Teaching guide

IDENTIFICATION DETAILS

Degree:	Biotechnology
Scope	Biology and Genetics
Faculty/School:	Experimental Sciences
Course:	BEST PRACTICES IN R and D AND BUSINESS
Type:	Optional
ECTS credits:	3
Year:	4
Code:	2046
Teaching period:	Seventh semester
Subject:	Company
Module:	Social, Historical and Economic Aspects of Biotechnology
Teaching type:	Classroom-based
Language:	Spanish
Total number of student study hours:	75

SUBJECT DESCRIPTION

Good Practices in R&D must focus on quality, ethics and compliance with a series of principles established for this field of action. Scientific research is an activity based on a principle of trust in which the results obtained by researchers are accepted as valid by the rest of the scientific community and society. In the industry this is not acceptable, and unfortunately there is less “trust” in R&D that is not governed by Good Practices every day. Researchers must be honest about their work and that of other colleagues. This responsibility should extend to all activities related to research, including experimental design, data generation and analysis, the request for public funding, the publication of results, and the recognition of all direct or indirect contributions from colleagues, collaborators, and others. Plagiarism and falsification of results are considered professional malpractice in any field, and may be a reason for sanction or expulsion. When applying for research grants, all information submitted by applicants is expected to be clear and accurate and is in line with this Code of Good Research Practices.

Society trusts science to find solutions to its problems and to discover tools and ways to improve the quality of life of citizens, from this assumption, it promotes and finances it. To maintain this trust, the exercise of science must be responsible, ethically and socially and its progress, of which research is the main engine, must be developed within the strictest integrity. During the course, various ethical issues affecting this R&D activity will be addressed directly. For this reason, there are intergovernmental institutions that deal with the binomial “science-ethics” such as the Council of Europe, UNESCO, the World Medical Association, or the American National Commission for the Protection of Human Subjects in Ethical Research, have developed major collective agreements for the practice of biomedical research and drafted standards or recommendations that address ethical dilemmas that arise with advances in science. The Declaration of Helsinki represents the basic document that biomedical researchers must accept.
During the course, the different quality systems that are mandatory in the health sector will be analyzed. Achieving this quality objective is the responsibility of management and requires the participation and commitment of both personnel from different departments and levels within the company, as well as suppliers and distributors. To achieve this quality objective, there must be a logically designed and correctly implemented Pharmaceutical Quality System. The basic concepts of Quality Management, Applicable Standards and Quality Risk Management are interrelated and their importance is fundamental in the production and control of drugs and all medical devices. A comprehensive view will be offered of the principles, regulations and standards that govern good practices in research and development (R&D), as well as in production and quality processes within the pharmaceutical industry. The course addresses key aspects such as Good Laboratory Practices (GLP), Good Manufacturing Standards (NCF or GMP), Good Clinical Practices (GPC) and Good Documentation Practices, providing students with the necessary tools to perform ethically, safely and in accordance with current regulations in regulated environments.

GOAL

The fundamental objective of this course is for students to learn about the importance of quality and how quality management is carried out in the health sector, from research to the commercialization of biotechnological and pharmaceutical products in human health. Quality Management represents the set of measures adopted in order to ensure that drugs, devices, products for their use are intended for all dimensions from research to the market in order to guarantee the quality and integrity of all products. As well as having an innovative vision of Quality Management in line with the regulatory requirements of the biotechnology sector. The specific objectives of the course will be:
Understand the national and international regulatory framework that governs pharmaceutical research and production.
Apply the principles of good practices in the design, execution and documentation of biotechnological R&D projects.
Familiarize yourself with quality assurance and control processes in the pharmaceutical industry.
Identify the ethical and regulatory challenges associated with the development of biotechnological products and drugs.
Integrate good practices in project management, data management, traceability and regulatory compliance.

The specific aims of the subject are:

The student will learn and work on the processes of monitoring and supervising good research practices for all staff, regardless of their rank, to guarantee excellent research.

Application of the quality management system to all dimensions of the development of pharmaceutical products from R&D to commercialization, in order to guarantee quality and integrity in the R&D, development and

commercialization of medicines.

Identify the quality requirements, voluntary or legal, before the placing on the market or use of a biotechnological product, that are being demanded by that market and that guarantee the safety and efficacy of the product.

Integrate good practices in project management, data management, traceability and regulatory compliance.

