1. OVERVIEW

Subject Area	Pharmaceutical Biotechnology
Degree	Bachelor's Degree in Biotechnology
School/Faculty	School of Biomedical and Health Sciences
Year	4
ECTS	6
Type	Compulsory
Language(s)	Spanish
Delivery Mode	On campus
Semester	S2
Academic Year	24-25
Coordinating professor	María Teresa Coiras López

2. INTRODUCTION

Pharmaceutical Biotechnology is a subject area worth 6 ECTS and is taught over three months in the fourth quarter of the Degree in Pharmacy and Biotechnology. This course aims to provide knowledge of the different types of biological and biotechnological medicines, how they are produced and quality control. We also discuss different ethical and regulatory aspects, together with its use in treatment. This course provides students with knowledge on the methods used in the field of pharmaceutical biotechnology. They will also learn how to critically judge therapeutic, technological, legal and ethical aspects of biotechnology.

3. LEARNING OUTCOMES (RA, by the acronym in Spanish)

KNOWLEDGE (CON, by the acronym in Spanish)

CON07. Describe the biotechnological production procedures of biological drugs, food and plants, together with their applications.

· Understand the basis for the biotechnological production of drugs and the use of biological drugs. (Biosimilars)

· Know the authorisation and registration procedures for biotechnological drugs.

ABILITIES (HAB, by the acronym in Spanish)

HAB04. Design experimental procedures and protocols choosing the most suitable technique in the field of biotechnological research, all the while meeting quality and legislative standards.

· Apply knowledge of pharmacogenetics/pharmacogenomics to the production of new biotechnological drugs.

· Apply the legal regulations on clinical trials with biotechnological drugs and new biological therapies.

· Apply analytical techniques for determining cell markers.

SKILLS
COMP13. Identify, describe and analyse the basis for the production of biotechnological drugs and their main uses.

4. CONTENTS

· Basis of pharmaceutical biotechnology.
· Bioindicators. Establishing therapeutic targets.
· Biotechnological production of drugs. Analysing raw materials of biological origin. Controls in process.
· Gene therapy. Gene transfer vectors. Target illnesses.
· Cell therapy. Cell therapy with embryonic stem cells and adult stem cells. Regenerative medicine. Tissue engineering.
· Genetic polymorphisms and phenotype: contribution to the response to different drugs.
· Pharmacogenetics. Individual differences in the pharmacokinetics of medicines.
· Research with biological products. Biosimilar drugs.

1. Introduction to Pharmaceutical Biotechnology:
- Biological/Biotechnological drugs
- Financial considerations
- Regulation of biosimilar drugs

2. Recombinant proteins
- Design of recombinant DNA, biophysical and biochemical analysis
- Production and purification, formulation of biotechnological products
- PD/PK of therapeutic proteins
- Immunogenicity of therapeutic proteins

3. Monoclonal antibodies with therapeutic use
- Characteristics
- Therapy based on mAb: cancer, solid organ transplants

4. Biotechnological drugs:
- Hormones: insulin, FSH, growth hormone, haematopoietic factors
- Blood products, recombinant coagulation factors, thrombotic agents
- Enzymes: DNase I
- Interferons and interleukins
- Vaccinations

5. Advanced therapies:
- Gene therapy
- Cell therapy
- Tissue engineering

6. Clinical research:
- Design of new drugs
- Clinical trials
- Biomarkers
- Personalised medicine

5. TEACHING/LEARNING METHODS

The types of teaching/learning methods are as follows:

- Lecture

- Case studies
- Collaborative learning

6. LEARNING ACTIVITIES

The types of learning activities, plus the amount of time spent on each activity, are as follows:

On campus:

Learning activity	Number of hours
Asynchronous lectures	26
Asynchronous master lectures	4
Practical classes	22
Written reports and essays	6
Tutorials	16
Independent working	50
Case Studies	26
TOTAL	**150**

7. ASSESSMENT

The assessment methods, together with how much they each count towards the final grade for the subject area, are as follows:

On campus:

Assessment system	Weighting
On-campus knowledge tests	60
Reports and written work	15
Case study/problem scenario	25

On the Virtual Campus, when you open the subject area, you can see all the details of your assessment activities and the deadlines and assessment procedures for each activity.

