



# **SOCIAL AND LEGAL ASPECTS OF BIOTECHNOLOGY GUIDE**

## **Course 2016-17**

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## 1. Descriptive Details.

<b>Name of the subject: Social and Legal Aspects of Biotechnology</b>	
<b>Code: 9970001404 / MBAF001605</b>	
<b>Degree program: Biotechnology / Pharmacy-Biotechnology</b>	
<b>Year in which is taught: 4º Biotechnology / 6º Pharmacy-Biotechnology</b>	
<b>ECTS credits: 6</b>	<b>Amount of classroom´s hours: 69 h</b> <b>Study mode: Classroom</b>
<b>Regulatory prerequisites:</b>	<b>Recommended: N/A</b>
<b>Teacher´s name: Emanuele Valenti</b>	
<b>Academic advising /guidance: Tuesday 11.30h. Email appointment req.</b>	

## 2. Contextualization of the content and skills of the subject.

Legal and Social Aspect applied to Biotechnology is a mandatory subject of 6 credits in the first trimester of the degree in Biotechnology. This course is part of the area Social & Economic Aspects of Biotechnology corresponding to 30 ECTS.

The overall goal of the course is the knowledge of legal and social aspects related to research and biotechnology.

## 3. Specific Skills

When completed (this course) the student should be capable to:

1. Analyze ethical issues in pharmaceutical profession
2. Identify professional responsibility in relation to the ethical and legal responsibility
3. Manage civil and individual ethics in the biomedical research
4. Respect ethical requirement of confidentiality and informed consent



5. Identify best practices in clinical research
6. Know professional deontology in reason of ethical and legal frameworks available in pharmaceutical world
7. Approach ethical and legal issues of research involving human beings
8. Prepare a research protocol respecting ethical and legal requirements
9. Know public and environmental health issues in order to promote, prevent individual and public diseases, contributing to the public health education in relation to the following aspects: genetics, gender, life style, demography, environment, society, economy, psychology and culture
10. Use and apply ethical, legal and economic frameworks in relation to the health care and drugs
11. Respect of ethical, deontological and legal requirements in order to collaborate with other professionals and contribute to the successful team strategy
12. Know technical and management skills related with a more general dimension of the profession
13. Identify principles and methodology applied to the pharmaceutical science, including history and social function of pharmacy
14. Basically know the National Health System, the laws related to the confidentiality respect, and the use of drugs and pharmaceutical care

#### **4. General Skills (UEM cross-disciplinary skills)**

1. Values, attitudes and professional strategies: identify and manage values involved in pharmaceutical research, societal and legal responsibilities related to the exercise of professional life
2. Evaluation: understanding the more general ethical codes related to pharmaceutical research and consider legal aspects regulating national and international clinical trials
3. Critical approach: evaluation of the economical and societal impact of pharmaceutical research in order to exercise professional responsibility in relation to the cultural and environmental consequences of the pharmaceutical professionalism
4. Information: use the general and specific sources of information in order to consider ethical and legal issues of pharmaceutical world



## **5. Contents** *(close number of ECTs appears in brackets)*

### **TOPIC 1. ETHICAL FRAMEWORK ON 20TH CENTURY**

Deontological ethics, consequentialist ethics and the ethics of responsibility

### **TOPIC 2. JUSTICE AND GLOBALIZATION**

The concept of justice; liberalism, socialism, utilitarianism, neoliberalism and globalization

### **TOPIC 3. GENETIC ENGINEERING AND GENIC THERAPY**

Eugenics, genetic counseling, genetic manipulating, cloning

### **TOPIC 4. THE BEGINNING OF LIFE**

Embryos ethics and abortion

### **TOPIC 5. TREATMENT AND REPRODUCTIVE SELECTION**

In vitro reproduction, stem cells, enhancement

### **TOPIC 6. THE IMPACT OF BIOTECHNOLOGY ON THE BODY**

Transplants and xenotransplants

### **TOPIC 7. NEUROETHICS**

Research ethics and neurosciences

### **TOPIC 8. ETHICS COMMITTEE**

Clinical ethics and research ethics, legal regulation in US, European Union and Spain

### **TOPIC 9. INTRODUCTION TO THE ADMINISTRATIVE LAW**

Definition and sources of administrative law

### **TOPIC 10. NATIONAL BIOTECHNOLOGY REGULATION**

Constitutional foundations, Law 42/1988, Law 815/1994, role of Autonomic Community on biosafety, Spain's Pharmaceutical and Health Care Product Agency



#### **TOPIC 11. INTERNATIONAL BIOTECHNOLOGY REGULATION**

European Directives (89/556/ECC), (90/220/ECC), Directive 2001/18 EC, Regulation EC 1830/2003, Directive 2010/63/UE on research with plants and animals, European Agency of Pharmaceutical Product, The VII Framework on Research