PRIOR KNOWLEDGE

Knowledge specific to the Degree

COURSE SYLLABUS

- Introduction to good practices in R&D and the pharmaceutical industry
- Quality, safety and efficacy of the pharmaceutical/biotechnological product.
- Regulatory Requirements: Regulations and regulatory bodies (EMA, FDA, ICH, OMS)
- Bases for organizing a quality system: Development and implementation of a quality management system. Audits, inspections and regulatory compliance.
- Quality in R+D+i: Quality processes in Research, GLP's, GMP and GCP's.
- Researchers' Responsibilities and Staff Training.
- Ethics and responsibility in pharmaceutical research and development.
- Intellectual property rights and commercial exploitation of research results.
- Quality: reference standards, specific requirements for some products (FDA, EMA...) and tools for managing the quality system.
- Validation: general concepts and development. Systems for improving and evaluating the quality system.
- Quality Risk Management (QRM) - Risk Management.

EDUCATION ACTIVITIES

The classes will be carried out in the theoretical-practical concept, in which learning about theoretical concepts is based on the practical activities carried out by students, both individually and in teamwork groups. In the course, the following methodologies will be developed to carry out student training:
FACE-TO-FACE ACTIVITY/VIRTUAL
Expositive-participatory classes: Classes will be taught in the “inverted class” format, which improves learning in the teacher-student relationship and using class time for better professional interaction of the theoretical contents that students have previously worked on. These classes taught by the teacher will present the theoretical and practical contents of the subject, as well as current topics related to the subject.

Practical classes: Presentation of the final group work related to all the subject taught throughout the course and discussion led by the teacher. Visit to a pharmaceutical plant for biotechnological products where you can observe the operation of everything explained in class.
1. Cooperative learning: in which students will work together on group work to achieve common objectives and maximize their learning.
2. Problem solution-based learning: actively involves students by learning knowledge and skills through the presentation of a contextualized problem or complex situation that reflects reality as best as possible.
AUTONOMOUS WORK
Student study of the lessons explained in the expositive-participatory classes
Carrying out work: Preparation of work related to the contents of the subject.
Virtual work on the network of forums to discuss current topics related to the subject.

Tutoring: personalized attention to the student to review the contents explained in class, answer questions or discuss scientific topics related to the contents of the subject. The learning model based on the theoretical-practical methodology actively involves students by learning knowledge and skills through the approach of a contextualized problem or complex situation always based on real cases in the biotechnology sector.

DISTRIBUTION OF WORK TIME

TEACHER-LED TRAINING ACTIVITIES	INDIVIDUAL WORK
30 Horas	45 Horas

SKILLS

Basic Skills

Students must have demonstrated knowledge and understanding in an area of study that is founded on general secondary education. Moreover, the area of study is typically at a level that includes certain aspects implying knowledge at the forefront of its field of study, albeit supported by advanced textbooks

Students must be able to apply their knowledge to their work or vocation in a professional manner and possess skills that can typically be demonstrated by coming up with and sustaining arguments and solving problems within their field of study.

Students must have the ability to gather and interpret relevant data (usually within their field of study) in order to make judgments that include reflections on pertinent social, scientific or ethical issues

Students must be able to convey information, ideas, problems and solutions to both an expert and non-expert audience

Students must have developed the learning skills needed to undertake further study with a high degree of independence

To acquire firm theoretical, practical, technological and humanistic training needed to develop professional activity.

To be aware of the theoretical and practical foundations underpinning the conception of enterprise, its organization, its operation, the obtainment of returns and organisational structure.

To understand the ethical implications of professional and personal activity.

Capacity for teamwork and group management.

To have acquired the ability for analytical, synthetic, reflective, critical, theoretical and practical thought.

To develop capacity for and a commitment to learning and personal development.

To be familiar with the basic principles and theories of human and experimental sciences.

General Skills

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Specific skills

To know in an integrated way the approach and development of an R+D+i process.

Manage current regulations and legislation that regulate biotechnological processes and products.

Know how to apply the techniques and procedures used in quality management and understand the importance of validation, accreditation and certification of biotechnological processes and products.

Cultivate attitudes of leadership and social responsibility in personal and professional performance.

Ability to communicate the knowledge acquired orally and in writing.

LEARNING RESULTS

Know the implications of the correct implementation and application of regulatory regulatory requirements of biotechnological processes; CE1

Ethically apply all activities related to research: management of biological samples, animal experimentation, including experimental design, data generation and analysis, CE2.

Know and know how to apply the regulations related to ethics that deal with evaluating the elements or principles related to good practices in research in order to know how to establish a final criterion of behavior that can be accepted by everyone within the framework of multiple scientific professions and disciplines.

