Universidad Zaragoza

Year : 2019/20

66028 - Quality control and legislation in biotechnological processes

Syllabus Information

Academic Year: 2019/20
Subject: 66028 - Quality control and legislation in biotechnological processes
Faculty / School: 100 - Facultad de Ciencias
Degree: 537 - Master's in Molecular and Cellular Biology
ECTS: 6.0
Year: 1
Semester: First semester
Subject Type: Compulsory
Module: ---

1.General information

1.1.Aims of the course

1.2.Context and importance of this course in the degree

1.3.Recommendations to take this course

2.Learning goals

2.1.Competences

2.2.Learning goals

2.3.Importance of learning goals

3.Assessment (1st and 2nd call)

3.1.Assessment tasks (description of tasks, marking system and assessment criteria)

4.Methodology, learning tasks, syllabus and resources

4.1.Methodological overview

The methodology followed in this course is oriented towards achievement of the learning objectives. A wide range of teaching and learning tasks are implemented, such as problem solving, case studies, and "on line" exercises; seminars and lectures (supported with slate, PowerPoint presentations and videos).

Classroom materials will be available via Moodle. These include a repository of the lecture notes used in class, the course syllabus, as well as other course-specific learning materials.

4.2.Learning tasks

The course includes the following learning tasks:

A) Lectures (30 hours). See syllabus in section 5.3.

B) Practice sessions sessions: problem solving and practical exercises (15 hours). The resolution of these exercises is done individually by the student. Students must submit a report at the end of each session following the guidelines and format that will explained at the beginning of each session. Grades and corrected exercises will be available to students at the beginning of the next session for reviewing purposes. Such exercises are part of the continuous assessment, which will track the learning process of the students. This part is graded from 0 to 10 points and contributes 20% to the final mark.

C) Seminars (15 hours). Development of a report 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 pairs. This report should be produced following the guidelines and the format that will be explained at the beginning of the course. The work will be presented and defended by each group of students in seminar sessions, in which the authors should intervene to explain and argue some of the points contained in the report, 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 graded from 0 to 10 points and it will contribute 40% to the final mark. Suggested 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) Assessment (2 hours). The written test will consist of questions requiring short answers (evidence of limited response) or requiring extensive development of a topic (essay or free and open response). The first part will allow to check the student knowledge on the subject sample, and the second one will allow to assess their ability to express, present and sustain arguments, and make critical judgments. The written test will be based on the syllabus of learning activities scheduled. It is graded from 0 to 10 points and it will contribute 40% to the final mark.

4.3.Syllabus

The course includes the following learning tasks:

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

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

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

Topic 4. Agencies: FDA, AEMPS

Topic 5. Organisms: CBER, WHO.

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

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

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

Topic 9. Biological Products and regulation.

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

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

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

4.4.Course planning and calendar

The course takes place during the first semester of the academic year. The seminars held by Guests Professors will be indicated in each case.

Further information concerning the timetable, classroom, assessment dates and other details regarding this course, will be provided on the first day of class or please refer to the Faculty of Science and the Master's in Molecular and Cellular Biology website (https://science. unizar.es/calendario-y-horarios), and the virtual platform Moodle.

4.5.Bibliography and recommended resources

http://biblos.unizar.es/br/br_citas.php?codigo=66028&year=2019