

**Project/Teaching Guide of the course**

Course	CELL THERAPY AND TISSUE ENGINEERING		
Subject	Advanced Therapies		
Module	-		
Degree	Degree in Biomedicine and Advanced Therapies		
Plan	710	Code	47915
Teaching period	2 nd Semester	Type/Character	Mandatory
Level/Cycle	DEGREE	Year	THIRD
ECTS credits	6		
Language in which it is taught	English		
Responsible professor/s	Dr. Margarita González-Vallinas Garrachón (coordination) Dr. Verónica García Díaz Dr. María Mercedes Alberca Zaballos		
Contact information (E-mail, telephone...)	margarita.gonzalez-vallinas@uva.es ; ext. 4688 vgarcia@uva.es ; ext. 6439 mmalberca@uva.es ; ext. 4461		
Department	Dept. of Biochemistry and Molecular Biology and Physiology		
Review date by Degree Committee	July 4th, 2024		



1. Situation / Sense of the Course

1.1 Contextualization

“Cell Therapy and Tissue Engineering” is a key mandatory course within the Degree in Biomedicine and Advanced Therapies, since it includes two of the three types of existing therapies within the so-called “advanced therapies,” which include cell therapy, gene therapy, and tissue engineering. The subject is taught by professors dedicated to the development of this type of treatments, with experience in both basic and preclinical research as well as in the conduct of clinical trials of advanced therapy and the manufacturing of these medicines under Good Manufacturing Practice (GMP/NCF) to be applied in patients.

1.2 Relationship with other subjects

It is related to most courses of the Subject “Advanced Therapies”, especially with “Gene Therapy”, “Immune Therapy”, “Nanomedicine” and “Biomaterials”. It is also related to “Human Anatomy”, “Human Physiology” (I and II), “Human Immunology”, “Basic Pharmacology” and “Biomedicine, Ethics and Law”.

1.3 Prerequisites

Basic knowledge of cellular and molecular biology, anatomy, histology and immunology.



2. Competences (RD 1393/2007) or Results of the training and learning process (RD 822/2021)

2.1 (RD1393/2007) General competences

CG1 - Know how to analyse and synthesize basic problems related to Biomedicine and Advanced Therapies, solve them using the scientific method and communicate them efficiently.

.CG2 - Know the scientific and technical bases of Biomedicine and Advanced Therapies, so that facilitate the learning of new methods and technologies, as well as the development of great versatility to adapt to new situations.

CG5 - Acquire, analyse, interpret and manage information.

CG6 - Prepare reports and make judgments based on a critical analysis of reality.

CG7 - Know the rules, regulations and legislation in force, so that the ability to define and make regulations specific to the area is developed.

CG8 - Understand the social, technological and economic changes that determine professional practice.

CG9 - Write, represent and interpret scientific-technical documentation.

2.2 (RD1393/2007) Specific competences

CE21 - Acquire a broad vision of new personalized therapies. Development, design and application of such therapies.

CE23 - Explain the bases and different modalities of cell, gene and tissue therapy, and identify what human pathological alterations can be treated with advanced therapies.

CE24 - Understand the normal processes of development and repair of injuries in the individual that allow advances in the field of biomedicine in relation to tissue and regenerative therapy.

CE30 - Know and understand the mathematical, physical, chemical and biological foundations of the science of biomaterials and their application in tissue therapy.

CE34 - Know the origin, nature, design, obtaining, analysis and control of medicines and medical devices.

CE41 - Know the main historical milestones of Biomedicine and Advanced Therapies and their influence on the human societies, as well as the most innovative and recent developments in this field.

CE43 - Acquire the skills that allow the search and analysis of relevant scientific information. Be able to adequately interpret and communicate that information.

3. Objectives

- ✓ Achieve a solid training in the cellular and molecular bases related to cell and tissue therapies.
- ✓ Distinguish the different types of stem cells according to their origin and differentiation.
- ✓ Delve into the methodologies applied to the development of cell and tissue therapies.
- ✓ Know the pathologies susceptible to cellular and tissue engineering treatment and the bases of their application.
- ✓ Gain a perspective of the frontier of current knowledge in cellular and tissue therapies.
- ✓ Develop a critical spirit in the assessment, interpretation and analysis of publications, works or projects related to cell and tissue therapy.