Learn the phases and requirements for the presentation of a research project

To know in an integrated way the approach and development of an R+D+i process

LEARNING APPRAISAL SYSTEM

1. Ordinary evaluation system.

The evaluation system of the subject will consist of 3 parts:

- Final cooperative work of the subject (50%). Through the theoretical classes and the resolution of the individual practical exercises carried out at the end of the topic, the student will acquire the necessary knowledge to carry out the chosen work. The teacher will provide students with different titles for their choice of work to be done, each group of students will choose one. The work will be prepared in a group and the exhibition will be carried out by all the members of the group, selecting the teacher, on the day of the presentation, what part each member of the team will present. The oral presentation of the papers will be evaluated both in their form and in their content. Papers will be submitted 15 days before their oral presentation through the virtual classroom. After their presentation, each student must defend the questions posed to them by the rest of their classmates.

- Practical exercises (40%) proposed at the end of each topic will be carried out individually. At the end of each block of subjects, an exercise will be solved individually as part of the autonomous work activities, and will be delivered to the teacher in electronic format. The resolution of the case, the reasoning provided, as well as your presentation of the work are evaluated.

- Active participation in theoretical classes, forums and tutoring (10%). The student must intervene at all teaching hours and in the forums proposed by the teacher on a current topic, contributing their ideas and presenting their doubts for the collective debate. The quality of these interventions will be evaluated in a reasoned manner by the student himself and by the teacher to complete the grade for the subject.

To pass the subject in the ordinary call, you must have passed each of the tests separately and the set. If not passed, the student will take an individual test of the total of the subject in the extraordinary call.
To pass the course in subsequent calls, no partial grade will be saved.

2. Alternative evaluation system:
Students in second or subsequent enrollment must contact the teacher to request to take advantage of this system.

Plagiarism, as well as the use of illegitimate means in evaluation tests, will be sanctioned in accordance with those established in the Evaluation Regulations and the University's Coexistence Regulations.

ETHICAL AND RESPONSIBLE USE OF ARTIFICIAL INTELLIGENCE

1.- The use of any Artificial Intelligence (AI) system or service shall be determined by the lecturer, and may only be used in the manner and under the conditions indicated by them. In all cases, its use must comply with the following principles:
a) The use of AI systems or services must be accompanied by critical reflection on the part of the student regarding their impact and/or limitations in the development of the assigned task or project.
b) The selection of AI systems or services must be justified, explaining their advantages over other tools or methods of obtaining information. The chosen model and the version of AI used must be described in as much detail as possible.
c) The student must appropriately cite the use of AI systems or services, specifying the parts of the work where they were used and describing the creative process followed. The use of citation formats and usage examples may be consulted on the Library website(https://www.ufv.es/gestion-de-la-informacion_biblioteca/).
d) The results obtained through AI systems or services must always be verified. As the author, the student is responsible for their work and for the legitimacy of the sources used.
2.- In all cases, the use of AI systems or services must always respect the principles of responsible and ethical use upheld by the university, as outlined in the Guide for the Responsible Use of Artificial Intelligence in Studies at UFV. Additionally, the lecturer may request other types of individual commitments from the student when deemed necessary.
3.- Without prejudice to the above, in cases of doubt regarding the ethical and responsible use of any AI system or service, the lecturer may require an oral presentation of any assignment or partial submission. This oral evaluation shall take precedence over any other form of assessment outlined in the Teaching Guide. In this oral defense, the student must demonstrate knowledge of the subject, justify their decisions, and explain the development of their work.

BIBLIOGRAPHY AND OTHER RESOURCES

Basic

FDA Federal Drug Administration FDA Federal Drug Administration Quality
(FDA Federal Drug Administration FDA Federal Drug Administration Quality ,
https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-

cgmpregulations)

Agencia European Medicines European Medicines Agency Eudralex
(Agencia European Medicines European Medicines Agency Eudralex ,
https://ec.europa.eu/health/documents/eudralex/vol-4_en)

International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) Quality International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) Quality
(International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) Quality International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) Quality , https://www.ich.org/)

Additional

European Medicines Agency for Clinical Trials Regulations
(European Medicines Agency for Clinical Trials Regulations , “Standards of good clinical practice for clinical trials in the European Community” (Document III/3976/88; July 1991) https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-clinical-practice)

Pardo, J. M Good Practices in Research Laboratories: Regulations, Biosafety and Quality 2020
(Pardo, J. M Good Practices in Research Laboratories: Regulations, Biosafety and Quality 2020 , ISBN: 9788491715534||Lehmann, K. et al Good Clinical Practice: A Question & Answer Reference Guide. 2021)