COURSE DATA

DATA SUBJECT

Code: 33188
Name: Legal aspects of molecular biosciencies
Cycle: Undergraduate Studies
ECTS Credits: 4.5
Academic year: 2026-27

STUDY (S)

Degree	Center	Acad. year	Period
1111 - Grado en Biotecnología	Facultat de Ciències Biològiques	3	First quarter

SUBJECT-MATTER

Degree	Subject-matter	Character
1111 - Grado en Biotecnología	Legal and business aspects of molecular biosciences	COMPULSORY

COORDINATION

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SUMMARY

Biotech legal aspects is a compulsory subject developed the first semester of the third course of the Degree in Biotechnology. It is 4.5 credits and 112,5 chargeable hours of work for the students.

The contents are the following:

- Eu and domestic Legislation about biotechnology and GMO.

- Experiments with animals

- CBiosecuriity and risk management.

- Quality international rules.

- Protection of innovation (patents and other rights)

- Contracts and biotecnology.

- Start-ups and biotecnology.

PREVIOUS KNOWLEDGE

RELATIONSHIP TO OTHER SUBJECTS OF THE SAME DEGREE

There are no specified enrollment restrictions with other subjects of the curriculum.

OTHER REQUIREMENTS

no law background is required

COMPETENCES / LEARNING OUTCOMES

1102 -

Capacidad de interpretar las consecuencias éticas y sociales de la experimentación Biotecnológica.

Capacidad para aplicar la legislación en materia de seguridad, manipulación de organismos y eliminación de residuos.

Capacidad para transmitir ideas, problemas y soluciones empresariales a partir de la Biotecnología.

Conocer las bases del diseño empresarial su aplicación a las empresas biotecnológicas.

Desarrollo de habilidades para transferir la formación biotecnológica al mundo empresarial.

Saber aplicar los conocimientos en Biotecnología al mundo profesional.

Saber diseñar y ejecutar un protocolo completo de elaboración de una patente.

Saber utilizar la lengua inglesa en la redacción de informes, patentes y comunicaciones.

1111 - Grado en Biotecnología

Actuar con autonomía en el aprendizaje, tomando decisiones fundamentadas en diferentes contextos, emitiendo juicios en base a la experimentación y el análisis y transfiriendo el conocimiento a nuevas situaciones

Apply and understand knowledge in biotechnology and use that knowledge in professional contexts.

Assimilate ethical and legal principles in scientific research in biotechnology.

Colaborar eficazmente en equipos de trabajo, asumiendo responsabilidades y funciones de liderazgo y contribuyendo a la mejora y desarrollo colectivo

Communicate ideas, problems and solutions within the field of biotechnology.

Conocer los elementos fundamentales de la comunicación y percepción pública de las innovaciones biotecnológicas y de los riesgos asociados a ellas

Conocer y comprender, desde el propio ámbito de la titulación, las desigualdades por razón de sexo y género en la sociedad; integrar las diferentes necesidades y preferencias por razón de sexo y de género en el diseño de soluciones y resolución de problemas

Contribuir en el diseño, desarrollo y ejecución de soluciones que den respuesta a demandas sociales, teniendo en cuenta como referente los Objetivos de Desarrollo Sostenible

Demostrar razonamiento crítico y autocrítico en el ámbito de la titulación, considerando aspectos tales como la ética profesional, los valores morales y las implicaciones sociales de las diferentes actividades realizadas

Disseminate and engage in public debate on issues related to biotechnology and its applications.

Participate in multidisciplinary teams, engaging in teamwork and collaboration.

Propose creative and innovative solutions to complex situations or problems, typical of the area of ¿¿¿¿connection, to donate responses to the various professional and social needs

Que el estudiantado sea capaz de identificar el tipo de responsabilidad legal derivada de la actividad investigadora y la explotación de sus resultados

Saber comunicarse de manera efectiva, tanto de forma oral como escrita, adaptándose a las características de la situación y de la audiencia

Search for and retrieve information from major patent databases and prepare the documentation required for patent applications of biotechnological products.

Ser capaz de analizar y asimilar de manera crítica la información científica y de entender la dimensión histórica del conocimiento científico

Tener una visión integrada del proceso I+D+i desde el descubrimiento de nuevos conocimientos básicos hasta el desarrollo de aplicaciones concretas de dicho conocimiento y de la introducción en el mercado de nuevos productos biotecnológicos

Understand and apply the criteria for evaluating biotechnological risks.

Use English to write reports and to interpret information from protocols, manuals and databases.

DESCRIPTION OF CONTENTS

1. LAW AND BIOTECHNOLOGY

1. Law's response to biotechnology.
2. Freedom of research and limits. Precautionary principle.
3. Biotechnology and environmental safety.
4. Biological products and conventional products.

2. GENETIC MODIFICATION IN THE EUROPEAN UNION

1. Reference to the system of regulatory sources in the EU and Spain. 2.
2. EU legislation on the subject.
3. Conflicting interests.
4. Contained use and release of GMOs.
5. Placing on the market of genetically modified organisms.

