



Universitat de Lleida

DEGREE CURRICULUM
**BIOENTERPRISE
MANAGEMENT AND ETHICS
AND SOCIAL ASPECTS**

Coordination: RAMOS GIRONA, ANTONIO JAVIER

Academic year 2021-22

Subject's general information

Subject name	BIOENTERPRISE MANAGEMENT AND ETHICS AND SOCIAL ASPECTS			
Code	101624			
Semester	ANUAL CONTINUED EVALUATION			
Typology	Degree	Course	Character	Modality
	Bachelor's Degree in Biotechnology	3	COMPULSORY	Attendance-based
Course number of credits (ECTS)	10.5			
Type of activity, credits, and groups	Activity type	PRALAB	PRAULA	TEORIA
	Number of credits	0.1	1.2	9.2
	Number of groups	4	2	1
Coordination	RAMOS GIRONA, ANTONIO JAVIER			
Department	FOOD TECHNOLOGY			
Teaching load distribution between lectures and independent student work	Face-to-face classes: 34.4% Non-contact classes: 65.6% Class hours: 105h Student work hours: 157,5h			
Important information on data processing	Consult this link for more information.			
Language	Catalan 50% Spanish 50%			

Teaching staff	E-mail addresses	Credits taught by teacher	Office and hour of attention
DEL RÍO MONGE, ÁNGEL ANTONIO	angel.delrio@udl.cat	2,5	
ELEZ MARTINEZ, PEDRO	pedro.elez@udl.cat	2,6	
JUAREZ RUBIO, FRANCISCO	francisco.juarez@udl.cat	2	
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Subject's extra information

Management of biocompanies and legal and ethical issues, is a compulsory subject that aims to provide an overview of the business world linked to the biotechnology field. Thus, the course addresses both aspects of business management organization, and management of innovation and quality requirements and legal considerations, and ethical, social and cultural implications.

Learning objectives

The student of this topic must:

- Become familiar with the basic principles of business administration, with particular emphasis on the aspects of planning, organization and management.
- Be aware of techniques of planning, organization, direction, control and management of human resources, as well as with the administrative environments in which research and development takes place.
- Be able to describe the environment for innovation.
- Demonstrate knowledge of fundamentals of creating biocompanies.
- Know and use the production, quality and project management in a biotech company
- Know in its essential aspects different standards that converge in the regulation of biotechnology.
- Take a critical awareness of the evolution of biotechnology from a legal perspective, taking into account the various interests involved and the various existing approaches.
- To reflect the role that biotechnology plays in society, both from an ethical point of view, as socio-economic and cultural.

Students must be able to:

- Learn to manage innovation activities in bio-business.
- Know how to manage research projects.

- Describe and implement various concepts, methods and techniques of quality management and food security
- Apply HACCP to the food industry
- Describe and analyze the role of the administration and legislation on food safety.
- Describe and implement the program of quality assurance in a laboratory.
- Distinguish between different sources of law, order and interpret its application the basic legal concepts.
- Discuss in public about the advantages and disadvantages of biotechnological inventions.
- Critically assess an enquiry about the social perception of biotechnology.
- Actively participate in a colloquium on a documentary or film related to biotechnology.

Competences

General skills

GC1 Being able to selectively search for and use sources of information necessary to achieve the training objectives.

GC3 Working in a team, with a multidisciplinary vision and with the ability to make a rational and efficient distribution of tasks among team members.

GC8: Being able to form a critical judgment on the implications of biotechnology at an ethical, legal and environmental level.

GC9: Being able to develop a professional activity in accordance with safety and environmental regulations and with ethical criteria.

Transversal skills

CT1 Being able to produce comprehensible written and oral reports on the work carried out, with a justification based on the theoretical-practical knowledge obtained.

Specific skills

CE36 Have an integrated vision of the development process of a biotechnological product or application, incorporating the socio-economic and market aspects of the process.

CE37 To know how to use production management, quality management and project management in a biotechnology company.

CE38 To know the legislation related to the obtaining and dissemination of new products, as well as the evaluation of biotechnological risks.

CE39 To know how to search and obtain information from patent databases and the process of applying for a new patent.

CE40 Be able to critically judge public information on biotechnological innovations and the associated risks and to debate on these issues with scientifically based criteria.

CE41 To know how to design a prospective market research for a specific biotechnological product.

CE42 To know the mechanisms and particularities of the creation of biocompanies.

CE43 Be able to critically interpret the different ethical positions related to the application of biotechnology.

