Teaching guide

IDENTIFICATION DETAILS

Degree:	Biotechnology
Scope	Biology and Genetics
Faculty/School:	Experimental Sciences
Course:	PROCESS VALIDATION AND QUALITY MANAGEMENT
Type:	Optional
ECTS credits:	3
Year:	4
Code:	2060
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

In this course, we address a direct view of practical tools to achieve safe and effective biotechnological products. We study the quality of the product from its design, the quality management systems, its requirements and implementation, analyzing the different systems, their legal or voluntary application and the different reference standards (ISO, UNE, EN, FDA, etc.). As a common requirement in these standards, we study the validation of production processes, test methods and products, considering their most complex aspects. We see how product risks are properly managed throughout its life cycle and their minimization through the application of adequate quality controls and well-documented work protocols.

GOAL

The objective of this course is to provide the student with a theoretical and practical vision of the area of Quality, within the biotechnology sector. The integration of both visions gives the student the ability to assimilate and understand quality requirements, voluntary or legal, before the placing on the market of a biotechnological product. It also prepares them to understand the requirements of the sector at an international level and provides them with the key tools to access the market with the guarantee of knowing the requirements of a regulated sector.

PRIOR KNOWLEDGE

The knowledge specific to the Degree

COURSE SYLLABUS

1. Quality: safety and efficacy of the biotechnology product
- What is quality?
- Evolution of the concept of quality
-The quality of the biotechnological product
- Voluntary and legal requirements.
- Different quality systems- certification vs accreditation vs...

2. Quality: Implementation of a quality management system
- Common requirements of a quality management system
- Specific requirements of a quality management system: ISO, GXps...
- Documentary requirements - Quality manual, work procedures and records.
-Staff competencies. Basic pillar in a quality management system and in product quality
-Equipment - maintenance/calibration/verification
-Work areas: special working conditions
-Technical requirements: methods, limits, tolerances

3. Quality: reference standards - specific requirements for some products (EMA, FDA...)
- UNE, EN, ISO standards
- AEMPS, EMA, FDA requirements
- CE marking of products
- ICH requirements
- Food products, health products, therapies, agroproducts,...

4. Quality Systems in the Biotechnology Company
- Good Manufacturing Practices (GMP)
- Good Laboratory Practices (GLP)
- ISOs

5. Validation: general concepts
- What is validating? What are your objectives?
- What can be validated?
- Validation parameters
- Validation methods
- Material for validation

6. Validation: Development
- Validation of methods
- Product validation
- Process validation
- Validation of work areas
- Validation of computer systems

7. Quality Risk Management (QRM) - Risk Management
- Basic principles in risk management
- General process for managing quality risks
- Assessment and minimization of risks with control measures
- Integration of quality risk management into the activities of the Industry.

EDUCATION ACTIVITIES

Participatory expository classes: classes taught by the teacher in which the theoretical contents of the subject are presented.

Practical classes, exercises, case studies: resolution of practical cases by students, led by the teacher.

Seminars and papers:
Oral presentation in class of work carried out by students related to the contents of the subject.
Discussion led by the teacher.

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.

DISTRIBUTION OF WORK TIME

TEACHER-LED TRAINING ACTIVITIES	INDIVIDUAL WORK
35 Horas	40 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 understand the social, economic and environmental implications of professional activity.

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.

Capacity for problem-solving and decision-making.

To be able to plan time effectively.

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

To develop an ability to search for, take in, analyze, sum up and relate information.

To develop oral and written communication skills.

General Skills

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Specific skills

Identify the unique characteristics of the biotechnology company in common topics such as Finance, HR, Costs, Quality, Communication.

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.

Develop habits of rigorous thinking.

Ability to communicate the knowledge acquired orally and in writing.

Know how to apply the theoretical knowledge acquired to solving problems and practical cases related to different subjects.

Know how to work as a team in an effective and coordinated way.

Be able to self-evaluate the knowledge acquired.

Develop criteria for problem solving and decision-making both in the professional and personal spheres.

LEARNING RESULTS

List the requirements of a Quality Management System and develop and implement them in a practical case||Assess the importance of the application of these systems in biotechnological products, depending on the

types of products. Respond reasonably and justifiably to the question: Is quality pure bureaucracy or a necessity?

Discern between your voluntary and legal application based on product types

List the different applicable quality systems, both European and American, their differences and similarities and their specificity depending on the products

Identify the product life cycle from its design and carry out the risk analysis associated with each of its stages

Identify measures to minimize risks, establishing control measures and quality controls appropriate to each stage to assess their reduction.

Identify incidents in process and use them as a feedback base for risk management and for continuous process and product improvement

Develop work protocols in accordance with the requirements of quality standards

Describe the objectives of validating a process, product or method; identify the parameters to be included in the validation according to the type of validation and product to be validated; identify the material needed to carry it out

Treat the results to obtain conclusions, make decisions and define product specifications (safety and efficacy)

LEARNING APPRAISAL SYSTEM

ORDINARY EVALUATION SYSTEM.
The evaluation system, based on continuous evaluation, distributes the final grade of the subject into:
- Test of 10 test-type questions (4 answers only one true) plus a question to be developed (90% of the weight of the subject).
- Active participation in theoretical classes, seminars, tutoring (10%). The student must intervene in all classroom hours, 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.

Spelling Correction Criteria (PAU LOE Guidelines 2009/10): For each misspelling, 0.5 points will be deducted from the exam score. The same repeated fault will be counted only one. By repeating the lack of accentuation and punctuation, up to two points can be deducted. Abbreviations, syntactic and drafting errors, etc. will be penalized.

ALTERNATIVE EVALUATION SYSTEM.
Students who enroll for the second or more times in the subject will be evaluated with
- Test of 10 test-type questions (4 answers only one true) plus a question to be developed (90% of the weight of the subject).
- Presentation of an oral paper on a topic addressed during the course (10%).
Students who take advantage of this system should contact the teacher to request exemption from attending face-to-face classes.

Plagiarism, as well as the use of illegitimate means in evaluation tests, will be sanctioned to 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

Not applicable Not applicable