

## 27120 - Social and Legal Elements

### Información del Plan Docente

<b>Academic Year</b>	2018/19
<b>Subject</b>	27120 - Social and Legal Elements
<b>Faculty / School</b>	100 - Facultad de Ciencias
<b>Degree</b>	446 - Degree in Biotechnology
<b>ECTS</b>	6.0
<b>Year</b>	3
<b>Semester</b>	Second semester
<b>Subject Type</b>	Compulsory
<b>Module</b>	---

### **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**

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 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**

#### **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 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.

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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.
  - o 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
  - o 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.
  - o C) PRACTICAL EXERCISES  
Analysis of working procedures, delivery notes and laboratory reagents sheets were made. In addition, complementary activities will be conducted in practice the subject of inventions and patents. documentation to students in class or through Moodle will be provided during the course.

### 4.3.Syllabus

The course will address the following topics:

1. Biomedicine, Biotechnology and Law. Basic concepts. Historical evolution. Introduction to criminal, civil, labor and administrative implications of biotechnology.
2. Introduction to Bioethics. Ethics in Scientific Research. Historical background and current projection.
3. Rights of Persons and scientific research in biotechnology. Information and consent, legal and ethical issues.
4. Biotechnology in the Service of Society and the Administration of Justice. Scientific research in the Expert Forensic Science Application.
5. Identification and Forensic Genetics I.
6. Identification and Forensic Genetics II.
7. Prevention of Risks to Human Health in Laboratories. Biotechnology and Health. Implementing rules. Liabilities arising.
8. Safety Laboratories. Risks Biological, physical and chemical. Toxicology.
9. Testing of biotechnology products.
10. Invention, know-how, patents, others. National and European patents.
11. Genetically Modified Organisms (GMOs). Reference standards. Use in bioremediation, agricultural, and others.

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12. Biological Products and regulation. Specific cases.
13. Tests on animals. Regulations. Animal welfare. Ethics of Animal Experimentation.
14. Pre-clinical trials. Clinical Trials. Types and Phases. Feelingly. Harmonization of regulations. Ethical committees.
15. Quality Control I: Introduction to Quality Control (CC) and objectives.
16. Quality Control II: Integrated System CC.
17. Quality Control III: Overview of application of CC in Biotechnology.
18. Quality Control IV and abroad involved in the main quality standards agencies.
19. Validation. Definition. Reasons and architects of validation. Parameters and validation 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 matters 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.

### 4.5.Bibliography and recommended resources