Subject contents

I. Business Administration (Prof. F. Juárez).

Unit 1. Definition of Directors. Administrative functions. Administrative skills. Productivity, effectiveness and efficiency.

Unit 2. Management as science and art. Evolution of management thought. Taylor, Fayol, Mayo, Roethlisberger.

Unit 3. Administration and society: external environment and responsibility. Economic, technological, social, political and legal conditions. Social responsibility of the administrators. The ethics of the administration. Confidence as the basis for a new administration.

Unit 4. Management and international corporations. Administration in specific countries. Comparative and competitive advantages. Porter competitive advantage.

Unit 5. Organization. Nature of the organization. Functional matrix organization, project. Formal and informal organization. Organizational and management levels. Factors that determine an effective stretch. Structure and process organization.

Unit 6. Departmentalization. Matrix organization. Strategic business units, global organizations, virtual organizations.

7. Authority subject line / staff. Types of authority. Concept line and staff. Empowerment and decentralization. Delegation of authority.

Unit 8. Errors in organization. Promoting appropriate organizational culture.

Unit 9. Planning. Types of plans. Objectives. The process of management by objectives.

Unit 10. Nature and purpose of strategies and policies. Strategic planning process. TOWS matrix. Hierarchy of strategies.

II MANAGEMENT OF INNOVATION AND QUALITY IN THE BIOTECHNOLOGY INDUSTRY (Prof. P. Élez).

Unit 11. Introduction to innovation. Definition and concept innovation. Classification of innovations. Advantages of innovation. Key factors to innovate. Innovation systems.

Unit 12. Innovation Management. Definition and concepts. Models of management systems of innovation.

Unit 13. strategic dimension of innovation. Innovation as a strategy. Technology strategy. Technological diagnosis. Strategic technology plan. Transfer and dissemination of technology.

Unit 14. Identification of innovative ideas. Creativity and innovation. Technology watch, benchmarking, competitive intelligence.

Unit 15. Development of innovation projects. Management of innovation projects. Innovation and financing.

Unit 16. Exploitation of innovation performance. Assurance innovation. Exploitation of innovation. Knowledge management.

Unit 17. Creating biocompanies topic. Introduction. Business plan. Company kick-off.

Unit 18. Quality Management. Quality: definition, importance. Quality management system. Standardization of quality in the industry.

Unit 19. Rules assurance and quality management in the industry. Quality management standards: ISO 9000 Environmental management standards: ISO 14000 Standards health and safety management at work: OHSAS 18000 integrated management systems: quality, environmental, and safety and health at work.

III QUALITY MANAGEMENT AND FOOD SAFETY (Prof. A. Teixidó)

Unit 20.- Definition of quality. Food fraud. Food Security. Social perception. Consumer protection. European legislation: hygiene package of the European Union. Risk Analysis. Dangers present in food. Prerequisites in the industry.

Unit 21.- Hazard Analysis and Critical Control Points system (HACCP/APPCC) in the biotechnology industry. Objectives of the system. Codex Alimentarius Principles. Elements of the system. Benefits and specific problems. Sequence of system application. Planning and Preparation of the system. Development of the HACCP system. Verification of the operation and efficiency of the system. Registry and documentation of the system. Checking, surveillance or monitoring. Application of the HACCP system to practical cases.

Unit 22.- Traceability systems. Current legislative situation. Support technologies. Coding of products. Certification Systems. Quality certifications (ISO 9001) and food security (ISO 22000, FSSC22000). Objective. Certification process. Audits Food product certification: ISO 22000, FSSC 22000, BRC, IFS and GlobalGAP. Quality management in laboratories. ISO 17025. Good laboratory practices.

IV LEGAL ASPECTS OF BIOTECHNOLOGY (Prof. A. del Río)

Unit 23. Introduction. The mission of the law in the field of biotechnology and the main obstacles are. The various

applications of biotechnology and its translation to the law. General and sectoral Biotechnology Law. The sources of law in Biotechnology. The relevance of international sources. The sources of national character. Biotechnology as an object of division of powers between the State and the Autonomous Communities.

Unit 24. The human rights and biotechnology. The dignity of the human person. Freedom. The principle of consent. Equality and non-discrimination for genetic reasons. The right to dispose of one's genetic information. The right to participate in the progress of biotechnology and its derivatives.

