63108 - Regulation and Quality Control Issues

Información del Plan Docente

Academic Year	2018/19
Subject	63108 - Regulation and Quality Control Issues
Faculty / School	100 - Facultad de Ciencias
Degree	572 - Master's in Quantitative Biotechnology
ECTS	4.0
Year	1
Semester	Second semester
Subject Type	Optional
Module	---

1.General information

1.1.Aims of the course

This is an optional subject, in the second semester of the Master in Quantitative Biotechnology.
The objectives of the course are common to the overall title.

Students will:

- Analyze and solve experimental problems in a biochemical or biotechnological research laboratory in the context of quality.
- To know the activity of organisms and the regulations related to the quality processes of the biochemical laboratories and with the transfer of solutions to the industry.
- Use data for decision-making in biotechnological experimentation.
- To value the relevance of the advances in the field of the regulation in Molecular Biology, Cell Biology and Biotechnology.

1.2.Context and importance of this course in the degree

It is a key to addressing quality issues in any laboratory activity in biochemistry, molecular and cell biology course.

1.3.Recommendations to take this course

As an optional subject of the Master is based on the knowledge acquired previously in the Degrees. Some material of the subject can be in English. For this reason, the student will need a good level of written understanding thereof.

2.Learning goals

2.1.Competences

3.2.1 BASIC AND GENERAL

- Sort, analyze critically, interpret and synthesize information

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- Obtain information from different types of sources and evaluate their reliability

- Learn efficiently through autonomous study and acquire a significant degree of independence

- Apply acquired knowledge and solve problems in new or unfamiliar environments within broader (or multidisciplinary) contexts related to the area of study

- Formulate, analyze, evaluate and compare new or alternative solutions to different problems

- Be able to work in multidisciplinary and international teams.

- Develop capacity for criticism and self-criticism.

- Make decisions taking into account social, ethical and legal responsibilities

- Be able to develop a project, participating in the stages of bibliographic search, planning experiments, obtaining results, interpreting, and disseminating them

- Possess and understand knowledge that provides a basis or opportunity to be original in the development and / or application of ideas, often in a research context

- Students should be able to apply acquired knowledge and problem-solving skills in new or unfamiliar environments within broader (or multidisciplinary) contexts related to their area of study

- That students are able to integrate knowledge and face the complexity of making judgments from information that, incomplete or limited, includes reflections on social and ethical responsibilities linked to the application of their knowledge and judgments

- That the students know how to communicate their conclusions and the latest knowledge and reasons that support them to specialized and non-specialized audiences in a clear and unambiguous way

- That students have the learning skills that allow them to continue studying in a way that will be largely self-directed or autonomous.

3.2.2 TRANSVERSALES

- Manage adequately the resources and time available for the resolution of a problem or the development of a project

- Communicate own conclusions and the latest knowledge and reasons that support them - to specialized and non-specialized audiences in a clear and unambiguous way.

- Transmit information in an oral, written or graphic form using appropriate presentation tools and with the limitations

imposed by time or space

- Communicate fluently in English (understanding scientific texts, writing reports, talks, colloquiums, exhibitions, etc.).

- Use Information and Communication (ICT) techniques as a tool for expression and communication.

- Possess and understand knowledge that provides a basis or opportunity to be original in the development and / or application of ideas, often in a Research context.

- Develop technological applications of biochemical processes and transfer solutions to the industry in the food, chemical, cosmetic, pharmaceutical and health sector

2.2.Learning goals

The learning goals for the student will allow him to:

· Know the aspects related to quality control and regulation in biochemical experimentation with direct application in the biotechnology industry; With the focus of Good Laboratory Practices
· Know the activity of national and foreign bodies involved in quality regulations, as well as in inventions and patents, among others.
· Become familiar with the search and discussion of information: solving concrete problems.

2.3.Importance of learning goals

This subject will develop competences in the student that may be useful in the future of their profession (Administration and Public Organizations, as well as in private companies, or alternatively in basic research)

3.Assessment (1st and 2nd call)

3.1.Assessment tasks (description of tasks, marking system and assessment criteria)

FORMATION ACTIVITIES

A) Master class. In these classes students are presented with the basic theoretical knowledge of the subject and the participation of the students is continuously demanded. **Hours 15. Class Attendance:100**

B) Classes of problem solving and practical cases. They will be interspersed with the master classes. The students will analyze the application of the methods developed in the master classes through the resolution of exercises and cases both in the classroom and on line * in the computer room. **Hours 10. In-person: 100**

C) Presentation and exhibition of a work or seminar. Students will collect individual or group information on a specific topic, led by the teacher. In general, the analysis of the information will lead to the elaboration of a structured memory in Introduction, Methods, Results, Discussion, Conclusions, and Bibliography, as well as to its exhibition and debate in

class. **Hours 10. Class Attendance: 100**

D) Workshops and debates. Discussion of a research topic or relevant technological development that has shown

A significant advance in recent years. The teacher or an external expert will present the subject and the relevant developments will be presented. Next, the topic will be discussed through the formulation of questions, by the students. In some cases, information will be distributed in advance to the students so that they already have knowledge about the topic to be debated. **Hours 5. Class Attendance**: **100**

