66028 - Quality control and legislation in biotechnological processes

Información del Plan Docente

Academic Year	2016/17
Academic center	100 - Facultad de Ciencias
Degree	537 - Master's in Molecular and Cellular Biology
ECTS	6.0
Course	1
Period	First semester
Subject Type	Compulsory
Module	---

1.Basic info

1.1.Recommendations to take this course

1.2.Activities and key dates for the course

2.Initiation

2.1.Learning outcomes that define the subject

2.2.Introduction

3.Context and competences

3.1.Goals

3.2.Context and meaning of the subject in the degree

3.3.Competences

3.4.Importance of learning outcomes

4.Evaluation

5.Activities and resources

5.1.General methodological presentation

The learning process that is designed for this subject is based on the following activities and resources: A

ACTIVITY: Problem solving, case studies, "on line" exercises
ACTIVITY: Seminars
ACTIVITY: Lectures (slate, power-point, videos)

66028 - Quality control and legislation in biotechnological processes

Documentation and materials for classes (presentations power.point), articles, exercises, web addresses, other) are provided directly to students and via Moodle University of Zaragoza

5.2.Learning activities

A) Theoretical Lectures (30 hours). Program section 5.3.

B) Practical sessions: problem solving and practical exercises (15 hours)

Solving practical problems. The resolution of these exercises is an individual work of the student. Students must submit a report at the end of each session following the guidelines and format that will mark the beginning of each session. Grades and corrected exercises will be available to students at the beginning of the next session for review. Such controls are part of the concept of continuous assessment, which will track the learning process. It is scored from 0 to 10 points and contributes 20% to the final rating.

C) Seminars (15 hours)

Seminars: Development of memory, exhibition and public defense of a practical work on a topic related to the Quality Control and Regulation in Biotechnology. The work will be performed individually or in groups of 2 students. This report should be produced following the guidelines and the format that will be marked at the beginning of the course. The work will be exposed and defended by each group of students in type-seminar sessions, in which the authors should intervene to explain and argue some of the points contained in the memory, and debate and discuss with other participants of seminars (teachers and students). The time available for the presentation and defense of the topic during the seminar sessions will be 10-15 minutes. It is scored from 0 to 10 points and it will contribute 40% to the final rating. Topics:

1. Aspects and quality control and regulation applied to design new vaccines

2. Aspects of quality control applied to the design and regulation of GMOs

3. Aspects and quality control of recombinant proteins and monoclonal antibodies.

4. Aspects and quality control and regulation in the use of drugs

5. Issues Bioethics

6. Other (to determine the novelty or special interest)

D) Written test (2h).

66028 - Quality control and legislation in biotechnological processes

The written test will consist of questions requiring short answers (evidence of limited response) or requiring extensive development of a topic (essay tests or free and open response). The first will allow to check the student knowledge on the subject sample, and the second will allow to assess their ability to express, to present and sustain arguments, and make critical judgments. The written test will be based on the program of learning activities scheduled. It is scored from 0 to 10 points and it will contribute 40% to the final rating.

5.3.Program

A) Theoretical Lectures

-1. Definition of Quality Control (QC). Goals. Importance in an organization. Historical development. QC leaders.

-2. QC by country. Integral DC system. And ISO Standards. QC in Biotechnology.

-3. Overview of application of CC in Biotechnology. Bioethics.

-4. Agencies: FDA, AEMPS

-5. Organisms: CBER, WHO.

-6. Concepts: Invention, know-how, patents, others. National and European patents. Organisations: EPO, OEPM

-7. Introduction to OMG. Introduction to its laws and regulations (WHO, FDA, etc.).

-8. Definition of Clinical Trial. Types and Phases.

-9. Biological Products and regulation.

-10. Definition and development of a PNT (group work in class from a specific case in a biotec lab)

-11. Validation. Definition. Reasons to validate. Architects of validation. ISO 17025 ISO 15189 GLP. NCFS. ISO 9001.

-12. Validation. Important parameters. Accuracy. Linearity. Range. Limits. Selectivity. Specificity and robustness. Recovery. Revalidation. Harmonization of standards.

5.4.Planning and scheduling

Schedule sessions and presentation of works

Reserved for this subject (first quarter). Hours and the scheduled dates for exams, on the website of the Faculty of Sciences in the corresponding section of the Master in Molecular and Cellular Biology: https: // science.

66028 - Quality control and legislation in biotechnological processes

unizar.es/calendario-y-horarios; and communication through the Moodle platform. The seminars held by Guests Professors will be indicated in each case.

5.5.Bibliography and recomended resources

- Quality Control Training Manual: Comprehensive Training Guide for API, Finished Pharmaceutical and Biotechnologies Laboratories. S. I. Haider, S. E. Asif, CRC Press, *ISBN: 1439849943.* 2011.
- Iso 9001: 2000 Document Development Compliance Manual; A Complete Guide and CD-ROM S. I. Haider, CRC Press, *ISBN:1574443089* . 2001
- Biotechnology: Quality Assurance and Validation K. E. Avis, C. M. Wagner, V. L. Wu, CRC Press, *ISBN:1574910892.* 1998