Universitat Autònoma de Barcelona

2023/2024

Research and Development of New Medicines

Code: 103973
ECTS Credits: 3

Degree	Type	Year	Semester
2502445 Veterinary Medicine	OT	5	2

Contact

Name: Fernando de Mora Pérez

Email: fernando.demora@uab.cat

Teaching groups languages

You can check it through this link. To consult the language you will need to enter the CODE of the subject. Please note that this information is provisional until 30 November 2023.

Prerequisites

It is advised to have passed the Pharmacology curriculum (3rd year veterinary graduate students) ar to have attended a basic pharmacology course.

Objectives and Contextualisation

The Main Objective is to convey the scientific criteria underlying medicines development, and to understand the role of the pharmaceutical industry in medicines development and marketing (human or veterinary industry as a potential professional development).

The Specific Objectives are:

- that the student understand the scientific rationale behind the studies needed for medicines approval:quality, efficacy and safety (used in human and animals) 35%

- that the student acknowledges the benefit-to-risk concept as a key paradigm in health sciences 10%

- that the student questions the recommendations for medicines approval and holds the ability to debate and propose alternative approaches 20%

- that the student acquires knowledge on pharmaceutical companies corporate organization to undertake research and marketing of medicines 20%

- that the student understands that regulation is science and that it offers reassurance to patients 10%

- raise awareness for futur clinicians of the need to follow up the therapeutic performance of marketed medicines (pharmacovigilance) 5%

Competences

- Analyse, synthesise and resolve problems and make decisions.
- Comunicar la informació obtinguda durant l'exercici professional de manera fluïda, oralment i per escrit, amb altres col·legues, autoritats i la societat en general.
- Demonstrate knowledge and understanding of standards and laws in the veterinary field and regulations on animals and their trade.
- Demonstrate knowledge and understanding of the aspects of organisation, finance and management in all fields of the veterinary profession.
- Demonstrate knowledge and understanding of the general bases of medical and surgical treatments.
- Demonstrate knowledge and use of statistical concepts and methods applicable to veterinary science.
- Have basic knowledge of the profession, and in particular of the organisation and functions of professional practice.
- Perform basic analytical techniques and interpret the clinical, biological and chemical results, and interpret the results of tests generated by other laboratories.
- Recognise ethical obligations in the exercise of responsibilities in terms of the profession and society.
- Seek and manage information related with professional activity
- Work effectively in single or multidisciplinary teams and show respect, appreciation and sensitivity for the work of others.

Learning Outcomes

1. Analyse, synthesise and resolve problems and make decisions.
2. Communicate information obtained during professional exercise in a fluid manner, orally and in writing, with other colleagues, authorities and society in general.
3. Conduct market studies applied to the obtainment of new drugs.
4. Define the basic concepts for developing drugs.
5. Describe the bodies for evaluating and monitoring medicines, as well as the mechanisms for approving the same.
6. Design and apply toxicity tests to guarantee the safety of pharmacological and non- pharmacological products.
7. Distinguish the different areas of the pharmaceutical industry.
8. Explain basic statistical inference and its relation with scientific behaviour.
9. Have basic knowledge of the profession, and in particular of the organisation and functions of professional practice.
10. Identify and define the concepts involved in the design of biological experiments and estimate sample size and potency of the test.
11. Identify the sources of drugs and biopharmaceuticals.
12. Identify the standards for the development of non-pharmacological products.
13. Recognise personal limitations and know when to ask for professional advice and help.
14. Recognise the standards in studies of quality, efficiency and safety as applicable to the development of drugs.
15. Seek and manage information related with professional activity
16. Work effectively in single or multidisciplinary teams and show respect, appreciation and sensitivity for the work of others.

Content

Live teaching: 26 hours per student

- 22 hours interactive theoretical sessions

- 2 hours: projects presentation

- 2 hours: visit to pharmaceutical company

+ Student's project + individual/team supervised work

Syllabus

Medicines R+D put into context

- Objectives of the course and sessions dynamics

- Brainstorming: R+D rationale

- Healthcare authroties role: regulation is science

- Recap: R+D steps

Setting up the project

- Projects setup

- Teams set up: subject per team

- Explanation of project execution

Discovery phase

- sources of identification and information of new molecules

Preclinical studies (1): objective and design

- Objectives of preclinical studies.

