Universidad Zaragoza

Academic Year: 2025/26

66028 - Quality control and legislation in biotechnological processes

Teaching Plan Information

Academic year: 2025/26
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

This subject provides knowledge so that the student can: acquire technical skills of analysis and resolution of experimental problems in research laboratories in quality contexts; know the bodies and regulations in the field of biotechnology; deal with the importance of patenting; and be able to communicate and organize experimentation.

2. Learning results

The student should be able to:

- Understand the quality control and regulatory issues surrounding biochemical experimentation and research, patents and technology transfer, with direct application to the biotechnology industry.

-Know the activity of national and foreign organizations involved in quality standards, as well as inventions and patents, among others.

- Become familiar with finding and discussing information, solving concrete problems.

- Know how to communicate the conclusions, knowledge and ultimate reasons that support them, to specialized and non-specialized audiences in a clear and unambiguous way.

3. Syllabus

The program:

1. Definition and Objectives. R+D+i. Integral QC System. Deming. ISO and Standardization. Best Practices (GLP).

2. Accreditation and Standardization. National and international organizations. Regulation in biotechnology. Bioethics.

3. Invention, know-how, patents. EPO, SPTO.

4. Patents I.

5. Patents II.

6. Patents III.

7. Biological products and regulation.

8. Testing Preclinical I.

9. Clinical Trials.

10. Reasons to validate.

11. ELISA validation.

12. Case studies.

13. Documentation Technique to analyse.

14. Virtual Biotechnology Laboratory.

15. Security.

In addition, seminars given by guest teachers, related to the contents of the program subject will be announced to the students in the corresponding ADD of the subject.

4. Academic activities

- Theoretical classes. They are conceived as a participative master class.

- Talks/Workshops. By invited specialists, who will contribute their knowledge and experience, each one from their own research, to the issues raised in the subject. The active participation of the student will be valued.

- Resolution of practical cases. The resolution of these exercises is an individual work of the student related with Patents and

Validation of processes in the Biotechnology Laboratory. They are framed within the concept of continuous evaluation, for the follow-up of the learning process.

- Seminar. Students will choose a specific topic related to the patent section. Its evolution will be supervised by the teacher through the tutoring schedule.

5. Assessment system

The evaluation will consist of the following tests:

- A written examination. The test will be based on the program of programmed learning activities of the subject.

It will consist of multiple-choice questions. It will be graded from 0 to 10 points and will contribute 60% to the final grade.

- Resolution of practical cases. The resolution of these exercises constitutes an individual work of the student related with: (1) Patents and (2) Process validation in the Biotechnology Laboratory. They will be graded from 0 to 10 points and will contribute 15% and 10%, respectively, to the final grade.

- Seminar. The activity consists of the elaboration of a report, its exhibition and public defense of a practical work on a topic related to the subject. The time for the presentation and defense of the topic will be 15 minutes. The quality of the report, presentation and participation in class discussion will be assessed. It will be graded from 0 to 10 points and will contribute 15% to the final grade.

6. Sustainable Development Goals

3 - Good Health and Well-being
12 - Responsible Consumption and Production
16 - Peace, Justice and Strong Institutions