3. BIOMEDICINE AND BIOMEDICAL RESEARCH IN SPAIN

1. Constitutional principles. Regulation of freedom of research.
2. Dignity of the person, Biotechnology and Biomedicine.
3. Use of cells and tissue of human embryonic origin. Reference to cloning.
4. Genetic analysis and sampling.
5. Biobanks.
6. Regulation of gene therapies.
7. Reference to data protection.

4. ANIMAL EXPERIMENTATION

1. Legal regime of animal handling and experimentation.
2. Legal framework for animal protection.
3. Treatment of animals in laboratories.

5. PROTECTION OF BIOTECHNOLOGICAL INNOVATION

1. Approach to Industrial Property: origin and foundations.
2. Patents and utility models.
3. Patents versus industrial secrets.
4. Dual protection of biotechnological innovations.
5. Legal regime of labour inventions.

6. SPECIAL REFERENCE TO THE BIOTECHNOLOGICAL PATENT

1. The question of patentability of biotechnological innovations and micro-organisms. 2.
2. Requirements for the patentability of biotechnological innovations.
3. Prohibitions on patentability in this area.
4. Scope and extent of patent law in this area.
5. Protection and actions of the holder of the patent right.

7. THE LEGAL REGIME FOR PLANT VARIETIES

1. Concept and scope of protection.
2. Requirements for registration.
3. Rights deriving from plant variety rights.
4. Reference to essentially derived varieties.

8. TRANSFER OF RESEARCH RESULTS

1. Industrial Property rights as an object of trade.
2. Assignment and licensing of patents and plant varieties.
3. University and protection of biotechnological innovation. Contractual figures.
4. Technology-based companies.
5. Aspects of innovation financing.
6. The informational model in the field of biotechnological innovation.

9. BUSINESS ORGANISATION AND RESEARCH ACTIVITY

1. Approach to the concept of company-entrepreneur. Concept of legal entity.
2. Forms of company. Special reference to the capital company and its characteristics.
3. Reference to the incorporation and capital contributions in public limited companies and limited liability companies.
4. Technology as an object of contribution to a company.
5. The organs of the capital company.

10. THE BIOTECHNOLOGY-BASED COMPANY

1. Typology of the biotechnology company.
2. The foundation-company in this field.
3. The biotechnology company as an association.

11. LIABILITY IN THE FIELD OF BIOTECHNOLOGY

1. Reference to tort law.
2. Civil liability.
3. Criminal liability.
4. Product liability.
5. Environmental liability.
6. Liability insurance.

WORKLOAD

PRESENCIAL ACTIVITIES

Activity	Hours
Tutorials	2,00
Theory	31,00
Classroom practices	12,00
Total hours	**45,00**

NON PRESENCIAL ACTIVITIES

Activity	Hours
Attendance at other activities	0,00
Individual or group project	0,00
Independent study and work	17,00
Preparation of lessons	50,50
Preparation for assessment activities	0,00
Resolution of case studies	0,00
Total hours	**67,50**

TEACHING METHODOLOGY

The course is taught primarily through a combination of theoretical and practical classes and purely

practical sessions, with the aim of familiarising students with the content, key concepts and issues relating to the subject areas covered by the course. In the theoretical-practical sessions, the lecturer will present and discuss the various topics on the syllabus, working with students using a range of sources (legal texts, case law, legal doctrine, etc.) relating to these topics. The theory sessions, which are delivered to the entire class, include three hours set aside for seminars. The methodology for these seminars, which are conducted in small groups, involves the preparation of a written report, followed by its presentation and defence in class. In the purely practical sessions, the case study method will be the primary approach. On social media, Twitter will be used to maintain a steady flow of information relating to the module and to encourage voluntary debate within the 140-character limit, so that students feel comfortable using contemporary communication styles.

EVALUATION

1.- A final exam will be held at the end of the course. It will consist of a single theoretical and practical test that will deal with the questions included in the syllabus and will be written. 2.- The final examination will cover the whole syllabus. 3.- Qualifications from one examination will not be kept or retained for another.4.- In relation to the practical classes, given that the qualification is, in any case, unique and appears in the same Qualifications Act, both the theoretical part and the practical part of the discipline will be assessed together, in order to obtain the final qualification. Therefore, the final exam will contain both theoretical and practical questions. 5.- Once the final theoretical and practical examination has been passed (an essential requirement for passing the module), the final mark will be calculated as follows: up to 7 marks for the examination result and up to 3 marks for attendance at theoretical and practical classes, completion of seminars, active participation in these, and the completion and content of the assignments and readings carried out for the practical classes

REFERENCES

- GUILLEM CARRAU, J., Manual de bioderecho para no juristas, Valencia, Tirant lo

Blanch, 2013.

- ROMEO CASABONA, C. M.ª (dir.) Manual de Bioderecho (adaptado a la docencia en ciencias, ciencias de la salud y ciencias sociales y jurídicas), Dykinson, 2025.

- BROSETA PONT, M. y MARTÍNEZ SANZ F., Manual de Derecho Mercantil, Vol 1, Madrid, Tecnos, 2025.

- GARCÍA VIDAL, A. (dir.), Derecho de las Obtenciones Vegetales, Valencia, Tirant lo Blanch, 2017.