Course Specifications
From the academic year 2017-2018 up to and including the

Course

Biotechnology (J000466)

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

<table>
<thead>
<tr>
<th>Credits</th>
<th>Study time</th>
<th>Contact hrs</th>
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<tr>
<td>3.0</td>
<td>90 h</td>
<td>20.0 h</td>
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Course offerings and teaching methods in academic year 2018-2019

A (semester 1) Dutch

lecture 15.0 h

group work 5.0 h

Lecturers in academic year 2018-2019

Deforce, Dieter

FW01 lecturer-in-charge

Offered in the following programmes in 2018-2019

Master of Science in Industrial Pharmacy

3 A

Teaching languages

Dutch

Keywords

Biotechnology, pharmacy, biotechnological drugs, industrial aspects, glycosylation, immunogenicity, pharmacokinetics, formulation, biosimilar

Position of the course

The goal of this course is to provide an in depth discussion of biotechnological drugs and techniques tailored towards the needs of the industrial pharmacist, so that the industrial pharmacist will be able to apply the biotechnological sciences on an industrial scale in a pharmaceutical context.

Contents

Part 1: A. Gils (KU Leuven):
The most important differences between biological and chemical drugs are highlighted. Pharmacokinetics (PK) of biologicals will be discussed as well as variables influencing the PK including, immunogenicity. Analytical techniques to monitor PK and immunogenicity are explained. Formulation of biologicals is discussed.

Part 2: D. Deforce (UGent):
The European and International regulatory requirements in relation to bio(techno)logical drugs are discussed by means of a couple of guidelines. The contents of (or parts of) some guidelines are discussed in the light of the expected data provided for these aspects (celbanking system, quality control, biosafety, ...). Protein glycosylation is discussed in detail going from differences in ghost cells, to effects on safety/PK/PD. Analytical aspects of glycoproteins are also discussed in detail.
The entire workflow of a bio(techno)logical drug is discussed (upstream/downstream/formulation). Special attention is payed to some critical steps and some validation aspects are looked into in more detail.

Part 3: A. Gils & D. Deforce
The students also have to prepare a presentation on one specific subject from a registration dossier and present that to the entire group.

Initial competences

Final competences of Master of Pharmaceutical Care or Master of Drug Development or having acquired the corresponding competences in another way.

Final competences

1 To understand the process of industrial scale production of biotechnological drugs.
2 To implement and supervise the quality control of biotechnological drugs.
3 To implement the techniques for the analysis of biotechnological drugs.
4 To know the advantages and disadvantages of different expression systems and
fermentation systems.
5 To know the advantages and disadvantages of different isolation and purification methods
6 To know the formulation of biologicals

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
Group work, lecture

Extra information on the teaching methods
Lectures and Teamwork.

Learning materials and price
The students have written course material combined with selected chapters from books and manuscripts. Some of the slides are available on the internet.
Price for course materials : 7.5 Euro

References

Course content-related study coaching
The professors are also available to help the students on topics related to but outside the scope of the course and in particular to prepare the teamwork presentation.

Evaluation methods
end-of-term evaluation and continuous assessment

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

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

Examination methods in case of permanent evaluation
Oral examination, participation, assignment

Possibilities of retake in case of permanent evaluation
examination during the second examination period is possible

Calculation of the examination mark
The student succeeds when he/she obtains a 10/20 score under the condition that a minimum score of 8/20 is reached for each subpart.
If the student has less than 8/20 on a subpart, the final result is deduced to this result.
If the student has a minimum of 8/20 for each subpart, the final score is calculated based on weight.
(a) part 1: Gils: weight 1;
(b) part 2 : Deforce: weight 1;
(c) part 3: Gils and Deforce: weight 1.
Final score: \([a+b+c]/3\)