cellulose, alginate, chitins, glycoproteins and fatty acids, etc..
- Describe prokaryotic and eukaryotic cell factories, including special features of eukaryotic hosts, such as codon usage, post-translational modifications, protein folding, protein processing, of disulfide bond formation
- Metabolic engineering of fungi and plant systems, including transformation system (e.g. plastid targeting, *Agrobacterium*)- emphasis on carbohydrate polymers, plasticizer, lipid-derivatives, and punctually on biofuel production
- Exploitation on other cell factory systems, such as algal system, and their metabolic pathways for the bioproduction.
- Describe new technologies in synthetic biology, and how this has impact in bioproduction
- Cost-benefit analysis (including environmental and social economical impact) for the sustainable production in the pathways specific/certain types of organisms which the products have potential applications
- Process of mammalian cell-based system (e.g. Chinese Hamster Ovary cells, HEK293) for the manufacturing of biologics Development of mammalian cell-based processes, fed-batch and perfusion, aimed at commercial production for the production of biopharmaceuticals including scale-up aspects, requirements of patient safety and compliance to regulatory constraints
- Demonstration of fed-batch bioreactor process using Chinese Hamster Ovary cell for the production of monoclonal antibody

## Behörighet

BB1100 Biochemistry laboratory or equivalent

## Examination

- *KON1- Intermediate Exam One, 1.0 hp, grade scale, P/F*
- *KON2 - Intermediate Exam Two, 1.0 hp, grade scale, P/F*
- *Lab Assignment - 1.0 hp, grade scale, P/F*
- *TEN1- Written Examination, 4.5 hp, grade scale: A-F*

Two intermediate exams (*KON1* and *KON2*) cover the course content from Module 1-3. Each exam consists of 8-10 questions based on theoretical knowledge and concepts within the course. To pass students need to possess basic knowledge and concepts within the course.

*Lab Assignment*, to pass student must be able to hand in the assignment on time and to demonstrate reasonable theoretical and practical knowledge in written form. Peer review is required.

Final exam of BB2450 (*TEN1*) consists of two parts. *TEN1* Part I consists of 5-7 basic questions, and *TEN1* Part II consists of 8-12 more advanced questions. The questions from Part I cover the basic knowledge and concepts within the course. Part II questions are based more on the details of knowledge and applications, and students need to be able to demonstrate the understanding and interconnection the complex metabolic pathways, the methods to manipulate them for the bio-production, and the scaling up bioprocessing steps. The latter half of Part II includes particularly advanced questions. Advance knowledge within the content of the course is required for higher grades.

***Assessment of Intended Learning Outcomes (ILOs)-***

The table below summarizes the assessment tasks associated with each ILOs.

| **Intended Learning Outcomes** | **KON1** | **KON2** | **Lab** | **TEN1 Part I** | **TEN1 Part II** |
|---|---|---|---|---|---|
| Describe and differentiate microorganisms and eukaryotic cellular systems, including mammalian cells, and their biochemical pathways | X | X | | X | |
| Discuss with reference to scientific literature the challenges and potential opportunities in using genetically engineered cell factories for the production of biopharmaceuticals/biomolecules/ chemicals/fuels at an industry scale | X | X | | X | |
| Exploit the fundamental knowledge from the course, and be able to re-design and critically evaluate appropriate systems and their integrated metabolic pathways for the production of biopharmaceuticals/biomolecules/chemicals/fuels at an industry scale | | | | | X |
| Design a cultivation process using mammalian cell system for the production of biologics fit for industrial purpose, i.e. robust and reproducible process using appropriate mammalian cell line and expression system, integrating scale-up constraints, Good Manufacturing Practice (GMP), and awareness of patient safety, as well as describe and discuss how such a process is developed | | | | | X |
| Design, evaluate, execute and present in written form an independent laboratory project report | | | X | | |

