



PHARMACEUTICAL BIOTECHNOLOGY GUIDE 2019-2020

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1. Descriptive Details

Name of Subject: Pharmaceutical biotechnology	
Code: 9976001409, MBAF001411, 9970001805	
Degree program: Pharmacy and Biotechnology	
Year in which is taught 4 ^o	
Nº of ECTS credits: 6	Nº of classroom hours: 75h Study mode: face-to-face
Regulatory prerequisites: N/A	Recommended prerequisites: Microbiology, Virology, Biology, Genetics
Name of Teacher: María Teresa Coiras	
Academic advising/guidance timetable: 1h/ per week	

2. Contextualization of Content and Subject Competences.

Pharmaceutical Biotechnology is a 6 ECTS subject that is taught on a quarterly basis in the second quarter on the fourth course of the Pharmacy degree and Biotechnology degree.

This course aims to provide knowledge on methods for the production and quality control of biological and biotechnological drugs. Furthermore, in this course ethical and regulation aspects and their therapeutic application are discussed.

This course allows the student to have a base on the methodology used in the area of pharmaceutical biotechnology, as well as to be able to make critical judgments both on legal and ethical aspects of biotechnology.

3. Specific Competences.

On completing this subject, the student will be able to:

1. Familiarity with the basic concepts in biotechnology and use them correctly
2. Familiarity with the biotechnological products of interest and their sources.
3. Familiarity with the bases for the production of biopharmaceuticals.
4. Knowledge about the therapeutic application of cell therapy and tissue engineering.
5. Knowledge about vectors design and the experimental strategies of gene therapy



4. General Competences

The following competences will be developed and assessed in this subject:

1. Communication oral / written communication

Skill that allows the person to transmit and receive data, ideas, opinions and attitudes, with oral which is done through words and gestures, and written by writing and / or graphics support.

2. Self-study

Skill that allows the person to be the author of their own development, choosing paths, strategies, tools and to learn and practice

5. Content.

1. Introduction to pharmaceutical biotechnology.

Biological / biotechnological drugs (vaccines, hemoderivatives, hormones, monoclonal antibodies).

2. Biosimilar drugs

Basic concepts. Production and control. Clinical research. Current situation. Regulation in the European Union (EU).

3. Production and control of biological / biotechnological drugs

Regulation of aspects of quality. Production systems. Purification. Characterization. Consistency of production. Stability. Microbiological / viral/prions/safety. Guidelines.

4. Development of different groups of biological medicines

Recombinant proteins, Immunological therapies. Blood products.

5. Applications of Pharmaceutical Biotechnology: Advanced Therapies

Basic concepts. Types (gene therapy, cell therapy, tissue engineering). Production and control. Clinical research. Current situation.

6. Clinical research

Development of new drugs (therapeutic targets). Clinical trials.

7. Biomarkers

Concepts. Clinical application



8. Pharmacogenetics / pharmacogenomics

Concepts. Clinical application

9. Regulation of biological and biotechnological medicines in the European Union (EU)

European Commission. European Medicines Agency, EMA (structure, operation, activities). Regulations. Directives. Guidelines. Initiatives to support the development of new medicines

6. Training Activities.

An active teaching methodology will be used in the classroom in order to promote contents integration and develop the competences and skills of the subject. There will be individual or group activities.

1. Lectures: encouraging discussion and student participation.
2. Problems and case studies, individually or in small groups
3. Activities to develop skills. Public presentation prepared by students on topics of interest, discussion of papers on topics of interest in the subject.
4. Tutorials, assessment and self-study

7. Teaching methodology.

The teaching methodology involves a mixed system where more traditional strategies such as lectures and classroom activities are combined, along with teaching based on real cases and the use of online tools through the blackboard platform. Of course, all activities will be supported by a bibliography and updated web resources, available to students.

8. Evaluation procedures.

It is done through **continuous assessment of the various training activities**. It is considered that each of the training activities has been pass by the student when the grade of this part is **equal or greater than 5.0**

Ordinary assessment

1. Midterm exams, 60% of the final grade.

- First midterm exam (first part of the subject) (40%).



- Second midterm exam:

- Students who have a grade equal to or higher than 5 in the 1st midterm exam: The second midterm exam will consist of 90% of contents of the second part of the subject and 10% of some topics of the first part (60%).

- Students who have a grade less than 5 in the first part: The second midterm exam will consist of two parts (The student should have at least a 5 in each part to pass):

- Part 1: first part of the subject (40%)
- Part 2: 90% of contents of the second part of the subject and 10% of some topics of the first part (60%)

2. Activities, problems and case studies, 40% of the final grade:

All mandatory activities will be passed with a grade equal to or higher than 5.

100%	EXAMS: <ul style="list-style-type: none">• First midterm exam (40%)• Second midterm exam (60%)	60%
	WORKSHOP CASES AND PROBLEMS	15%
	GROUP ORAL PRESENTATION + minitest	25%

Extraordinary assessment:

Those students whose final grade is less than 5 in the exams or in any mandatory activity will be considered to have failed the educational objectives of the course and will have to attend the extraordinary call and retake the midterm tests and or active learning activities graded below 5.

The extraordinary call shall be equivalent to the ordinary (contents and assessment). Students must retake only the activities that are graded below 5.

If the student does not pass all the different parts in the extraordinary call, the student will receive a failing grade, and will have to repeat all the activities the next academic year.

9. Materials and other considerations

Materials: Digital whiteboard, documents for collaborative activities and case studies.

Bibliography:

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)



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Pharmaceutical biotechnology. Fundamentals and application. Crommelin, Daan J.A, Sindelar, Robert D, Meibohm, Bernd. 4th ed. 2013 (e-book).

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