Universitat Autònoma de Barcelona

2020/2021

Legal Aspects of Biotechnology

Code: 100971
ECTS Credits: 6

Degree	Type	Year	Semester
2500253 Biotechnology	OB	3	2

The proposed teaching and assessment methodology that appear in the guide may be subject to changes as a result of the restrictions to face-to-face class attendance imposed by the health authorities.

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Use of Languages

Principal working language: catalan (cat)
Some groups entirely in English: No
Some groups entirely in Catalan: Yes
Some groups entirely in Spanish: No

Teachers

Xavier Vallve Sanchez

Noemi Maria Pont Noguero

Prerequisites

There are no prerequisites for taking the course. In spite of this, in order to ensure the proper monitoring of the subject by the student and the achievement of the learning outcomes proposed, it is recommended that the student have basic knowledge about biotechnology, as many techniques that will appear throughout the course Development of the subject will be given by acquaintances.

On the other hand, in a scientific discipline like Biotechnology it is frequent to use sources of information, norms and international guidelines, in English. It is therefore recommended that students have some basic knowledge of this language.

Objectives and Contextualisation

The Subject of Legal Aspects of Biotechnology has a complementary character within the degree and with it it is intended that the student acquires knowledge about the ethical and legal aspects related to Biotechnology and associated research. It is also intended that students know the translational aspects of research, intellectual property and aspects related to the development of new Biotechnological products and the national and international regulations that regulate them.

The training objectives are that the student, at the end of the subject, is able to:

1. Apply the ethical principles and the legislative norms within the framework of the manipulation of the biological systems.
2. Discuss, apply and assume the basic principles in bioethics.
3. Apply the legal principles on research and development of Biotechnological products.
4. Understand the legislation that regulates intellectual property, in the field of knowledge and the application of Biotechnology.

5. Apply the principles of the right of intellectual and industrial property in the processes of research and development of Biotechnological products.
6. Apply the patent regulations.
7. Apply the biotechnological risk assessment criteria.
8. Carry out a biotechnological risk analysis in the fields of new foods, medicines, health products and GMOs.
9. Demonstrate that it has an integrated vision of an R & D & I process, from the discovery of basic knowledge, application development and market introduction, and to know how to apply the main concepts of organization and management in a biotechnological process .
10. Search, obtain and interpret the information of the main biological, bibliographic and patent databases, and use basic bioinformatic tools.

Competences

- Apply the criteria for evaluating biotechnological risks.
- Comply with ethical principles and legislation in the manipulation of biological systems.
- Learn new knowledge and techniques autonomously.
- Read specialised texts both in English and ones own language.
- Reason in a critical manner
- Search for and manage information from various sources.
- Search for, obtain and interpret information from the principal databases on biology, bibliography and patents and use basic bioinformatic tools.
- Understand the legislation that regulates intellectual property in the area of knowledge and application of biotechnology.
- Use ICT for communication, information searching, data processing and calculations.
- Work individually and in teams

Learning Outcomes

1. Apply patent regulations.
2. Apply the principles of intellectual and industrial property law to processes of research and development of biotechnological products.
3. Comply with legal stipulations regarding research and development of biotechnological products.
4. Discuss and apply the basic principles of bioethics
5. Learn new knowledge and techniques autonomously.
6. Perform an analysis of biotechnological risk in the area of new foods, medicines, healthcare products and GMOs.
7. Read specialised texts both in English and ones own language.
8. Reason in a critical manner
9. Search for and manage information from various sources.
10. Search for, obtain and interpret information from the principal bibliographic databases.
11. Use ICT for communication, information searching, data processing and calculations.
12. Work individually and in teams

Content

Part I.

1. Principles of Bioethics: Definition of Bioethics. Fundamental ethical theories in Bioethics. Analysis in bioethics. Basic principles in Bioethics. Other relevant principles in Bioethics
2. Ethics in research: ethical principles in scientific practice. Obligations of the researchers. Codes of Good Practices in Research. Ethical principles of research in Biomedicine
3. The ethical design of animal experimentation: Ethical aspects of animal research. The basic principles: the 3R. Legal aspects of the use of experimental animals: RD 53/2013
4. The ethical design of experimentation with human beings: Ethical principles. The subjects Legal aspects of research in human beings, embryos and reproductive cells: Law 14/2007 and 14/2006

5. Ethical aspects of new technologies. Biomedicine. Genetics Legal aspects: Law 15/1999

Part II.