- Efficacy studies:Target identification and validation. Biological and in silico systems

Preclinical studies (2): toxicity

- Safety pre-assessmnt: Characterization of toxicity.

- NOAEL. Genotoxicity, Immunotoxicicty, etc

Production and formulation of medicines + quality control (1)

- Medicines manufacturing: chemically synthesized and biologics.

- Phases: active substance characterization.

- Formulation

Production and formulation of medicines + quality control (2)

Projects presentation - Debate

- Presentation : teams

- Feed back

- Assessment

Clinical studies: Objectives

- Objectives of clinical research - Design rationale

- Phase I (First-in-human): PK, safety and tolerability

- Objectives and execution

Patient studies

Innovators - Biosimilars etc

Veterinary medicines development

Biopharmaceutical industry

Overview

Projects exhibition

Methodology

Case-studies and problem solving
Theoretical sessions
Field sessions
Seminars
Project execution and search for information
Supervision and coaching

Annotation: Within the schedule set by the centre or degree programme, 15 minutes of one class will be reserved for students to evaluate their lecturers and their courses or modules through questionnaires.

Activities

Title	Hours	ECTS	Learning Outcomes
Type: Directed			
Field sessions	2	0.08	4, 7
Seminars	2	0.08	15, 2, 4, 5, 7, 11, 14
Theoretical sessions	22	0.88	1, 4, 5, 7, 8, 10, 11, 3, 14, 13, 16
Type: Supervised			
Tutorials	12	0.48	1, 4, 5, 7, 8, 10, 11, 3, 14, 13, 16

Assessment

IN THIS COURSE THE "SINGLE ASSESSMENT SYSTEM" IS NOT CONSIDERED

ACTIVITY 1 -Team Work (TeE): 30% of the final mark. The TeE grade will be made up of a Written Report (50%) and an Oral Presentation (50%). The members of the same team will have the same grade in the Work regardless of their contribution to it.

ACTIVITY 2 - Intervention in class (IeC): 40% of the final mark. The IeC mark can be (a) 10/10: intervenes (i.e. asks or gives an opinion spontaneously) in all or the vast majority of classes, (b) 7.5/10: intervenes frequently in most classes , (c) 5/10: intervenes sometimes, usually coming to class, (d) 2.5/10: intervenes rarely even though he attends class, and (e) 0/10: attends class very little or, even if he does attend, usually does not intervene except by direct questions from the teacher. Class attendance is NOT evaluated, although it should be remembered that low attendance prevents frequent intervention.

ACTIVITY 3 - Class Exam (EeC): 30% of the final grade. It can be exclusively multiple choice, or a combination of multiple choice and short question/s (hybrid), and never last more than 1 hour. Questions about all the content of the subject, including the Works presented by others, the interventions of invited directors or the visit to the Pharmaceutical Laboratory.

The final mark will result from the weighted average of the three evaluated activities.

Explanatory Notes

Team work:

• The student will demonstrate the skills acquired throughout the course |

MANDATORY

• Mandatory to attend (1) sessions with industry executives (2 sessions),

Not attending one of those session would preclude from passing (unles justified ahead with a written document)

Attending theoretical sessions is not mandatory, but it is advised not to skip many of those sessions given that cl

Assessment Activities

Title	Weighting	Hours	ECTS	Learning Outcomes

Involvement-participation (engagement in questioning and debating)	40%	0	0	1, 15, 2, 4, 5, 6, 7, 8, 10, 12, 11, 3, 14, 13, 16
MCQ Exam (30% of final mark)	30%	12	0.48	1, 15, 2, 4, 5, 6, 7, 8, 10, 12, 11, 14, 13, 9, 16
Team work (written + presentation)	30%	25	1	1, 15, 4, 5, 7, 11, 14, 13, 9

Bibliography

Se entregará a principio de curso.

Software

No software is used