4. Contents and /or thematic blocks

Block 1: Cell therapy and tissue engineering

Workload in ECTS credits: 6.0

a. Contextualization and justification

(Previously described in section 1.1).

b. Learning objectives

(Previously described in section 3).

c. Contents

- Lesson 1. Stem cells: origin, types, characteristics and potential applications.
- Lesson 2. Early embryogenesis
- Lesson 3. Cell renewal in adults
- Lesson 4. Induction of specific cell lineages: morphogens and cocultures
- Lesson 5. Models of therapeutic applications of adult cells
- Lesson 6. Introduction to tissue engineering
- Lesson 7. Three-dimensional matrices to produce simple structures: cartilage and bone.
- Lesson 8. Artificial skin for the treatment of ulcers and large burns.
- Lesson 9. Induced pluripotent cells (iPSCs), genetic correction and organoids
- Lesson 10. Applications in degenerative diseases
- Lesson 11. Applications in congenital haematological diseases (Fanconi anaemia)
- Lesson 12. Applications in cancer (TILs, TCR-T and CAR-T)
- Lesson 13. The problem of availability: autologous and allogeneic treatments. Cellular banks
- Lesson 14. Cells as drug substances. Substantial and non-substantial modifications
- Lesson 15. Regulation of cell-based therapy manufacturing
- Lesson 16. Pharmaceutical quality: in-process and final-product controls
- Lesson 17. Clinical trials and their particularities in cell therapy: masking and distribution
- Lesson 18. Compassionate use and hospital exemption

PRACTICAL CONTENTS

- Manufacturing (simulated) of a cell therapy product based on mesenchymal stem cells.
- Preparation of a combined product of mesenchymal stem cells and biocompatible matrix.
- Stability study of cellular products with different excipients at different time points.

d. Teaching methods

- **Theoretical classes:** face-to-face classes will be taught at the time established for the course (Monday, Tuesday and Thursday, from 11:30 to 12:30) and in the usual spaces provided by the Faculty of Medicine.
- **Seminars and classroom practices:** different tasks will be carried out (solving exercises, problems and/or questions, presentation and discussion of cases, etc.) with student contributions oriented and supervised by the teacher. Active participation of all students in open discussions about the issues raised will be encouraged.
- **Laboratory practices:** work in the cell culture laboratory, in small groups, to carry out the proposed practical objectives (see section "c. Contents").

e. Workplan

Three hours of theoretical class will be taught per week during the 2nd semester until the theoretical contents are completed. Seminars and classroom practices will also take place at the same time. Laboratory practices will take place in the afternoons from Monday to Thursday, in groups of 8-12 students. Each group will carry out 15 hours of laboratory practices, distributed over 4 days.

f. Assessment

The final mark will correspond to that obtained in the written exam (80%) and in the continuous assessment (20%), which will include the marks from the seminars, classroom practices and laboratory practices.

g Teaching material

*It is essential that the references provided in this course are up to date and complete. Professors have access to the **Library's Leganto platform** to update their recommended bibliography ("Reading Lists"). If you have already done so, you can put the permanent link to Leganto in both the Teaching Guide and the Virtual Campus.*

The Library is based on the bibliography recommended in the Teaching Guide to adapt its collection to the teaching and learning needs of the degrees.

If you need to update your bibliography, the link is the following, <https://buc-uva.alma.exlibrisgroup.com/leganto/login?auth=SAML> (access using your UVA keys). This link sends you to the Uva directory authentication page, which redirects you to Leganto. Once there, the reading lists corresponding to the different courses you teach ("Instructor" in Leganto/Alma terminology). From here, you could add new titles to existing lists, create sections within them or, on the other hand, create new lists of recommended bibliography. You can consult existing reading lists using the search engine located in the top left menu, option "búsqueda de listas".

At the top right of each reading list there is a button with the omission sign "•••" (suspension points), through which a menu is displayed that, among other options, allows to create a shareable link ("Crear un enlace compartible") which can be directed either to the specific reading list or to the course ("Curso"). This link can be indicated both in section "g. Teaching materials" (and subsections) of the Teaching Guide and in the bibliography section of the corresponding course of the Virtual Campus.