1. Intellectual and industrial property rights. Introduction. Copyright. Brands. Internet domains. Geographical indications Industrial designs. Patents Industrial secret Unfair competition
2. Patents and utility models. What is a patent and what is it for? What can be patented? Requirements and exclusions. How to obtain patents? Processing
3. Patents in chemistry, pharmacy and biotechnology. Inventions in chemistry and pharmacy. Inventions in biotechnology and biomedicine
4. Writing of the patent and infringement. Read a patent, structure and information of the document. Writing of the patent application, claims. Protection area. Infringement
5. Patent documentation. Importance of documentation in patents. How to locate patents Free and professional databases Examples of searches and retrieval of documents. Interpretation of results. Situation of patents
6. Commercial exploitation of the patent. Business policy Technology transfer, valuation of the patent

Part III.

1. Legislation and associated regulations: basic concepts and definitions.
2. CE marking of conformity. Conformity assessment procedures. Marketing and Market Surveillance System. Advertising
3. Risk management Legislative and regulatory framework. Concepts and definitions. ISO 14971 and ICH Q9 standards. Risk management process. Risk analysis techniques.
4. Quality management systems. Legislative framework ISO 9001, ISO 13485, ICH Q10 and NCF standards. Implementation of quality systems. Quality audits.
5. Legislation on medicines, health products and cosmetics.
6. Legislation on GMOs.

*Unless the requirements enforced by the health authorities demand a prioritization or reduction of these contents.

Methodology

The Subject of Legal Aspects of Biotechnology consists of theoretical classes and analysis and commentaries of proposed cases. The following describes the organization and teaching methodology that will be followed in these two types of training activities.

Theoretical classes:

The content of the theory program will be taught mainly by the teacher in the form of master classes with audiovisual support. Presentations used in class by the teacher will be previously available on the Virtual Campus of the subject. It is recommended that students print this material and take it to class, to use it as a support when taking notes.

Although it is not essential to extend the content of the classes taught by the teacher, unless expressly requested by the latter, it is advised that students regularly consult the books and recommended normative texts in the Bibliography section d 'this teaching guide in order to consolidate and clarify, if necessary, the contents explained in class.

On the other hand, the student will have to work individually the content of the legal texts referred to in this guide. The student will be provided with documents where the full text will appear, as well as a clearing of the normative text in order to facilitate this task.

In addition to the attendance to the classes, the follow-up of the subject will also imply an active role of the student, who will have to analyze and comment on a series of cases and real assumptions related to the contents of the theory program. It is intended that these cases serve to consolidate the contents previously worked in the theory classes and also for the student to develop a critical spirit in the face of ethical and legal problems related to research in Biomedicine. As this comment of the cases will be done in the case of small

work groups, it is intended to promote the habit of teamwork and critical argumentation among peers in the student.

Seminars:

The student will have to analyze and comment on a series of real cases and assumptions related to the contents of the theory program. It is intended that these cases serve to consolidate the contents previously worked in the theory classes and also for the student to develop a critical spirit in the face of ethical and legal problems related to Biotechnology. As this comment of the cases will be done in the case of small work groups, it is intended to promote the habit of teamwork and critical argumentation among peers in the student.

The students will analyze and comment on 2 cases proposed outside the class schedule (corresponding to parts I and III of the subject), in groups of work between 4 and 6 people that the students themselves must train at the beginning of the course and communicate to the teacher. This discussion will be reflected in individual work that students will deliver (two unique deliveries per group) within the established deadlines, work that will be evaluated by the teacher, sharing all the members of the group the same note (group evaluation). Subsequently, the cases will be commented and corrected in sessions of one hour. In the case of the seminar of Part I this discussion will also be evaluated individually.

On the other hand, within the dynamics of the theoretical classes of part II, the professor will propose real choices that the students will have to comment and analyze in a directed way. It is intended that these classes serve to consolidate the contents previously worked in the theory classes and with the resolution of conflicts based on real situations.

*The proposed teaching methodology may experience some modifications depending on the restrictions to face-to-face activities enforced by health authorities.

Activities

Title	Hours	ECTS	Learning Outcomes
Type: Directed			
Case study: general discussion	2	0.08	5, 2, 3, 11, 1, 9, 10, 4, 8, 6, 12
Theoretical sessions	48	1.92	2, 3, 1, 4, 6
Type: Autonomous			
Case study	31	1.24	2, 3, 11, 1, 9, 10, 7, 8, 6, 12
Study	62.5	2.5	5, 2, 3, 11, 1, 9, 10, 4, 7, 8, 6, 12

Assessment

The evaluation of the subject, which will be a continuous assessment throughout the semester, will consist of the following evaluation activities:

1. Partial tests of the theory contents (individual assessment): During the semester there will be three partial written tests on the theoretical contents of the subject, which the students will have to answer individually. There will be a model of these tests on the Virtual Campus of the subject. These tests will consist of a series of objective and semiobjective questions about the corresponding topics of the theory program. The objective questions will usually be questions with multiple option response. Semiobjective questions will be short answer questions, but in which it will be necessary for the student to construct their response and reason.

