

27120 - Social and Legal Elements

Información del Plan Docente

Academic Year	2016/17
Academic center	100 - Facultad de Ciencias
Degree	446 - Degree in Biotechnology
ECTS	6.0
Course	3
Period	Second semester
Subject Type	Compulsory
Module	---

1. Basic info

1.1. 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.

1.2. Activities and key dates for the course

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.

2. Initiation

2.1. Learning outcomes that define the subject

2.2. Introduction

3. Context and competences

3.1. Goals

3.2. Context and meaning of the subject in the degree

3.3. Competences

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3.4.Importance of learning outcomes

4.Evaluation

5.Activities and resources

5.1.General methodological presentation

The learning process that is designed for this subject is based on the following:

- This course is scheduled to address an intensification of theoretical knowledge with student participation. 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.

5.2.Learning activities

The program that the student is offered to help you achieve the expected results includes the following activities:

I. THEORETICAL classes. 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. PRACTICAS classes (including presentation and exhibition of a work).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

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.

5.3.Program

They are presented to students the basic theoretical knowledge of the subject, which will focus on the above aspects.

Agenda:

1. Biomedicine, Biotechnology and Law. Basic concepts. Historical evolution. Introduction to criminal, civil, labor and

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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.
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.

5.4.Planning and scheduling

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.

5.5.Bibliography and recommended resources

- La prueba del ADN en medicina forense : la genética al servicio de la ley en el análisis de indicios criminales y en la investigación biológica de la paternidad / directora M^a Begoña Martínez Jarreta Barcelona : Masson, 1999
- La prueba pericial médica en el derecho / coordinadora, Begoña Martínez Jarreta . - 1^a ed. Zaragoza : Servicio de Publicaciones, Universidad de Zaragoza, 1996
- Ciencia forense : revista aragonesa de medicina legal Zaragoza : Institución Fernando el Católico, 1999- [Publicación periódica] (Ver también enlaces Web)
- Enciclopedia de Bioderecho y Bioética / Carlos María Romeo Casabona (Director) Granada : Comares, 2011
- Vásquez Marías, Patricia. Documentos médico-legales / Patricia Vásquez Marías, M^a Begoña Martínez Jarreta . - [1^a ed.] Zaragoza : Institución Fernando el Católico, 2003
- Derecho sanitario y bioética : cuestiones actuales / coordinadoras Marina Gascón Abellán, M^a del Carmen González Carrasco, Josefa Cantero Martínez Valencia : Tirant lo blanch, 2011
- Tratado de Medicina del trabajo / Fernando Gil Hernández, [coordinador] ; [colaboradores, Víctor Alcalde Lapiedra, M^a Begoña Martínez Jarreta... et al.] . - 2^a ed. Ámsterdam ; Barcelona ; Madrid [etc.] : Elsevier Masson , D.L. 2011

Páginas web

Ética en investigación del CSIC

<http://www.csic.es/>

Cátedra de Derecho y Genoma Humano

<http://www.catedraderechoygenomahumano.es>

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Instituto Borja de Bioética

<http://www.ibbioetica.org/es/>

Red de Comités de Ética de Universidades y Organismos Públicos de Investigación de España

<http://www.ub.edu/rceue/>

Observatori de Bioètica i Dret

<http://www.pcb.ub.edu/bioeticaidret/>

Sociedad Internacional de Bioética

<http://www.sibi.org/>

European Science Foundation

<http://www.esf.org/>

Asociación Española de Bioética y Ética Médica

<http://www.aebioetica.org/>

Comité de Ética de Experimentación Animal de la Universidad

<http://www.unav.es/ceea/>

Scientific and Cultural Organization UNESCO

<http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/>

[European Society for Agricultural and Food Ethics \(EurSafe\)](#)

<http://www.eursafe2010.es/>

Escuela Profesional de Medicina del Trabajo de la Universidad de Zaragoza

<http://www.medicinatrabajo.es/>

American Academy of Forensic Science

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<http://www.aafs.org/>

Federal Bureau of Investigation

<http://www.fbi.gov/>

Forensic Science Society

<http://www.forensic-science-society.org.uk/index.html>

The American Society of Crime Laboratory Directors

<http://www.asclid.org/>

Society of Forensic Toxicologists

<http://www.soft-tox.org/>

Internet drug index

<http://www.rxlist.com>

[Comisión Nacional de Seguridad y Salud en el Trabajo](#)

<http://www.mtas.es/insht/cnsst/index.htm>

[Salud laboral](#) (Ministerio de Sanidad y Consumo)

<http://www.msc.es/ciudadanos/saludAmbLaboral/saludLaboral/home.htm>

Agencia Europea para la Seguridad y la Salud en el Trabajo

<http://es.osha.europa.eu/>

National Institute for Occupational Safety and Health (USA)

<http://www.cdc.gov/niosh/>

Organización Internacional del trabajo

<http://www.ilo.org/public/spanish/index.htm>

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The World Health Organization

http://www.who.int/topics/occupational_health/en/