Quality processes in the biomedical industry. Regulatory basis

Academic Year: (2023 / 2024) **Review date: 19-05-2022**

Department assigned to the subject: Bioengineering Department

Coordinating teacher: QUILEZ LOPEZ, CRISTINA

Type: Compulsory ECTS Credits : 5.0

Year : 1 Semester : 2

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 fundamentals 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 requirements and the importance of regulatory issues in the research and development process of Advanced Therapy Medicinal Products.

DESCRIPTION OF CONTENTS: PROGRAMME

a. Introduction to pharmaceutical quality systems
- GMP standards. Origin and development
- Quality Systems and Personal. Facilities and Equipment.
- Production and Quality Control
- Manufacturing and analysis by contract, claims, withdrawals, audits and administrative procedure in inspections

b. Regulatory agencies of different countries (AEMPS, MHRA, Paul Ehrlich Institute) and EMA and FDA central agencies. Regulatory aspects in Asia

c. Manufacturing:
- GMP, GLPs, authorizations and requirements.
- Legislation of sanitary products.
- ISO13485 and standards required for the manufacture of ATMPs required

d. Drug Registry and marketing authorization

e. Clinical trial authorization

f. PEI (IMPD), CTD etc.

g. CE Marking

h. Examples of Spanish companies

LEARNING ACTIVITIES AND METHODOLOGY

LEARNING ACTIVITIES
- Theoretical classes
- Practical classes
- Theoretical-practical classes
- Tutorships

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.

ASSESSMENT SYSTEM

The attendance to 80% of sessions is mandatory to be evaluated.

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

CONTINUOUS EVALUATION (40% of the final score of the subject): 20% test and 20% practical exercise. Failure to attend any test or submit the exercises before the deadline will result in a mark of 0 in the corresponding continuous evaluation block.

FINAL EXAM: The final exam will cover the whole subject and it will account for the 60 % of the final score (6 points of the TOTAL SCORE). The minimum score in the final exam to pass the subject is 4.5 over 10, notwithstanding the mark obtained in continuous evaluation.

EXTRAORDINARY EXAM: the mark for students attending any extraordinary examination will be either a) 100% extraordinary exam mark, or b) 60% extraordinary exam mark and 40% continuous evaluation if it is available on the same course and if the student requests it.

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:	60
% of continuous assessment (assigments, laboratory, practicals…):	40

BASIC ELECTRONIC RESOURCES

- . EUROPEAN COMMISION: Eudralex : http://ec.europa.eu/health/documents/eudralex/index_en.htm. http://ec.europa.eu/health/human-use/index_en.htm
- . European Medicine Agency (EMA): http://www.ema.europa.eu/ema/
- . Spanish Agency of Medicines and Medical Devices: http://www.aemps.gob.es/
- . AENOR: Spanish Association for Standardisation and Certification: http://www.aenor.es/aenor/inicio/home/home.asp
- . ICH: International Conference of Harmonisation: http:// http://www.ich.org
- . ISO: International Organization for Standardization: http://www.iso.org/iso/home.html
- . GLP - OECD: http://www.oecd.org/chemicalsafety/testing/oecdseriesonprinciplesofgoodlaboratorypracticeglpandcompliancemonitoring.htm
- . GMP - EU: http://ec.europa.eu/health/documents/eudralex/vol-4/index_en.htm
- . GMP ¿ Spain: http://www.aemps.gob.es/industria/inspeccionNCF/guiaNCF/home.htm
- . GCP - EU: http://ec.europa.eu/health/files/eudralex/vol-10/2009_11_03_guideline.pdf
- . GDP - Spain: http://www.aemps.gob.es/industria/distribucion_medicamentos/home.htm
- . Good Tissue Practices (Euro GTP): http://eurogtps.com/
- . Good pharmacovigilance practices (GFVP): http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000345.jsp
- . GLP Spain (AEMPS): http:// http://www.aemps.gob.es/industria/inspeccionBPL/home.htm
- . GCP Spain: http://www.aemps.gob.es/industria/inspeccionBPC/home.htm
- . GDP EU: http://ec.europa.eu/health/human-use/good_distribution_practice/index_en.htm