The objective of these tests is to evaluate not only that students have acquired the conceptual knowledge of the subject but, more importantly, that they have bought them and they know how to integrate and relate to each other. On the other hand, it will also be assessed that students use the right terminology when answering the questions in the exam.

The first test will include part I, the second test will include part II and the third part III. The relative weight of each of these tests on the final mark will be 24%, 36% and 28% respectively.

2. Evaluation of the comments to the proposed cases (group evaluation): The work presented by each group will be evaluated. The fulfillment of delivery times will be considered, so the work presented will not be valid after the discussion of the cases in the seminars.

In the global evaluation, this evaluation will have a 4% weight for the work of part I (distributed by 3.5% group commentary and 0.5% individual interventions in the public discussion) and 8% of the part III.

In order to pass the subject, students must complete the three partial tests. On a total of 10 points, the student must obtain a grade equal to or greater than 4points in each of the three partial tests and a global grade equal to or greater than 5 points for the total of assessment tests of the subject . Students who do not score a minimum of 4 points in any of the partial tests may not pass the subject and receive a maximum final grade of the subject of 4 points.

2. Final Evidence of Recovery (Individual Assessment): In the event that the student obtains a qualification of less than 4 points in any of the partial tests, he will be able to perform a test of recovery of the corresponding contents. Students who, having passed the partial tests, want to improve their qualification, will also be able to carry out this recovery test. It must be taken into account, however, that the fact of carrying out this recovery test will imply the resignation on the part of the student of the qualifications obtained in the partial tests.

To participate in the recovery, the students must have previously been evaluated in a set of activities whose weight equals to a minimum of two thirds of the total grade of the subject or module. Therefore, students will obtain the "Non-Valuable" qualification when the evaluation activities carried out have a weighting of less than 67% in the final grade

NOT EVALUATION: The student will receive the non-evaluable qualification when when the assessment activities carried out have a weighting of less than 67% in the final grade.

Review of exams
The review of exams will be done by appointment and within the schedule proposed by the teacher.

*Student's assessment may experience some modifications depending on the restrictions to face-to-face activities enforced by health authorities.

Assessment Activities

Title	Weighting	Hours	ECTS	Learning Outcomes
Case discussion assessment. Part I	4%	1	0.04	3, 9, 10, 4, 7, 8, 12
Case discussion assessment. Part II	8%	1	0.04	3, 9, 10, 7, 8, 6, 12
First theoretical test: Part I	24%	1	0.04	5, 3, 9, 4, 7, 8, 12
Second theoretical test: Part II	36%	1.5	0.06	5, 2, 3, 11, 1, 9, 10, 7, 8, 12
Third theoretical test: Part III	28%	2	0.08	5, 9, 10, 7, 8, 6, 12

Bibliography

Basic Bibliography:

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• Egozcue J., Shenfield. F. (eds.). Responses to human cloning. Sèrie Jornades Científiques nº 5. Institut d'Estudis Catalans. Barcelona. 1998.

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• Patents for Chemicals, Pharmaceuticals and Biotechnology: Fundamentals of Global Law, Practice and Strategy. Phillip W Grubb. 4a Edició.

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• Sánchez-Caro J., Abellán F. (eds.) Investigación Biomédica en España. Aspectos Bioéticos, Jurídicos y Científicos. Fundación Salud 2000 y Editorial Comares. Granada. 2007.

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• Steinbock B. (ed.). The Oxford Handbook of Bioethics. Oxford University Press. Oxford. 2007.

Enllaços web:

Agencia Española del Medicamento y Productos Sanitarios: http:/www.aemps.es/

Boletín Oficial del Estado: http://www.boe.es/

Berman Institute of Bioethics: http://www.bioethicsinstitute.org/

Clinical Trials: http://www.clinicaltrials.gov/

Comissió d'Ètica en Experimentació Animal i Humana de la UAB: http://www.recerca.uab.es/ceeah/

Comité de Bioética de España: http://www.comitedebioetica.es/

EuroBioBank: http://www.eurobiobank.org/

Observatori de Bioètica i Dret: http://www.pcb.ub.es/bioeticaidret/

The European Group on Ethics in Science and New Technologies: https://ec.europa.eu/research/ege/index.cfm

Stanford Encyclopedia of Philosophy: http://www.science.uva.nl/%7Eseop/

The Hasting Center: http://www.thehastingscenter.org/

The Hinxston Group: http://www.hinxtongroup.org/

European Patent Academy: http://www.epo.org/about-us/office/academy.html

Fundació Grífols: http://www.fundaciogrifols.org/es/web/fundacio/home

OEPM: http://www.oepm.es

Web oficial de la Generalitat de Catalunya: http:/www.gencat.cat/

Web oficial de la Unió Europea: http:/www.europa.eu/

WIPO: http://www.wipo.int