

Course size (nominal values; actual values may depend on programme)

Credits 4.0      Study time 108 h      Contact hrs 48.0 h

Course offerings and teaching methods in academic year 2019-2020

A (semester 2)	English	lecture	25.0 h
		seminar: coached	9.0 h
		exercises	

Lecturers in academic year 2019-2020

Callewaert, Nico	WE10	lecturer-in-charge
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Offered in the following programmes in 2019-2020

<a href="#">Bachelor of Science in Molecular Biotechnology</a>	crdts	offering
	4	A

Teaching languages

English

Keywords

Biopharmaceuticals, vaccines, nucleic acid therapy, cell-based therapy, molecular diagnostics.

Position of the course

In this advanced biotechnology course, the student will learn how the molecular life science technologies are used to produce recombinant pharmaceutical proteins, nucleic acids (and cells) to be used in therapy or prophylaxis of disease.

Contents

1. Drug/diagnostics development basics
  - The regulatory environment (FDA, EMEA)
  - Clinical trials
  - The economics of the biopharmaceutical sector.
2. Biopharmaceutical protein development.
  - Properties of the current main expression host cells (E. coli, Pichia pastoris, insect cells, CHO and HEK293 cells); technologies for protein overexpression in these cells.
  - Upstream and downstream processing.
  - Bio-analytics to support biopharmaceutical development (biophysical analysis, post-translational modification analysis)
3. Overview of main classes of biopharmaceutical proteins
  - Vaccines o Monoclonal antibodies and scaffolds
  - Cytokines and protein hormones
  - Enzymes
4. Nucleic acid synthesis and therapy
  - Nucleic acids synthesis and
  - Gene therapy (ex vivo, in vivo): risks and opportunities (evolution of viral delivery vectors etc.)
  - RNA interference-based therapy
5. Example of cell-based therapy
  - CAR T-cells
6. Protein engineering methods
  - Protein engineering through recombinatorial and non-recombinatorial methods.
  - Library generation and screening/selection

Initial competences

Thorough knowledge of gene technology, genetics, molecular biology and analytical biochemistry are required for this course.

## Final competences

- 1 Insight in the technologies behind the biopharmaceutical sector.
- 2 Solving case problems in biopharmaceutical development by proposing the most adequate technological solutions.
- 3 A good working understanding of the regulatory environment in this sector and grasps the timelines and economics involved in biopharmaceutical/molecular diagnostics product development.
- 4 Awareness of current trends in the biopharmaceutical/molecular diagnostics product development and capability of further monitoring these trends.

## Conditions for credit contract

Access to this course unit via a credit contract is determined after successful competences assessment

## Conditions for exam contract

This course unit cannot be taken via an exam contract

## Teaching methods

Lecture, self-reliant study activities, seminar: coached exercises

## Learning materials and price

*Syllabus, 10 EUR*

## References

Syllabus

## Course content-related study coaching

*Advice on how to study for this course will be available during the workshops and upon appointment with the lecturers during the course.*

## Evaluation methods

end-of-term evaluation and continuous assessment

## Examination methods in case of periodic evaluation during the first examination period

Written examination with open questions, written examination with multiple choice questions, open book examination

## Examination methods in case of periodic evaluation during the second examination period

Written examination with open questions, written examination with multiple choice questions, open book examination

## Examination methods in case of permanent evaluation

Assignment

## Possibilities of retake in case of permanent evaluation

examination during the second examination period is not possible

## Extra information on the examination methods

*Open book exam ONLY for the module on protein engineering.*

## Calculation of the examination mark

17/20 points based on the exam, 3/20 points based on evaluation of assignment