***Assessment level for each Intended Learning Outcomes***

| Intended Learning Outcomes | E | D | C | B | A |
|---|---|---|---|---|---|
| Describe and differentiate microorganisms and eukaryotic cellular systems, including mammalian cells, and their biochemical pathways. | X | | X | | X |
| Discuss with reference to scientific literature the challenges and potential opportunities in using genetically engineered cell factories for the production of biopharmaceuticals/biomolecules/chemicals/fuels at an industry scale | X | | X | | X |
| Design a cell factory approach to the production of a given product, with reference to supporting scientific literature | X | | X | X | X |
| Design a cultivation process using mammalian cell system for the production of biologics fit for industrial purpose, i.e. robust and reproducible process using appropriate mammalian cell line and expression system, integrating scale-up constraints, Good Manufacturing Practice (GMP), and awareness of patient safety, as well as describe and discuss how such a process is developed | X | | X | X | X |
| Design, evaluate, execute and present in written form an independent laboratory project report | X | | | | |

***Grading criteria for each ILOs related to KON1 and 2 (Pass/fail), Lab assignment# (Pass/fail), and TEN1 (levels E)***

| Intended Learning Outcomes | (KON1 & 2 and lab assignment#) Fail | (KON1 & 2 and lab assignment#) Pass | E (TEN1) |
|---|---|---|---|
| Describe and differentiate microorganisms and eukaryotic cellular systems, including mammalian cells, and their biochemical pathways. | Lack of basic knowledge and concepts within the course | Possess basic knowledge and concepts within the course | Possess basic knowledge and be able to differentiate cellular organization and metabolic systems between prokaryotic and eukaryotic cell factories. |
| Discuss with reference to scientific literature the challenges and potential opportunities in using genetically engineered cell factories for the production of biopharmaceuticals/biomolecules/chemicals/fuels at an industry scale | Lack of basic knowledge and concepts within the course | Possess basic knowledge and concepts within the course | Possess ability to discuss and briefly describe possibilities, limitations and advantages in relation with complexity of emerged genetically engineered cell factory systems used today |
| Design a cell factory approach to the production of a given product, with reference to supporting scientific literature | | | Demonstrate ability to discuss, re-design and critically evaluate appropriate systems and their integrated metabolic pathways for the bioproduction |
| Design a cultivation process using mammalian cell system for the production of biologics fit for industrial purpose, i.e. robust and reproducible process using | | | Show ability to design a cultivation process using mammalian cell system for the production of biologics |

| | | | |
|---|---|---|---|
| appropriate mammalian cell line and expression system, integrating scale-up constraints, Good Manufacturing Practice (GMP), and awareness of patient safety, as well as describe and discuss how such a process is developed | | | fit for industrial purpose, i.e. robust and reproducible process using appropriate mammalian cell line and expression system, integrating scale-up constraints, Good Manufacturing Practice (GMP), and awareness of patient safety, as well as show ability to discuss how such a process is developed |
| Design, evaluate, execute and present in written form an independent laboratory project report# | Absent from lab.<br><br>Without reasonable theoretical practical knowledge.<br><br>Without critical peer-review evaluation. | Active participation.<br><br>With reasonable theoretical and good practical knowledge.<br><br>With critical peer-review evaluation. | |

*ILO that can only be assessed at level E, not higher

## Litteratur

*Om uppgift inte kan anges vid fastställande av kursplan ska följande mening anges:*
Uppgift om kurslitteratur meddelas i kurs-PM.

*Observera att meningen i Kopps ska anges i fältet "Kurslitteratur (översätts)" och att fältet "Kurslitteratur (översätts ej) ska lämnas tomt.*

Biochemistry (Voet and Voet, last edicition)

Microbial Physiology (Moat et al., 4th edition)

Gene IX (Lewin)

Ozturk S and Hu W-S (2006) "Cell Culture Technology for Pharmaceutical and Cell-based Therapies" Taylor and Francis ISBN 0-8247-5334-8