

**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

### Use of Languages

Principal working language: spanish (spa)  
Some groups entirely in English: No  
Some groups entirely in Catalan: No  
Some groups entirely in Spanish: No

### Teachers

Fernando de Mora Pérez  
Anna Puigdemont Rodriguez

### Prerequisites

It is advised to have passed the Pharmacology curriculum from 3rd year of studies.

### Objectives and Contextualisation

The Main Objective is to convey the scientific criteria underlying medicines research that reassure on their use in clinical practice, with the goal of both optimize its therapeutic use in veterinary medicine, and, if the student aims at it, facilitate a professional futur within the pharmaceutical industry (human or veterinary)

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 incorporated the benefit-to-risc concept as a key paradigm in health sciences 10%
- that the student questions the recomendations for medicions approval and holds the ability to debate and propose alternative approaches 25%
- that the student acquires knowledge on pharmaceutical companies corporate organization to undertake discovery, research and marketing of medicines 10%
- that the student understands that regulation is science that offers reassurance to patients 10%
- raise awareness for futur clinicians of the need of following up the therapeutic performance of marketed medicines (pharmacovigilance) 10%

## 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.
- 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. Distinguish the different areas of the pharmaceutical industry.
7. Explain basic statistical inference and its relation with scientific behaviour.
8. Have basic knowledge of the profession, and in particular of the organisation and functions of professional practice.
9. Identify and define the concepts involved in the design of biological experiments and estimate sample size and potency of the test.
10. Identify the sources of drugs and biopharmaceuticals.
11. Recognise personal limitations and know when to ask for professional advice and help.
12. Recognise the standards in studies of quality, efficiency and safety as applicable to the development of drugs.
13. Seek and manage information related with professional activity
14. 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 authorities 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-assessment: Characterization of toxicity.
- NOAEL. Genotoxicity, Immunotoxicity, 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, 6
Theoretical sessions	22	0.88	1, 4, 5, 6, 7, 9, 10, 3, 12, 11, 14
Type: Supervised			
Tutorials	10	0.4	1, 4, 5, 6, 7, 9, 10, 3, 12, 11, 14
Work execution and search of information	16	0.64	1, 13, 4, 5, 6, 7, 9, 10, 3, 12, 11
Type: Autonomous			
Case-studies and problem solving	24.5	0.98	1, 13, 4, 5, 6, 7, 9, 10, 3, 12, 11, 14

## Assessment

Team work:

- The student will demonstrate the skills acquired throughout the course |
- Individual or team work.
- Attendance at the seminar sessions and visits to the industry and the w

## Assessment Activities

Title	Weighting	Hours	ECTS	Learning Outcomes
-------	-----------	-------	------	-------------------

Assessment of Knowledge (exam)	30%	0.5	0.02	1, 13, 2, 4, 5, 6, 7, 9, 10, 3, 12, 11, 8, 14
Involvement-participation	20%	0	0	1, 13, 2, 4, 5, 6, 7, 9, 10, 3, 12, 11, 14
Project discussion	50%	0	0	1, 13, 4, 5, 6, 10, 12, 11, 8

## **Bibliography**

Se entregará a principio de curso.

## **Software**

No software is used