7.1. Ordinary exam period

To pass the subject area in the ordinary exam period you must obtain a mark of 5.0 or more out of 10.0 in all assessed parts of the subject. Any part you do not pass in the ordinary exam period will need to be recovered in the extraordinary exam period (resits).

Your final grade will be the average of the partial marks in each of the learning activities you have passed. The continuous assessment system for the learning activities requires attendance to at least 50% of the classes.

It is compulsory for students studying degrees on-campus to accredit attendance to at least 50% of classes. This requirement qualifies students for the right to obtain academic counselling, support and monitoring from the professor. Failure to accredit attendance to at least 50% of the classes by any of the means proposed by the University will mean that the professor awarding a fail to the student for that subject area in the ordinary exam period in accordance with the grading system outlined in these regulations. All of the above, without prejudice to the other requirements or higher attendance percentages that other faculties may stipulate in their learning guides or internal regulations. Regulations for the assessment of official degree programmes, Art. 1 point 4.

(*https://universidadeuropea.com/documents/1798/6.__Reglamento_evaluacion_titulaciones_oficiales_grado_UEM_v2.pdf*)

7.2. Extraordinary exam period (resits)

To pass the subject area in the extraordinary exam period (resits), the students must obtain a mark equal to or above 5.0 out of 10.0 in all parts of the subject assessment they did not pass during the ordinary exam period.

The student must submit the activities not passed in the ordinary exam period taking into account the corrections or comments made by the teacher. The student must also submit any activities which were not submitted.

The final grade will be the average of the partial marks in each of the activities passed (with a mark equal to or higher than 5 out of 10). The marks for the assessable activities the student passed in the ordinary exam period will be maintained for calculating this grade.

8. TIMELINE

The timeline with delivery dates of assessable activities in the subject area is indicated in this section:

Assessable activities	Date
Activity 1. Online questionnaire 1	Week 4
Activity 2. Online questionnaire 2	Week 7

Activity 3. PO1	Week 11
Activity 4. Online questionnaire 3	Week 15
Activity 5: Group Spoken presentations	Week 4-18
Activity 6. Objective test 2	Ordinary exam period

The timeline may be subject to modifications for logistical reasons of the activities. Students will be informed of any changes in due time and course.

9. BIBLIOGRAPHY

Books for consultation:

- Pharmaceutical Biotechnology. Drug Discovery and Clinical Applications. O. Kayser, H Warzecha (Eds). Wiley-Blackwell 2013 (e-book)
- Pharmaceutical biotechnology: concepts and applications. Gary Walsh 2007 (e-book)
- Pharmaceutical biotechnology. Fundamentals and application. Crommelin, Daan J.A, Sindelar, Robert D, Meibohm, Bernd. 4th ed. 2013 (e-book).

Websites of interest:

- www.aemps.gob.es
- www.ema.europa.eu
- www.edqm.eu
- http://ec.europa.eu/index_es.htm
- www.fda.gov/BiologicsBloodVaccines/default.htm
- www.clinicaltrials.gov
- www.clinicaltrialsregister.eu

10. EDUCATIONAL GUIDANCE AND DIVERSITY UNIT

The Educational Guidance and Diversity Unit (ODI in Spanish) offers support throughout your time at university to help you with your academic achievement. Other cornerstones of our educational policy are the inclusion of students with special educational needs, universal access in all our university campuses and equal opportunities.

This ODI unit offers students:

1. Support and monitoring through counselling and personalised student plans for those who need to improve their academic performance.

2. Curricular adaptations to uphold diversity, with assistance for those students who require specific educational support, leading to equal opportunities without significant changes to methodology or evaluation.
3. We offer students a range of extracurricular educational resources to reinforce skills which will enhance their personal and professional development.
4. Career guidance by offering tools and advice to students with doubts regarding their professional careers or those who believe they have chosen the wrong line of study.

Students who need educational support can contact us at:
orientacioneducativa@universidadeuropea.es

11. SATISFACTION SURVEYS

Your opinion matters!

Universidad Europea encourages you to complete our satisfaction surveys to identify strengths and areas for improvement for staff, degree courses and the learning process.

These surveys will be available in the surveys area of your virtual campus or by email.

Your opinion is essential to improve the quality of the degree.

Many thanks for taking part.