



Universitat de Lleida

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

Coordination: RAMOS GIRONA, ANTONIO JAVIER

Academic year 2023-24

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, ENGINEERING AND SCIENCE			
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	Antonio J. Ramos: Spanish M. Mercè Clop: Catalan Pedro Élez: Spanish Aurora Teixidó: Catalan Ángel del Río: Spanish Catalan 40% Spanish: 60%			
Distribution of credits	Antonio J. Ramos: 19% (coordinator) M. Mercè Clop: 19% Pedro Élez: 19% Aurora Teixidó: 19% Ángel del Río: 24%			

Teaching staff	E-mail addresses	Credits taught by teacher	Office and hour of attention
CLOP GALLART, MARIA MERCE	mariamerce.clop@udl.cat	2	By appointment
DEL RIO MONGE, ANGEL ANTONIO	angel.delrio@udl.cat	2,5	By appointment
ELEZ MARTINEZ, PEDRO	pedro.elez@udl.cat	2,6	By appointment
RAMOS GIRONA, ANTONIO JAVIER	antonio.ramos@udl.cat	2,3	By appointment
TEIXIDÓ JOVÉ, AURORA	aurora.teixido@udl.cat	2,6	

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. M.M. Clop).

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

Unit 2. Administration and society: external environment and responsibility. Economic, technological, social,

political and legal conditions. Social responsibility of administrators. The ethics of administration. Trust as the basis for a new administration.

Unit 3. International administration and multinational corporations. Alliances between countries and economic blocks. International administration: cultural differences and between countries. Comparative and competitive advantages. Porter's competitive advantage of nations.

Unit 4. Direction. Human factors and motivation. Human factors in administration. Motivation and motivation theories. Special motivation techniques. Job enrichment.

Unit 5. Leadership. Definition and components. Approaches in leadership. Charismatic leadership. Behavior and styles of leadership. Situational or contingency approach to leadership. Transactional and transformational leadership.

Unit 6. Committees, teams and group decision-making. Nature and reasons for using committees and groups. Disadvantages and misuse of committees. The successful operation of committees and groups. Groups. Teams. Conflict in committees, groups and teams.

Unit 7. Communication. Purpose and process of communication. Communication in the organization. Barriers and interruptions in communication. Effective communication. Electronic media in communication.

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

Unit 8. Introduction to innovation. Definition and concept innovation. Classification of innovations. Advantages of innovation. Key factors to innovate. Innovation systems.

Unit 9. Innovation Management. Definition and concepts. Models of management systems of innovation.

Unit 10. strategic dimension of innovation. Innovation as a strategy. Technology strategy. Technological diagnosis. Strategic technology plan. Transfer and dissemination of technology.

Unit 11. Identification of innovative ideas. Creativity and innovation. Technology watch, benchmarking, competitive intelligence.

Unit 12. Development of innovation projects. Management of innovation projects. Innovation and financing.

Unit 13. Exploitation of innovation performance. Assurance innovation. Exploitation of innovation. Knowledge management.

Unit 14. Creating biocompanies topic. Introduction. Business plan. Company kick-off.

Unit 15. Quality Management. Quality: definition, importance. Quality management system. Standardization of quality in the industry.

Unit 16. 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 17.- 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 18.- 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 19.- 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 20. 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 21. Human rights and Biotechnology. The dignity of the human person. The right to personal integrity and liberty. The basic principle of consent. Requirements, limits and special assumptions of consent. Equality and the

prohibition of discrimination for genetic reasons. Formal equality and material equality and protection in Biotechnology. The right to privacy and the protection of personal genetic data.

Unit 22. The general principles in Biotechnology. The precautionary principle. The principle of participation. The principle of transparency. The principle of co-responsibility.

Unit 23. Biotechnological research. The regulatory framework. The Biomedical Research Law. Principles and limits of biomedical research. Control of biomedical research. Ethics Committees. The liability system in clinical trials.

Unit 24. Genetically modified organisms. Genetically modified organisms from a global and European perspective. The Law on genetically modified organisms. The role of regional legislators. The basic principles in the legal treatment of transgenic plants. The importance and modes of control in pursuit of safety. Transparency and citizen participation in the authorization of operations with transgenic plants. The mode of the contained use. The voluntary release regime. Commercialization.

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

Unit 25.- 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 26.- 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. M.M. Clop)

Individual assignments:

- Short tests at the beginning of each class using the "Tests i Qüestionaris" tool of the Virtual Campus.
- Analysis and discussion of three articles on research administration.

Group assignments (Direction practice):

- In groups of 5 students: report on a topic applying their knowledge to the business field.