Unit 25. The human rights and biotechnology. Concern for human rights in the vicinity of the Biotechnology and its reflection at international and national level. The Oviedo Convention. The UNESCO declaration. The Charter of Fundamental Rights of the European Union. The dignity of the human person as a cornerstone. Freedom. The principle of consent. Equality and non-discrimination for genetic reasons. The right to dispose of one's genetic information. The right to participate in the progress of biotechnology.

Unit 26. Biomedical research topic (I). The regulatory framework of biomedical research. Principles and limits of biomedical research. The control of biomedical research. Ethics Committees. The Bioethics Committee of Spain.

Unit 27. Biomedical research topic and its connection with the assisted human reproduction (II). The right to life. The embryo as a constitutionally protected right. The techniques of assisted human reproduction. The pre-embryo in vitro. Preimplantation diagnosis and selection of pre-embryos in vitro. The use of in vitro pre-embryos for research purposes.

Unit 28.- The protection of genetic data. Concept and characteristics of personal genetic data and its various applications. The need for qualified protection. The identification through DNA and its judicial applications. Genetic analysis and medical applications. The ban on commercial applications of DNA analysis.

Unit 29. Genetically modified organisms from a global and European perspective. The diversity of responses of States to the transgenic plant. The position of the World Trade Organization. The position of the World Health Organization. The position of the European Union. Directives on transgenic plants. The resistance of some States of the European Union to the directives on plant GMOs.

Unit 30. The legal status of GMOs in Spain. The Genetically Modified Organisms Act 2003 and its implementing regulation. The role of regional legislators. The basic in the legal treatment of transgenic plants principles. The importance and control modes towards safety. Transparency and public participation in the approval of transactions with transgenic plants. The regime of the contained use. The system of deliberate release. Marketing. The procedure at Community level.

Unit 31.- The patent biotechnology. On the significance and importance of industrial property, and its various manifestations. The regulatory framework for biotechnology patent. The Munich Convention. The directive on biotechnology patents. The Spanish Patent Act. Concept and requirements of biotech patent. Limits and bans on biotech patent. In particular, public order and its projection on biotechnological inventions.

V. ETHICAL AND SOCIAL ASPECTS OF BIOTECHNOLOGY (Prof. AJ Ramos)

Unit 32.- The social and ethical implications of research in areas related to biotechnology. Bioethics and Biotechnology. Bioethics in animal and human reproductive technologies. Cloning. Biotechnology and Religion. Public perception of biotechnology. Protection of genetic privacy. Presence of Biotechnology in culture: literature and cinema.

Unit 33.- Social and scientific positions in relation to genetically modified organisms. Biotechnology and Sustainable Agriculture. Biotechnology and Environment. Biotechnology and Biodiversity. Gene Pollution and its implications. Risks and Safety in the use of GMOs. The confrontation between scientists and environmental organizations.

Practical lessons

Section I (Prof. F. Juárez)

Individual works:

- Test at the beginning of each class using Socratic.
- Analysis and discussion of three articles about research management.

Collective work (practice organization):

- In groups of 5 students: work on a topic of applying their knowledge to the business. All groups of 5 students are coordinated by a directive group, to obtain the final work, which is a synthesis of the different advances in each

group.

Section II (Prof. P. Élez)

- Workshop on entrepreneurship and innovation.
- Workshop on creativity.
- Seminar on quality systems.

Section III (Prof. A. Teixidó)

- Problems/cases on the HACCP system in biotechnology industries. Compulsory activity to be able to pass the course.
- Seminar on quality assurance in a laboratory. ISO 17025. Compulsory activity to be able to pass the subject

Section IV (Prof. A. del Río)

- Learning in the search for standards and the location of judgments.
- Debate on the legal use of supernumerary pre-embryos for scientific research.
- Judgment simulation regarding a case of environmental pollution by GMO cultivation.

Section V (Prof. AJ Ramos)

- Realization and interpretation of a inquiry on the level of awareness of the public about biotechnology issues (mandatory to pass the course).
- Participation in a debate on advantages and disadvantages of GM foods (mandatory to pass the course).
- *Cine-forum* about a movie that will focus on the genetic determinism and/or ethics in the world of biotechnology (mandatory to pass the course).

Methodology

Due to the special circumstances derived from the health crisis caused by COVID-19, this subject will have both face-to-face classes and virtual teaching. In principle, exams, seminars and some practical activities (debates). In the event that the circumstances evolve towards a change in attendance, it will be reported in due course.