E) Individual work of the student. **Hours 60**

4.Methodology, learning tasks, syllabus and resources

4.1.Methodological overview

The methodology followed in this course is oriented towards achievement of the learning objectives. A wide range of teaching and learning tasks are implemented, such as:

- Lectures will generally use computer screen projections (PowerPoint), including small animations, videos and offline browsing. Blended learning will be used to exchange information with the students and to advise them on the presentation of their individual assignment.
- Problems and case studies will be distributed via the e-learning platform and, after the theoretical presentation, will be solved and discussed in class. The main tool will be the blackboard. Students will be instructed in how to design experiments, present and discuss data and results by means of theoretical-practical cases. This part of the course requires both team and individual work of the students, as well as the search and discussion of information, and the resolution of concrete problems. These activities will allow the students to acquire the necessary skills and abilities to analyze and solve experimental problems related to the course's techniques, the design of experiments independently (and/or applications), and to describe, quantify, analyze and critically evaluate the obtained results.
- The preparation of seminars and individual assignments will train students in the search for relevant information on the Internet, the use of databases, scientific bibliography and on-line applications. Students will be encouraged to use and interpret original scientific material (scientific publications, patents) for the presentation of the information to both a specialized and the general public. This activity will help students in how to communicate conclusions —and the ultimate knowledge and reasons behind them— in a clear and unambiguous way.

4.2.Learning tasks

The course includes the following learning tasks:

- Problem solving and practical cases. The resolution of these exercises may be done individually or in groups by the students. They are required to submit a report at the end of each session following the guidelines and the presentation format decided by the teacher. Grades and solved exercises will be made available to students for reviewing purposes. This type of tasks are part of the continuous assessment, which allows the follow-up of the learning process. *MINIMUM WEIGHT: 25.0. MAXIMUM WEIGHT: 25.0*
- Assessment. The written test will consist of questions that require short answers (closed answers) or a elaborate answer of the topic (essay and open answers). The former will allow a broad sampling of the student's knowledge on the course, and the latter will allow them to assess their capacity for expression, to present and sustain arguments, and to make critical judgments. The written test will be based on the syllabus topics. *MINIMUM WEIGHT: 45.0. MAXIMUM WEIGHT: 45.0*

1. Seminars. Elaboration of report, its presentation and public defense on a topic related to the course. The report will be done individually or in pairs. The assignment will be presented and defended by each group of students in seminar-type sessions. The time available for the presentation and defense of the topic during the seminar sessions will be 10-15 minutes. The assessment criteria is based on the use of a coherent structure and appropriate bibliography. During the defense, the clarity and organization of the presentation will be evaluated, as well as the

maturity of the discussion. *MINIMUM WEIGHT: 45.0. MAXIMUM WEIGHT: 45.0*

4.3.Syllabus

The course will address the following topics:

1. Topic 1. Introduction and overview of CC application in Biotechnology. Key concepts: accreditation, certification, regulation, others. National and international organizations highlighted by their regulatory activity in Biotechnology. Comprehensive view of regulation and quality control.
2. Topic 2. Importance of Validation Parameters in Quantitative Biotechnology. (GLPs, etc). Protocol. Report. Certificate Standard Procedures of Work. Validation of quantitative measurement methods (biochemical, immunochemical). Biological matrices. Standardization and harmonization of biological patterns. Reasons to validate. Specific examples.
3. Topic 3. Importance of Patents in R & D & I. Technology transfer. Need to patent: the researcher's vision, company vision. Priority. Via EPO or via OPEM. Alternative options to the patent.
4. Topic 4. Regulation and Quality Control in the Preclinical Phase trials. Experimentation with animals (different types). Production of sera and antisera. Experimentation with cell cultures. Collections of cell lines (ATCC). GMOs.
5. Topic 5. Biobanks, The Law of Biomedical Research. Bioethical committees. Informed Consent.
6. Topic 6. Clinical Trials. Pharmacovigilance. Specific examples: Vaccines and other biological medicines (different levels of regulation Phase I, Phase II, Phase III). AEMPS and EMA. Patents and Generics.
7. Topic 7. Biosecurity. Laboratory Types - Recent examples. Future needs for biotechnology quality control and regulation. Consequences of the Human Genome Project. Gene therapy. Cloning for discussion. Stem cells. Tissue therapy. (These topics will be discussed in more depth by the students in the seminars).

4.4.Course planning and calendar

The course runs in the second semester of the academic year.

The seminars held by guests professors will be indicated in advance.

Further information concerning the timetable, classroom, assessment dates and other details regarding this course, will be provided on the first day of class or please refer to the Faculty of Science website, Master's in Quantitative Biotechnology Biology website (https: //science.unizar.es/calendario-y-horarios), and the virtual platform Moodle.

For those students enrolled, the places, schedules and dates of theoretical classes and practical sessions will be made public through the TABLON OF ANNOUNCEMENTS OF THE MASTER in the platform Moodle of the University of Zaragoza: https://moodle2.unizar.es/add/, in the section Master in Quantitative Biotechnology.

Provisional dates can be consulted on the website of the Faculty of Sciences in the section of the Master in Quantitative Biotechnology: https://ciencias.unizar.es/calendario-y-horarios. In this web, studends will also be able to consult the dates of exams, in the section Master in Quantitative Biotechnology. They also could contact to the Master Coordinator.

4.5.Bibliography and recommended resources