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

The course methodology will be that of master classes, seminars and practical activities, which include individual and group work, debates, surveys and public presentations. The exams, seminars and some evaluative practical activities (debates) will be face-to-face and compulsory.

Development plan

Course 2023-2024

FIRST SEMESTER

Month	Day	Hour	Professor
September	15-Friday	17.10-19.00h	AR 2
	18-Monday	15.00-16.50h	MC 2
	25-Monday	15.00-16.50h	MC 4
	26-Tuesday	17.10-19.00h	PE2
October	5-Thursday	15.00-16.50h	PE 4
	9-Monday	15.00-16.50h	MC 6
	16-Monday	15.00-16.50h	PE 6
	19-Thursday	17.10-19.00h	PE 2 GM B
		19.10-21.00h	PE 4 GM A
	23-Monday	15.00-16.50h	MC 8
	27-Friday	15.00-16.50h	PE 8
November	9-Thursday	17.10-19.00h	MC 10
	13-Monday	15.00-16.50h	PE 10
	14-Tuesday	17.10-19.00h	PE 6 GM A
	16-Thursday	17.10-19.00h	PE 8 GM B
	22-Wednesday	17.10-19.00h	MC 12
	23-Thursday	15.00-16.50h	PE 12
	28-Tuesday	17.10-19.00h	PE 14
	30-Thursday	17.10-19.00h	PE 10 GM B
		19.10-21.00h	PE 12 GM A
December	5-Tuesday	17.10-19.00h	MC 14
	15-Friday	15.00-16.50h	MC 16

	21-Thursday	15.00-16.50h	MC 18
	22-Friday	15.00-16.50h	MC 20
January	15-Monday	15.00-18.00h	Exame part PE Classroom 3.1.07

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

TEACHERS

AR: Antonio J. Ramos. Dpt. Technology, Engineering and Food Science.

MC: Mercè Clop. Dpt. Economy and Business.

PE: Pedro Élez. Dpt. Technology, Engineering and Food Science.

SECOND SEMESTER

Month	Day	Hour	Activity	Professor
February	6-Tuesday	15.00-16.50h	GG	AT 2
	8-Thursday	17.10-19.00h	GG	AT 4
	13-Tuesday	17.10-19.00h	GG	AT 6
	15-Thursday	17.10-19.00h	GG	AT 8
	19-Monday	15.00-16.50h	GG	AT 10
	21-Wednesday	17.10-19.00h	GG	AdR 2
		19.10-21.00	GM Group A	AT 2 GM
	22-Thursday	19.10-21.00h	GM Group B	AT 4 GM
	23-Friday	15.00-16.50h	GG	AT 12
	27-Tuesday	15.00-16.50h	GG	AdR 4
	28-Wednesday	17.10-19.00h	GM Group A	AT 6 GM
	29-Thursday	17.10-19.00h	GM Group B 3.1.08	AT 8 GM
March	4-Monday	15.00-16.50h	GG	AT 14
	5-Tuesday	17.10-19.00h	GG	AdR 6
	6-Wednesday	17.10-19.00h	GM Group B	AT 10 GM
		19.10-21.00h	GM Group A	AT 12 GM
	7-Thursday	15.00-16.50h	GG	AdR 8
	12-Tuesday	17.10-19.00h	GG	AdR 10
	13-Wednesday	15.00-16.50h	GG	AdR 12
	14-Thursday	17.10-19.00h	GG	AdR 14
April	5-Friday	15.00-19.00 h	Exame (3.1.07)	Part AT

	15-Monday	17.10-19.00h	GG	AdR 16
	17-Wednesday	15.00-15.50h 16.00-16.50j	GG	AdR 17 AR 3
	24-Wednesday	15.00-16.50h	GG	AdR 19
	26-Friday	15.00-16.50h	GG	AdR 21
	29-Monday	15.00-16.50h		AdR 23
May	2-Thursday	15.00-16.50h	GG	AdR 25
	6-Monday	15.00-16.50h	GG	AR 5
	8-Wednesday	15.00-16.50h	GG	AR 7
	13-Monday	15.00-16.50h		AR 9
	15-Wednesday	15.00-16.50h	GG	AR 11
	17-Friday	15.00-16.50h	GG	AR 13
	20-Monday	15.00-15.50h	GG	AR 15
	22-Wednesday	15.00-16.50h	GG Group work	AR 17
	23-Thursday	9.00-9.50h	GP III (debat) 3.1.06	AR 1 GP
		10.10-11.00h	GP II (debat) 3.1.06	AR 2 GP
		11.10-12.00h	GP I (debat) 3.1.06	AR 3 GP
		12.10-13.00h	GP IV (debat) 3.1.06	AR 4 GP
	24-Friday	17.10-19.00h	GG (cineforum)	AR 19
June	7-Friday	15.00-18.00h	Exam (3.1.07)	Part AdR+AR
	25-Tuesday	15.00-18.00h	Exam (3.1.07)	Recovery 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 subject consists of 5 thematic blocks

THEMATIC BLOCK 1.- BUSINESS ADMINISTRATION + INNOVATION AND QUALITY MANAGEMENT IN THE BIOTECHNOLOGY INDUSTRY (Value: 22%). Minimum mark: 4.0. Recoverable.