To solve any question you can consult your centre's library. [Professor help guide](#)

g.1 Basic bibliography

It can be consulted at the following link to Leganto:

https://buc-uva.alma.exlibrisgroup.com/leganto/public/34BUC_UVA/lists/7277335910005774?auth=SAML

g.2 Complementary bibliography

Guidelines on Good Manufacturing Practice specific to Advanced Therapy Medicinal Products, by the European Medicines Agency (EMA): https://health.ec.europa.eu/document/download/ad33d9dd-03f0-4bef-af53-21308ce2187d_en?filename=2017_11_22_guidelines_gmp_for_atmps.pdf

g.3 Other telematic resources (knowledge pills, blogs, videos, digital journals, massive courses (MOOC), ...)

Website of the Spanish Agency of Medicines and Medical Devices (AEMPS) on advanced therapies.

<https://www.aemps.gob.es/medicamentos-de-uso-humano/terapias-avanzadas/>

Website of the European Medicines Agency (EMA) on advanced therapies:



<https://www.ema.europa.eu/en/human-regulatory/overview/advanced-therapy-medicinal-products-overview>

Both links contain different resources on the classification and definitions of advanced therapies, their current regulation, relevant related articles, etc.

h. Necessary resources

Access to the UVa Virtual Campus (Moodle platform).

Laboratory practices will be carried out in the cell culture room on the 3rd floor of the Faculty of Medicine.

i. Timing

ECTS load	EXPECTED DEVELOPMENT PERIOD
6.0	2 nd semester

5. Teaching methods and methodological principles

The face-to-face training activities of this subject include the following modalities:

Theoretical classes: they will consist of sessions with participatory and open formats, so that the student can actively engage in their own learning by asking questions related to taught subject.

Seminars: they will be based on sessions oriented and/or supervised by the teacher where students work on scheduled tasks and/or participate in discussions on topics related to the subject, after the students are prepared by prior consultation of the indicated resources.

Classroom practices: they include student work guided and supervised by the teacher on case studies, problems, exercises, etc.

Laboratory practices: to be carried out in a cell culture laboratory with the necessary equipment, where the practical contents of the subject will be developed while learning to work in that specific environment. A booklet will be provided with the necessary information. Deliverable tasks of these practices will be part of the continuous assessment.

Individual or group tutorials: students will be assisted to discuss specific issues and/or resolve any doubt or question related to the course, in case they need it. Tutorials will be arranged with the teacher, who will communicate his/her time availability.

Finally, non-face-to-face training activities correspond to the individual work that the student carries out without the presence of the teacher. These work hours include studying, expanding and synthesizing the information received, reading related documentation, completing tasks and assignments to be delivered, and preparing for the exam.

6. Table of student dedication to the course

FACE-TO-FACE ACTIVITIES or REMOTE FACE-TO-FACE ⁽¹⁾	HOURS	NON-FACE-TO-FACE ACTIVITIES	HOURS
Theoretical classes	20	Individual study of the contents	50
Seminars	5	Preparation for classes (reading articles or other documents)	30
Classroom practices	5	Tasks to deliver related to the seminars	15
Laboratory practices	15	Work to be delivered related to laboratory practices	10
Total face-to-face	45	Total non-face-to-face	105
TOTAL face-to-face + non-face-to-face			150

(1) Remote face-to-face activity is when a group sitting in a classroom on campus follows a class via videoconference synchronously, taught by the professor.

7. Assessment system and characteristics

INSTRUMENT/PROCEDURE	WEIGHT IN THE FINAL MARK	OBSERVATIONS
Written exam	80%	Test and/or short questions.
Continuous assessment	20%	Includes participation in class, exercises to be delivered, practical work, etc.

ASSESSMENT CRITERIA

- **Ordinary call:**
 - Exam (80%). It is needed to obtain a 5 out of 10 in this exam for the continuous assessment mark to be added.
 - Continuous assessment (20%)
- **Extraordinary call^(*):**
 - The same as in the ordinary call. In this case, the continuous assessment mark will only be taken into account if it improves the student's final mark.

() An extraordinary call is understood to be the second call.*

REMINDER The student must be able to score out of 10 in the extraordinary call except in the special cases indicated in Art 35.4 of ROA 35.4. Participation in the extraordinary call will not be conditioned to class attendance or presence in previous tests, except in cases of external practices, laboratories or other activities whose evaluation would not be possible without prior completion of the aforementioned tests.

<https://secretariageneral.uva.es/wp-content/uploads/VII.2.-Reglamento-de-Ordenacion-Academica.pdf>

8. Final considerations