Development plan

Course 2021-2022

FIRST SEMESTER

Month	Day	Hour	Teacher
September	13-Monday	15.00-16.50h	AR 2
	17-Friday	17.10-19.00h	FJ 2
	20-Monday	15.00-16.50h	PE 2
October	1-Friday	17.10-19.00h	FJ 4
	7-Thursday	15.00-16.50h	PE 4

	11-Monday	15.00-16.50h	FJ 6
	13-Wednesday	17.10-19.00h	PE 6
	18-Monday	15.00-16.50h	FJ 8
	19-Tuesday	10.10-12.00	PE 2 GM A
	21-Thursday	17.10-19.00h	PE 4 GM B
	25-Monday	15.00-16.50h	FJ 10
	28-Thursday	15.00-16.50h	PE 8
November	11-Thursday	17.10-19.00h	FJ 12
	15-Monday	15.00-16.50h	PE 10
	16-Tuesday	17.10-19.00h	PE 6 GM A
	17-Wednesday	17.10-19.00h	PE 8 GM B
	24-Wednesday	17.10-19.00h	FJ 14
	25-Thursday	15.00-16.50h	PE 12
	30-Tuesday	17.10-19.00h	FJ 16
December	2-Thursday	17.10-19.00h	PE 10 GM B
	9-Thursday	17.10-19.00h	PE 14
	10-Friday	17.10-19.00h	PE 12 GM A
	14-Tuesday	17.10-19.00h	FJ 18
January	11-Tuesday	15.00-16.50h	FJ 20
	14-Friday	15.00-18.00h	Exame PE

TEACHERS

AR: Antonio J. Ramos. Dpto. Tecnologia d'Aliments.

FJ: Francisco Juarez. Dpto. AEGERN.

PE: Pedro Élez. Dpto. Tecnologia d'Aliments.

SECOND SEMESTER

Month	Day	Hour	Activity	Teacher
February	8-Tuesday	15.00-16.50h	GG	AT 2
	10-Thursday	17.10-19.00h	GG	AT 4
	15-Tuesday	17.10-19.00h	GG	AT 6
	17-Thursday	15.00-16.50h	GG	AT 8

	21-Monday	15.00-16.50h	GG	AdR 2
	22-Tuesday	17.10-19.00h	GM Grupo A	AT 2 GM
	23-Wednesday	17.10-19.00h	GM Grupo B	AT 4 GM
	24-Thursday	17.10-19.00h	GG	AT 10
	25-Friday	15.00-16.50h	GG	AdR 4
March	1-Tuesday	15.00-16.50h	GG	AdR 6
	2-Wednesday	17.10-19.00h	GM Grup A	AT 6 GM
	3-Thursday	17.10-19.00h	GM Grup B	AT 8 GM
	4-Friday	15.00-16.50h	GG	AdR 8
	8-Tuesday	17.10-19.00h	GG	AT 12
	9-Wednesday	17.10-19.00h	GM Grup B	AT 10 GM
	11-Friday	15.00-16.50h	GM Grup A	AT 12 GM
	15-Tuesday	17.10-19.00h	GG	AT 14
	16-Wednesday	15.00-16.50h	GG	AdR 10
	17-Thursday	17.10-19.00h	GG	AdR 12
	21-Monday	15.00-16.50h	GG	AdR 14
	24-Thursday	15.00-16.50h	GG 3.0.02	AdR 16
	30-Wednesday	15.00-19.00 h	Exam (3.1.07)	Bloc AT
April	21-Thursday	15.00-16.50h	GG	AdR 18
	25-Monday	15.00-16.50h	GG	AR 4
	27-Wednesday	15.00-16.50h	GG	AdR 20
	29-Friday	15.00-16.50h	GG	AR 6
May	2-Monday	15.00-16.50h	GG	AdR 22
	4-Wednesday	15.00-16.50h	GG	AR 8
	6-Friday	15.00-16.50h	GG	AdR 24
	12-Thursday	15.00-15.50h	GG	AdR 25
		16.00-16.50	GG	AR 9
	16-Monday	15.00-16.50h	GG	AR 11
	19-Thursday	15.00-16.50h	GG	AR 13
	23-Monday	15.00-16.50h	GG 3.0.02	AR 15
	25-Wednesday	15.00-16.50h	GG	AR 17
	26-Thursday	9.00-9.50h	GP III (debate) 3.1.08	AR 1 GP
		10.10-11.00h	GP II (debate) 3.1.08	AR 2 GP
		11.10-12.00h	GP I (debate) 3.1.08	AR 3 GP
		12.10-13.00h	GP IV (debate) 3.1.08	AR 4 GP
	27-Friday	15.00-16.50h	GG (cineforum) Sala de Graus	AR 19

June	6-Monday	15.00-18.00h	Exam (3.1.07)	AdR+AR
	27-Monday	15.00-18.00h	Exam	Final exam

The classroom is always 3.1.07, unless otherwise indicated in the schedule.

