

Academic Year/course: 2022/23

27120 - Social and Legal Elements

Syllabus Information

Academic Year: 2022/23

Subject: 27120 - Social and Legal Elements

Faculty / School: 100 - Facultad de Ciencias

Degree: 446 - Degree in Biotechnology

ECTS: 6.0

Year: 3

Semester: Second 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.

1.3. Recommendations to take this course

As a mandatory subject from Grade is based on previously acquired knowledge by the student. It is very convenient to have passed all the subjects of previous courses and first semester. The working material of the subject may be in English so the student will need a good level of understanding written in it. It aims to provide students an overview of aspects related to quality control and regulation surrounding experimentation and biochemical research resulting in the biotechnology industry. national and international bodies involved in regulatory activities are presented.

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 the achievement of the learning objectives. A wide range of teaching and learning tasks are implemented, such as lectures, practice sessions, autonomous work and study and assessments tasks.

Students are expected to participate actively in class throughout the semester. This strategy will allow the student to revise a topic, closely with an outstanding professional. This process approach the student to a research aspect which can provide a subsequent professional development.

Further information regarding the course will be provided on the first day of class.

4.2. Learning tasks

The course includes the following learning tasks:

- I. Lectures. (4 ECTS). They are presented to students basic theoretical knowledge of the subject, which will focus on the above aspects, according to the program of the subject.
Downloadable documents interest web
CSIC Research Ethics (<http://www.csic.es/>)
Codi de pràctiques bones científiques PRBB (pdf 2.3M) [Download]
Research ethics - Arbor Magazine No. 730
HAS Science Ethics Code (PDF 255K) [Download]
CBE Recommendations on CBP of Spain (pdf 321k) [Download]
Stewards of Integrity - ESF (pdf 5.94M) [Download]
CBP Research - University of Barcelona (pdf 535 k) [Download]
- II. Practice sessions (including presentation and exhibition of an assessment task). (2 ECTS). Students will gather information on a particular topic that will update helped by the teacher. Professor monitor the individual work of students by scheduling tutoring sessions. Finally, the works are presented and debated in class.
 - A) LEGAL DOCUMENTS-BIOMEDICAL.
Formal structure, content, purpose and usefulness of the main documents (report, certificate, trade) to develop in the exercise of work activity.
Document processing and presentation
Analysis from an ethical and legal perspective
Expert reports
Forensic Genetics reports. criminal cases, identification, paternity testing
 - B) VIDEOS AND ANALYSIS OF EVIDENCE
Program may informally complementary activities of interest to students consistent in seminars and lectures by experts, students will be announced during the course.
 - C) PRACTICAL EXERCISES
Resolutions of specific cases will be made through the analysis of work procedures, delivery notes and sheets of laboratory reagents. Likewise, complementary practical activities will be carried out on the subject of inventions and patents. Documentation will be provided during the course to students in class or through Moodle.

4.3. Syllabus

The course will address the following topics:

1. Biomedicine, Biotechnology and Law. Basic concepts. Historical evolution. Introduction to the administrative consequences of criminal, civil and labor biotechnology.
2. Introduction to Bioethics. Ethics in scientific research. Historical background and current projection.
3. The rights of people and scientific research in biotechnology. Information and consent, legal and ethical.
4. Biotechnology in the service of society and the Administration of Justice. Scientific investigation in the application for expert forensic science.
5. Identification and Forensic Genetics I.
6. Identification and Forensic Genetics II.
7. Prevention of risks to human health in laboratories. Biotechnology and Health. The rules of execution. Liabilities arising.
8. Security laboratories. Biological, physical and chemical risks. Toxicology.
9. Trials of biotechnology products.
10. Invention, know-how, patents, others. national and European patents.
11. Biological Products and regulation. Genetically Modified Organisms (GMO). Reference standards. The specific cases.
12. Animal testing. Regulations. Animal welfare. Ethics of Animal Experimentation.
13. Preclinical trials. Clinical trials. Types and phases. Consents. Harmonization of regulations. Ethical committees.
14. Introduction to quality control (QC) and the objectives in Biotechnology.
15. CC Integrated System. Good practices.
16. General information on the application of CC in Biotechnology.
17. Main national and international regulatory agencies.
18. Validation. Definition. Validation reasons and architects. parameters and design. Documentation. Certificates. Good laboratory Practices.

4.4. Course planning and calendar

Schedules of lectures and problems will coincide with the officially established and will be available at: <https://ciencias.unizar.es/grado-en-biotecnologia>.

The places, calendar and groups for training and practical sessions will be established in coordination with the rest of maters at beginning of course. The Coordinator will produce the groups of students for these activities at beginning of course to

avoid overlaps with other subjects.

For students enrolled in the subject, places, times and dates of lectures and practical sessions will be public via Bulletin Board advertisements of the grade on the platform Moodle at the University of Zaragoza, <https://moodle2.unizar.es/add/>, and in the moodle page for the course. These routes will be also used to communicate enrolled students their distribution by groups of practical sessions, which will be organized by the coordination of degree. Provisional dates will be available on the website of the Faculty of Sciences in the corresponding section of the Degree in Biotechnology: <https://ciencias.unizar.es/grado-en-biotecnologia>.

In this web there will be also available the dates of exams.

Note: "The teaching and evaluation activities will be carried out in the presential manner unless, due to the health situation, The provisions issued by the competent authorities and by the University of Zaragoza provide for them to be carried out in a telematic manner"

4.5. Bibliography and recommended resources

<http://psfunizar10.unizar.es/br13/egAsignaturas.php?codigo=27120>