

ChE-436

Pharmaceutical biotechnology

Pick Horst

| Cursus | Sem. | Type |
|---------------------|----------|------|
| Biotechnology minor | H | Opt. |
| Ing.-chim. | MA1, MA3 | Opt. |

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|----------------------------|-----------------|
| Language of teaching | English |
| Credits | 3 |
| Session | Winter |
| Semester | Fall |
| Exam | Written |
| Workload | 90h |
| Weeks | 14 |
| Hours | 3 weekly |
| Courses | 2 weekly |
| Exercises | 1 weekly |
| Number of positions | |

Summary

The course focuses on the development and application of biotechnology-based approaches to human diseases. It provides current information on the engineering and pharmaceutical production of highly specific therapeutic proteins, vaccines, and other important biologicals at an industrial scale.

Content

- Origin and spread of viral and bacterial infectious diseases
- Antibiotics, antibiotic resistances, sources for new antibiotics
- Vaccines: development and production (e.g. mRNA vaccines, vector-based vaccines, live-attenuated vaccines, inactivated vaccines, cancer vaccines)
- Recombinant therapeutic proteins (e.g. monoclonal antibodies, anti-cancer therapeutics, insulin, etc. as blockbuster therapeutics)
- Gene therapy
- Cell therapies
- Precision medicine
- Basics of cell culture, development of media, cell lines for industrial production of therapeutics
- Genetic cell engineering for the production of therapeutics: Transposons, gene amplification
- Chinese hamster ovary cells (CHO): The most prominent system for the production of therapeutic proteins
- Transgenic plants, transgenic animals for the production of therapeutics
- Bioreactors: Large-scale production of therapeutic proteins
- Patent law: How to protect intellectual property in pharmaceutical biotechnology
- Regulatory issues (e.g. preclinical studies, clinical studies, drug approval)

Keywords

Infectious diseases, diseases of modern civilization, vaccines, antibiotics, monoclonal antibodies, immunology, therapeutic proteins, protein engineering, bacterial and mammalian cell culture, cell line engineering, immortalized cells, large-scale production, bioreactor, downstream processes, biosimilars, regulatory issues, patent law

Learning Prerequisites**Required courses**

No course requirement

Recommended courses

No course recommendation

Learning Outcomes

By the end of the course, the student must be able to:

- Define approaches in pharmaceutical biotechnology to fight human diseases
- Describe the basics of bacterial and mammalian cell culture
- Define strategies for the industrial production of therapeutic proteins
- Compare suitable cell systems for the production of a desired therapeutic protein
- Describe strategies for engineering cells for the production of recombinant proteins
- Specify essential steps to obtain market approval for a therapeutic protein
- Specify possible issues in copying complicated pharmaceutical proteins
- Discuss fields of intellectual property protection and steps to filing a patent in pharmaceutical biotechnology
- Realize that the biology of an organism determines the way how it can be used for production processes

Transversal skills

- Set objectives and design an action plan to reach those objectives.
- Use a work methodology appropriate to the task.
- Demonstrate the capacity for critical thinking

Teaching methods

Lectures, exercises

Expected student activities

Attendance at lectures, completing written exercises

Assessment methods

Written exam (3 hours)

Resources**Moodle Link**

- <https://go.epfl.ch/ChE-436>

Prerequisite for

The course is recommended to provide the theoretical background for the practical course "Biotechnology lab" where students learn to produce, purify, and characterize therapeutic proteins out of bacterial or mammalian cell culture.