

Academic Year/course: 2022/23

## 66028 - Quality control and legislation in biotechnological processes

### Syllabus Information

**Academic Year:** 2022/23

**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

**The course and its expected results respond to the following approaches and objectives:**

The general objective of this subject is to provide students with knowledge of the fundamentals of quality control and regulation that surround these experiments and to familiarize them with their applications so that students perceive the advances, controversies and challenges that the advancement of research provides in current moments. This objective will be acquired through theoretical classes and seminars. With the elaboration of a personal work, it is intended that students deepen previous knowledge and acquire additional skills related to the search for scientific information and its critical analysis, writing and communication.

These approaches and objectives are aligned with the following Sustainable Development Goals (SDGs), United Nations 2030 Agenda (<https://www.un.org/sustainabledevelopment/es/>), in such a way that the acquisition of learning outcomes of the subject provides training and competence to contribute to some extent to its achievement:

Objective 3: Health and well-being.

Objective 4: Quality education.

Objective 5: Gender equality.

Objective 12: Responsible production and consumption

Goal 16: Peace, justice and strong institutions.

Objectives 17: Alliances to achieve the objectives.

## 2. Learning goals

## 3. Assessment (1st and 2nd call)

## 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:

**1. ACTIVITY: Problem solving, practical cases (Patents).** It will be scored from 0 to 10 points and will contribute 20% to the final grade.

? **METHODOLOGY:** The teacher will distribute the practical cases-problems in advance and after a period of reflection, they will be resolved and discussed in class. The blackboard will be used above all, as well as exercises in the "on-line" computer room.

? **COMPETENCES ACQUIRED:** Search and discussion of information, resolution of specific problems

**2. ACTIVITY: Final work of the subject.** Exposure and defense time (10-15 minutes). Teamwork is encouraged. It will be scored from 0 to 10 points and will contribute 30% to the final grade.

? **METHODOLOGY:** In the seminars, students will be instructed in the search for relevant information on the Internet, the use of databases and network applications. Likewise, students will be encouraged to learn about this type of technology for presentation of information to a specialized public and to the general public.

? **COMPETENCES ACQUIRED:** Know how to communicate conclusions -and the knowledge and ultimate reasons that support them- to specialized and non-specialized audiences in a clear and unambiguous way.

**3. ACTIVITY: Theoretical classes.** They will be evaluated with a written test with short questions, limited response tests. Be a block of multiple choice questions. With the former, it is possible to assess their ability to express themselves, to present and sustain arguments and to carry out critical analysis; and the second will allow a broad sampling of the student's knowledge on the subject. It will be scored from 0 to 10 points and will contribute 40% to the final grade.

? **METHODOLOGY:** For the master classes, the Blackboard and computer screen projections (PowerPoint) will be used, including small animations and videos and off-line navigation.

? **COMPETENCES ACQUIRED:** Acquire the theoretical knowledge of the subject

**4. ACTIVITY: Seminars by invited specialists.** Student participation will be evaluated on an ongoing basis. It will be scored from 0 to 10 points and will contribute 10% to the final grade.

? **METHODOLOGY:** Computer screen projections (PowerPoint) are used for the seminars.

? **COMPETENCES ACQUIRED:** Acquire the knowledge of the subject applied to the real world, of applied research and of the corresponding company or organization.

*Note: "Teaching and evaluation activities will be carried out in person unless, due to the pandemic situation, the provisions issued by the competent authorities and by the University of Zaragoza require them to be carried out electronically".*

## 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

All the documentation and material for the classes (power.point presentations), articles, exercises, web addresses, others are

provided to the student, also through the Moodle platform of the University of Zaragoza.