TEACHERS:

AT: Aurora Teixidó. Dpto. Tecnologia d'Aliments.

AdR: Ángel del Río. Dpto. Dret Públic.

AR: Antonio J. Ramos. Dpto. Tecnologia d'Aliments.

Evaluation

GENERAL COMMENTS ON THE EVALUATION

The course consists of 5 thematic sections that are evaluated independently. The note of each section accounts for 20% of the final mark of the course. To pass the course, you must have a global evaluation of each 5.0, but in any case the course will be approved if in the evaluation of some of the 5 sections the grade obtained was lower than 4.0.

Students who score less than 4 in any of the tests could go to the recovery exam, but in this exam they must obtain at least 5.0 to average for the rest of notes that section.

In principle, the evaluation will follow what is described below. In the event that due to restrictions caused by the health crisis, the planned face-to-face evaluations cannot be carried out, alternative evaluations will be carried out in person.

SPECIFIC COMMENTS ON EVALUATION

Section I (20%)

- Discussion of papers: 15% of the note.
- Test of the different units: 40% of the note.
- Group work: a) classification of administrative aspects: 15%, b) original information aspects of the report 30%.

Section II (20%)

1 exam of 2h on the contents explained in class: 70% of the mark. This part of the course will be suspended if an equal or higher than 4 out of 10 is not obtained in this test.

Active participation and resolution of practical cases in seminars: 30% of the mark

Section III (20%)

1 exam, of 2.5 hours of duration, on the theoretical contents explained in class and the resolution of a problem or case of HACCP (85% of the mark).

Active participation and presentation of a practical work on the knowledge acquired in the application of a HACCP plan of a food preparation process (15% of the mark).

In the case of not being able to carry out the face-to-face evaluation, the evaluation will be carried out as follows:

- Theory: by carrying out and delivering activities on theory and seminars explained, sent through the Virtual Campus. Value: 75% of this part.
- Practices: delivery of a practical work on HACCP. Value: 25% of this part.

Section IV (20%)

The evaluation of this section have 2 elements:

A. The first (60%) is the result obtained in the theoretical exam to be held at the end of this part. This will consist of 3 questions (1 hour total). The questions attempt to capture not only the memorization of content, but also understanding and internalization of meaning and virtuality of the institutions. Passing this test will require obtaining at least a 4.0.

B. In second place (40%), the student must successfully pass the resolution of a practical test that you will consider a case from which must resolve a number of issues, among two- and three- in, approximately, 1 hour. To carry out this test, the student will have available all the standards required whenever the objective sought is to be able to work on the basis of an assumption: I subsume the norm, order supplies, draw conclusions legal and, ultimately, provide a reasoned, coherent and answer legal basis. To successfully pass this test is essential to have previously practiced through case studies that will be resolved during the course. As in the theoretical test, also here it will require overcoming the score of 4.0.

Section V (20%)

- 1 exam on the theoretical contents explained in class (exam with 2 short questions: 60% of the mark). It is necessary to obtain a 4 out of 10 in this exam in order that this mark averages with the mark of the other activities in this section.

- Active participation in the debate: 20% of the mark. Mandatory attendance activity, either in person or virtually.

- Presentation of poll results: 10% of the mark. If it can be done in classroom, the presentation of results will be made public. If it cannot be done in person, a power point will be delivered with recorded audio in which the group will explain the results of the survey.

- Cineforum: attendance and subsequent debate, 10% of the mark. This activity is planned to be carried out in classroom, in which case it will be of compulsory attendance. In the case of not being able to do it in this way, the film will be viewed by the student and a questionnaire that will evaluate the academic achievement of the activity must be sent, whose value will also be 10% of this section.

Regarding the repeating students of the subject, it is only necessary to re-take the modules in which they have obtained overall less than 5.0 or in which theoretical examinations have obtained less than 4.0 in the first call or less than 5.0 in the recovery. The note applied will be 5.0 in each module that does not repeat, and can again take the module if you wish to obtain a higher note. This note reservation only applies to an academic course.

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Complementary references

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