Innovation in the pharmaceutical Industry: advanced medicines and biotechnology

Academic Year: (2023 / 2024) **Review date: 10-07-2020**

Department assigned to the subject: Bioengineering Department

Coordinating teacher: VELASCO BAYON, DIEGO

Type: Compulsory ECTS Credits : 5.0

Year : 1 Semester : 1

REQUIREMENTS (SUBJECTS THAT ARE ASSUMED TO BE KNOWN)

Bachelor courses closely related to Biochemistry and/or Cellular and Molecular Biology.

OBJECTIVES

BASIC COMPETENCES
CB6. Acquire knowledge and understanding to provide the basis to develop and/or apply original ideas, often in a research context.
CB7. Apply the acquired knowledge and the ability to solve problems in new contexts within broader (or multidisciplinary) contexts related to their field of study.
CB8. To be able to integrate the acquired knowledge and handle complexity of formulate judgments based on incomplete or limited information, including reflections on social and ethical responsibilities linked to the application of their knowledge and judgments.
CB9. To be able to communicate their conclusions and thoughts to a specialized and non-specialized audience in a clear and unambiguous manner.
CB10. Learn skills that will enable the students to continue their studies.

GENERAL COMPETENCES
CG1. Achieve a multidisciplinary scientific view, with a clear translational orientation and applied in the field of biomedical science and technology.
CG3. Ability to lead and manage groups and research teams, and also to promote teamwork, knowledge management and competitive intelligence.
CG4. Ability to analyze, synthesize and apply knowledge to propose original solutions to biomedical problems.
CG5. Develop abilities to identify and understand the social needs and to provide scientific and technological solutions in the biomedical field.
CG6. Identify the keys of technology transfer in the Spanish and in the EU market and understand the basis for the management and building of a biomedical based company.

SPECIFIC COMPETENCES
CE7. Learn the methodology and the basis of evidence-based clinical research.
CE8. Analyse the drug development process, from the discovery phase to the clinical research phases prior to registration.
CE9. Learn the requirements of the regulatory agencies for the different phases of biomedical research, from preclinical to clinical.

LEARNING RESULTS
Learn the process of evidence-based clinical research and the differential characteristics of Advanced Therapies.

DESCRIPTION OF CONTENTS: PROGRAMME

a. Innovation in the pharmaceutical Industry: drug development analysis, from the discovery phase to the clinical research phases prior registration
- Drug discovery
- Preclinical research required by the regulatory agents: Absorption, Distribution, Metabolism and Excretion (ADME). Toxicology (acute and subacute)
- Evidence-based clinical research: Phase I, II, III and IV

b. Innovation in biotechnology

c. Cell therapy

- Production of advanced therapy medicinal products (ATMPs)
- Preclinical research
- Clinical research

d. Gene therapy
- Production of advanced therapy medicinal products (ATMPs)
- Preclinical research
- Clinical reserach

LEARNING ACTIVITIES AND METHODOLOGY

LEARNING ACTIVITIES
- Theoretical classes
- Practical classes
- Theoretical-practical classes
- Tutorships
- Group work
- Student´s individual work

TEACHING METHODOLOGIES
- Teacher explanations supported with audiovisual media and information technology, in which the main concepts of the subject are developed and the reference literature is provided to supplement student learning.
- Critical reading of international references recommended by the professor: journal papers, reports and manuals for further discussion in class, to enhance and consolidate the knowledge acquired.
- Solving practical cases, presented by the professor to the students either individually or in groups. Debates
- Presentation and discussion in class, under the moderation of the professor, of subjects related to the course.
- Reports and projects (working individually or in groups).

ASSESSMENT SYSTEM

Attendance to 80% of sessions is mandatory to be evaluated.

GRADING:
Total score: 10 points
Continuous evaluation: 6 points out of 10
Final exam: 4 points out of 10

CONTINUOUS EVALUATION: It accounts for up to 60% of the final score of the subject (6 points of the TOTAL SCORE), and includes two components:
1) One test: 4 points of THE TOTAL SCORE. This test will take place mostly during lectures and will be announced at least one week in advance. If a student passes the continuous evaluation test (minimum score: 5 over 10), topics included in the corresponding test will not be included in the final exam.
2) Project preparation: 2 points of THE TOTAL SCORE.

FINAL EXAM: it will account for the 40 % of the final score (4 points of the TOTAL SCORE). The minimum score in the final exam to pass the subject is 5 over 10, notwithstanding the mark obtained in continuous evaluation

EXTRAORDINARY EXAM: there are two possibilities:
a) Examination of all the topics of the course (100% extraordinary exam mark)
b) Examination of the topics included in the continuous evaluation test and/or the final exam when failing any/both of those tests. The weights of those test will be kept (4 points).

ACADEMIC CONDUCT: Unless otherwise specified, the tests will be closed book, no computer or phone, or anything else other than a writing instrument and the examination itself. Plagiarism, cheating or other acts of academic dishonesty will not be tolerated. Any infringement of any kind will result in a failing grade.

% end-of-term-examination:	40
% of continuous assessment (assigments, laboratory, practicals…):	60