PHARMACEUTICAL BIOTECHNOLOGY GUIDE
2016-2017

1. Descriptive Details

Name of Subject: Pharmaceutical biotechnology	
Code: 9976001409, MBAF001411, 9970001805	
Degree program: Pharmacy and Biotechnology	
Year in which is taught 4º	
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: Olga Greciano	
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. **Regulation of biological and biotechnological medicines in the European Union (EU)**

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

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. **Clinical research with biotech drugs and advanced therapies**

   Development of new drugs (therapeutic targets). Clinical trials. Clinical research in Spain.

5. **Biomarkers**

   Concepts. Clinical application

6. **Genomics and proteomics.** Pharmacogenetics / pharmacogenomics

   Concepts. Clinical application

7. **Biosimilar drugs**

   Regulation in the European Union (EU). Current situation.

8. **Advanced Therapies**

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

9. **Development of different groups of biological 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. Procedimientos de Evaluación.

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**

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:**

100%	**EXAMS**	**60%**
	WORKSHOP CASES AND PROBLEMS	30%
	GROUP ORAL PRESENTATION	10%

Extraordinary assessment:

Those students whose final grade is less than 5, 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)

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

Webs:

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. Coursework Outline.

Introduction to pharmaceutical biotechnology.

Competences	Content	Specific objectives	Materials
Communication oral / written communication Self-study	Biological/ biotechnological drugs (vaccines, hemoderivatives, hormones, monoclonal antibodies).	Knowledge of pharmaceutical products of biological origin and their most important characteristics from the pharmaceutical point of view.	Digital whiteboard. PowerPoints.

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

Competences	Content	Specific objectives	Materials
Communication oral / written communication Self-study	European Comission. European Medicines Agency, EMA (structure, operation, activities). Regulations. Directives. Guidelines. Initiatives to support the development of new medicines	Knowledge of the marketing authorization products of biological medicines in the European Union.	Digital whiteboard. PowerPoints.

Production and control of biological / biotechnological drugs

Competences	Content	Specific objectives	Materials
Communication oral / written communication Self-study	Regulation of aspects of quality. Production systems. Purification. Characterization. Consistency of production. Stability. Microbiological / viral/prions/safety. Guidelines.	Knowledge of production and quality controls required for biological products	Digital whiteboard. PowerPoints.

Clinical research with biotech drugs and advanced therapies

Competences	Content	Specific objectives	Materials
Communication oral / written communication Self-study	Development of new drugs (therapeutic targets). Clinical trials. Clinical research in Spain.	Knowledge about the regulation of clinical trials with biological drugs.	Digital whiteboard. PowerPoints.

Biomarkers

Competences	Content	Specific objectives	Materials
Communication oral / written communication Self-study	Concepts. Clinical application	Basic knowledge about biomarkers and their possible clinical application	Digital whiteboard. PowerPoints.

Genomics and proteomics. Pharmacogenetics / pharmacogenomics

Competencias a desarrollar	Content	Specific objectives	Materials
Communication oral / written communication Self-study	Concepts. Clinical application	Basic knowledge on pharmacogenetics and pharmacogenomics Personalized medicine	Digital whiteboard. PowerPoints.

Biosimilar drugs

Competences	Content	Specific objectives	Materials
Communication oral / written communication Self-study	Regulation in the European Union (EU). Current situation.	Knowledge about the regulation of biosimilar drugs to ensure their quality, safety and efficacy	Digital whiteboard. PowerPoints.

Advance therapies

Competences	Content	Specific objectives	Materials
Communication oral / written communication Self-study	Types (gene therapy, cell therapy, tissue engineering). Basic concepts. Production and control. Clinical research. Current situation.	Basic knowledge of the different types of advanced therapies and the current situation with regard to advanced therapies in the EU.	Digital whiteboard. PowerPoints.

Development of different groups of biological medicines.

Competences	Content	Specific objectives	Materials
Communication oral / written communication Self-study	Biologic/biotech drugs	Knowledge of the most important biological medicines	Digital whiteboard. PowerPoints.

11. Resources.

Rubrics

GROUP ORAL PRESENTATIONS

Oral presentation	2	Well prepared presentation. Student voice is clear. Student do not consult notes.
Content/information quality	2	The student demonstrates full knowledge of the subjet. The information is clear, accurate, consistent. The student uses appropriate scientific language.
PowerPoint presentation	2	PowerPoint presentation well organized. The student uses clear charts and figures
Group coordination	2	Group members presented their information or ideas in a clear and logical manner. Team work
Time management	2	Student meet deadline. The presentation conforms to time
TOTAL	**10**	