



PRESENTATION

Therapeutic proteins in biomedicine

Proteins become increasingly common components of drugs already available on the market or being tested in clinical trials as they exhibit high specificity and activity. The number of protein-based therapeutics has been augmenting exponentially over the past few years. The purpose of this subject is to present a general overview about this topic, describing novel production and purification systems, the benefits and the main strategies to avoid the challenges involved in the use of this macromolecules, relevant concepts in the field as “protein engineering” or biosimilars, new protein delivery systems, etc. The diseases and disorders in which these proteins are potential drug candidates will also be discussed and several on-going novel research projects concerning therapeutic proteins will be presented by experts in the field. The course will include the visit to an enterprise specialised in the production of therapeutic proteins.

- **Type of subject:** Required in the specialty of traslational research and elective for other specialties
- **ECTS:** 2 ECTs
- **Calendar description:** Second semester
- **Language:** English
- **Degree:** Master in Biomedical Research
- **Module:** Module II: Specialty in traslational research
- **Area:** Fundamental aspects in the specialty of traslational research
- **Department and School:** Biochemistry and Genetics, School of Sciences
- **Calendar description:** Second semester
- **Classroom and schedule:** Room 31. Specified in the [Master Calendar](#)
- **Professors:**

- **Dr. Eduardo Ansorena** (Biochemistry and Genetics, *UNAV*) Subject coordinator
(eansorena@unav.es)

- **Dra. María Blanco Prfeto** (Pharmaceutical Technology and Chemistry, *UNAV*)

- **Dra. María Pilar Pérez de Obanos** (Head of Project Management. *3P Biopharmaceuticals*)

COMPETENCES

Basic competences

- BS6: Possess and understand knowledgeable facts that serve as a basis or opportunity for being original in the development and/or application of ideas, frequently within the context of research.
- BS7: The students will be able to apply acquired knowledge and problem solving abilities to fields outside this program, including that which is new and scarcely known, within a more ample or multidisciplinary context related to the research, development and innovation of drugs.
- BS8: The students will be able to integrate concepts and manage the complex task of drawing valid conclusions from information which, in spite of being incomplete or limited, includes reflections regarding social and ethical



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responsibilities linked to the application of general knowledge, specific concepts and common sense to the research, development and innovation of drugs.

- BS9: The students will learn to relay their conclusions -and the most recent facts and reasoning supporting said conclusions- to specialized personnel and to the general public in a clear and precise manner.
- BS10: The students will have acquired learning abilities that will permit them to continue studying in a self-directed and autonomous manner.

General competences

- CG1: Ability to deal with biomedical challenges in depth, from different viewpoints, identifying the state of present-day science.
- CG2: Identification of significant questions or hypotheses regarding biomedical issues or problems and definition of the steps necessary to resolve such questions.
- CG4: Ability to select and use appropriate techniques in order to efficiently and accurately carry out biomedical research work.
- CG7: Ability to orally communicate biomedical research matters or data in a fluent way, in both Spanish and English, taking into account the audience for which the presentation is intended.

Traslational research specialty competences

- CEE2: Knowledge of the main techniques used in the analysis, purification and quantification of proteins, lipids, carbohydrates and their application to translational research in biomedicine.
- CEE7: Knowledge of new protein supply systems, different routes of administration and pathologies in which they are used. Familiarization with the concept of intellectual property and patents for biopharmaceutical products, as well as procedures for carrying out clinical trials involving therapeutic proteins.
- CEE8: Ability to select appropriate techniques in order to respond to questions posed within the field of translational research and to use said techniques to obtain precise and reproducible results which allow valid and objective conclusions to be drawn.

PROGRAM

The program of the subject will cover the following topics:

- Therapeutic proteins. Introduction and pharmacological classification.
- Production and purification of therapeutic proteins.
- Traditional and novel expression systems of therapeutic proteins.
- Cellular engineering for therapeutic protein production.
- Protein engineering.
- Immunogenicity of therapeutic proteins.
- Therapeutic antibodies.
- Biosimilars.
- Microencapsulation of proteins and research projects involving encapsulated therapeutic proteins. Sustained release of neurotrophic factors for neurodegenerative diseases (*María Blanco Prieto*)
- Therapeutic proteins and its biomedical application in cancer, regenerative medicine.
- Clinical trials with therapeutic proteins. (*María Pilar Pérez de Obanos, 3P Biopharmaceuticals*)



EDUCATIONAL ACTIVITIES

Methodology

This is a subject of 2 ECTS (50 h). The work is distributed as follows:

1. Class activities: (0,84 ECTS, 21 h)

- Lecture format (0,44 ECTS, 11 h)

The lectures are based on the presentation of a topic by the professor. The content of the classes is based on this theory program.

- Individual or teamwork presentations (0,24 ECTS, 6 h).

Students will present a work related to the program of the subject, preferentially in English.

- Laboratory practice (0,16 ECTS, 4 h)

Students will have a guided visit through a biotech company specialized in the development and manufacture of therapeutic proteins. This visit will take place depending on the availability of the company.

2. Personal work: (1,16 ECTS, 29 h)

Student's personal work is part of the learning process. It involves the use of scientific sources of information mainly for the preparation of the topic presentation and to go into detail about the contents explained in the lectures.

ASSESSMENT

Evaluation

The final qualification will be obtained as the mean of the following activities:

Continuous assessment	35 %
Oral presentation of the topic	65 %

The **student's participation** in class discussions may add **up to 1 point** to the final grade

Re-sit examinations

To obtain a pass in this subject it is necessary to obtain a final grade of 5 (50%) or above. Those students that obtain a grade below 5 will have to present an additional work proposed by the coordinator.

Grades:

10-9.0: SB

8.9-7.0: NT

5.0-6.9: AP



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0-4.9: SS

Those students with a final grade of 9 or above are eligible for Honors.

OFFICE HOURS

Contact

In order to contact with the subject coordinator ask for an appointment by e-mail:

- Eduardo Ansorena (eansorena@unav.es).

The program coordinator will attend the students in the Research Building, 2nd floor, Department of Biochemistry and Genetics, Room 2200.

- Timetable: Monday, Wednesday and Friday 16:30- 18:30 h

BIBLIOGRAPHY

- The subject coordinator will provide relevant papers related to the topic