#### **TOPIC 12. INTELLECTUAL PROPERTY**

Introduction to intellectual and industrial property, Political and moral arguments on the intellectual property in biotechnology

#### **TOPIC 13. LEGAL AND INTERNATIONAL FRAMEWORK OF THE INTELLECTUAL PROPERTY**

Paris Convention, European Trade-Mark Convention, European Office of Trademark, The cooperation treaties and WIPO, Budapest Treatise, the Convention on Biodiversity UNCED

#### **TOPIC 14. LEGAL FRAMEWORK OF INTELLECTUAL PROPERTY IN SPAIN**

Harmonization process in European Union States member and Directive (98/44), Spanish legislation: 11/1986 on trade-mark, Intellectual Property Law (1987), Law on the protection and plants productions (1975) and its actualization 3/2000

#### **TOPIC 15. DATABASE AND TRADE-MARK**

Requirements to use intellectual property

#### **TOPIC 16. THE CONCEPT OF INVENTION AND DISCOVERY**

Classification of the invention in biotechnology: invention in human and animal health, plants and environment

## **6. Training's Activities**

The training activities, which will be carried out in order to facilitate the mixture of the different topics along the entire subject, will include the following activities:

- **Lectures:** we will follow the seminar methodology exposing each topic before exposing theory and then approaching a specific practice case, in order to stimulate a common discussion around the group
- **Problem based learning:** we will consider an ethical case conforming to the topic previously introduced. Students we will use deliberative



methodology in order to analyze the case and manage the case following a specific model of moral reasoning.

- **Driven discussion:** the analysis of the case proposed will stimulate a discussion around the topic identifying students' proposals to approach the ethical issues and a general debate on the national and international circumstances influencing the ethical case, with strong reference to legal and societal framework.
- **Narrative:** narrative methodology will stimulate discussion and learning of the most important aspect of the subject: role play, simulation of conflictive circumstances of the professional life, use of video facilitating the understanding of the topic, analysis of the text and scientific material

## 7. Teaching's Methodologies

Teaching methodology involves a mixed system of strategies such as Theory lecture, Case Based Learning, Deliberative Methodology along with power point presentation, and paper writing, as well as the use of moodle on-line platform resources as support for the activities of teachers and students. Of course, all activities will be supported by a bibliography and updated web resources, scientific rigor available to students.

## 8. Assessment's Procedures

**Objective evaluation:** it consists in the 60% of the final mark and evaluates the specific knowledge of the student in relation to the theory and topic lectured in the classroom. Evaluation up 5/10 will be enough to pass this part.

**Active methodology:** it consists in 40% of the final mark and evaluates students' performances to interact with the group, present lecture and discuss ethical aspects of an assigned topic. Evaluation up 2/4 will be enough to pass this part

Attendance to lecturers is mandatory being necessary **at least to justify 50% attendance** in order to receive academic guidance and support by the teacher. Otherwise, assistance and guidance by the teacher might be refused. Additionally, inability to prove minimum level of students' attendance allows the teacher to reject them to perform the knowledge tests of the ordinary call.



To achieve this point and to know their attendance's levels, the students have to register themselves by means of the GPR electronic system, which is supplied by the University and located at the entry of each classroom. The system represents a key tool to warranty the active role of the students.

### Assessment Scheme According To Indicated Training Activities:

100%	Knowledge Tests:	Test and/or short questions	60%
	Scientific Papers and Problems	Activities, scientific articles, Blackboard Chats	40%

## 9. Materials and Other Considerations

Materials: Digital whiteboard, documentary material, collaborative activities and case studies. Biochemistry and molecular biology's lab material.

### References:

#### Fundamental references

- Sánchez González MA. Ética, bioética y globalidad. Madrid, CEP, 2006.
- Gracia D. Fundamentos de bioética. 2ª ed, Madrid, Triacastela, 2007.
- Sánchez Caro J. Investigación biomédica en España: aspectos bioéticos, jurídicos y científicos. Granada, Comares, 2008.
- Sánchez Caro J. Medicina genética clínica del siglo XXI: consideraciones científicas, éticas y legales. Granada, Comares, 2008

#### Complementary References

- Scherlock R, Murray JD eds. Ethical Issues in Biotechnology. Lanham, Rowman & Littlefield, 2002
- Goldberg R, Lonbay J eds. Pharmaceutical Medicine, biotechnology and European law. Oxford, Oxford University Press 2000



## **10. Course work Outline (only indicative)**

## **11. Resources**

Education material will be provided in classroom or through virtual campus.