Activity 1.- Tests of the part of Business administration. Value: 8% of the subject.

Activity 2.- Exam of the Innovation and quality management part. Value: 14% of the subject.

THEMATIC BLOCK 2.- QUALITY MANAGEMENT AND FOOD SAFETY (Value: 17%). Minimum mark: 4.0. Recoverable.

Activity 3.- Theory exam (on the theoretical contents explained in class and the resolution of a HACCP problem or case). Value: 17% of the subject.

THEMATIC BLOCK 3.- LEGAL ASPECTS OF BIOTECHNOLOGY (Value: 20%). Minimum mark: 4.0. Recoverable.

Activity 4.- Theory exam: it will consist of questions for which the student will have approximately 1 hour to answer. The questions will try to capture not only the pure memorization of the contents, but also the understanding and internalization of the meaning and virtuality of the institutions. Value: 12% of the subject.

Activity 5.- Practical case exam: a scenario will be proposed from which a set of questions – between two and three – will have to be resolved within approximately 1 hour. To carry out this exam, the student will have at his disposal all the norms that he needs, since the objective is to be able to work on the basis of an assumption: subsume it in the norm, order the sources, draw consequences and, ultimately, provide a reasoned, coherent and legally-based response. In order to successfully pass this exam, it is essential to have previously practiced through the practical cases that will be solved during the course. Value: 8% of the subject.

THEMATIC BLOCK 4.- ETHICAL AND SOCIAL ASPECTS OF BIOTECHNOLOGY (Value: 12%). Minimum mark: 4.0. Recoverable.

Activity 6.- Theory exam. Value: 12% of the subject.

THEMATIC BLOCK 5.- PRACTICAL ACTIVITIES (Value: 29%). Unrecoverable.

Activity 7.- Active participation in proposed activities in classroom (block 1). Value: 3% of the subject.

Activity 8.- Group work (block 1). Value: 9% of the subject.

Activity 9.- Seminars: active participation and resolution of practical cases (block 1). Value: 6% of the subject.

Activity 10.- Practical work on the application of a HACCP plan for a food industry process: active participation and presentation of a practical work (block 2). Value: 3% of the subject.

Activity 11.- Public debate on transgenics (block 4). Value: 4% of the subject.

Activity 12.- Design, realization and public exhibition of a enquiry on social perception of Biotechnology (block 4). Value: 2% of the subject.

Activity 13.- Attendance and participation in a cineforum (block 4): Value: 2% of the subject.

Unjustified absence to one activity of the block 5 means a zero in this activity.

COPY AND PLAGIARISM: In case of detecting copy and/or plagiarism during the evaluation activities, the activity will be withdrawn and it will be suspended. It may also lead to the opening of a disciplinary file.

JUSTIFICATION OF ABSENCES

In relation to the justification of the absences, the reasons for which the absence is considered justified, will be the same as those stated in the **NORMATIVA DE L'AVALUACIÓ I LA QUALIFICACIÓ DELS APRENENTATGES EN ELS GRAUS I MÀSTERS** for not attending the assessment tests scheduled in the teaching guide or on the degree website.

ALTERNATIVE ASSESSMENT

Realization of 2 exams and 1 student work:

- exam 1: block 1. Minimum mark to pass: 5.0. Exam date: Monday, January 15 at 3:00 p.m. in classroom 3.1.07. Value: 40%.

- exam 2: blocks 2 (value 17%), 3 (value 20%) and 4 (value 20%), separately. Minimum mark to pass: 5.0 in each block. Exam date: Friday, June 7 at 3:00 p.m. in classroom 3.1.07.

- Presentation of a work, during the second term, on the HACCP of at least 2 steps of a food elaboration process, the management dashboard, and the analysis of a CCP, to be agreed with the teacher of block 2. Value: 3%. Unrecoverable.

The blocks that have not been passed will be recovered on Tuesday, June 25 at 3:00 p.m. in the classroom on 3.1.07. Minimum grade to pass each block: 5.0.

Bibliography

Basic references

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Complementary references

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