



Proyecto/Guía docente de la asignatura

Project/Course Syllabus

Se debe indicar de forma fiel cómo va a ser desarrollada la docencia. Esta guía debe ser elaborada teniendo en cuenta a todo el profesorado de la asignatura. Conocidos los espacios y profesorado disponible. Los detalles de la asignatura serán informados por el Campus Virtual.

Se recuerda la importancia que tienen los comités de título en su labor de verificar la coherencia de las guías docentes de acuerdo con lo recogido en la memoria de verificación del título y/o en sus planes de mejora. Por ello, **tanto la guía, como cualquier modificación** que sufra en aspectos "regulados" (competencias, metodologías, criterios de evaluación y planificación, etc..) deberá estar **informada favorablemente por el comité de título ANTES** de ser colgada en la aplicación web de la UVa. Se ha añadido una fila en la primera tabla para indicar la fecha en la que el comité revisó la guía.

The syllabus must accurately reflect how the course will be delivered. It should be prepared in coordination with all teaching staff involved in the course and once the available teaching spaces and instructors are confirmed. Specific details regarding the course will be communicated through the Virtual Campus.

It is important to recall the key role of the Degree Committees in verifying the coherence of course syllabi with the official degree verification report and/or any improvement plans. Therefore, the syllabus — as well as any changes affecting "regulated" aspects (such as learning outcomes, teaching methods, assessment criteria, and course schedule) — must receive prior approval from the Degree Committee BEFORE being published on the UVa web application. A new row has been added to the first table to indicate the date on which the Committee reviewed the syllabus.

Asignatura <i>Course</i>	CELL THERAPY AND TISSUE ENGINEERING		
Materia <i>Subject area</i>	Advanced Therapies		
Módulo <i>Module</i>	-		
Titulación <i>Degree Programme</i>	Degree in Biomedicine and Advanced Therapies		
Plan <i>Curriculum</i>	710	Código <i>Code</i>	47915
Periodo de impartición <i>Teaching Period</i>	2 nd Semester	Tipo/Carácter <i>Type</i>	Mandatory
Nivel/Ciclo <i>Level/Cycle</i>	DEGREE	Curso <i>Course</i>	THIRD
Créditos ECTS <i>ECTS credits</i>	6		
Lengua en que se imparte <i>Language of instruction</i>	English		
Profesor/es responsable/s <i>Responsible Teacher/s</i>	Dr. Margarita González-Vallinas Garrachón (coordination) Dr. María Teresa Gallego Martín Dr. María Mercedes Alberca Zaballos		
Datos de contacto (E-mail, teléfono...) <i>Contact details (e-mail, telephone...)</i>	margarita.gonzalez-vallinas@uva.es teresa.gallego.martin@uva.es mmalberca@uva.es		
Departamento <i>Department</i>	Dept. of Biochemistry and Molecular Biology and Physiology		
Fecha de revisión por el Comité de Título <i>Review date by the Degree Committee</i>	4 de julio de 2025		

En caso de guías bilingües con discrepancias, la validez será para la versión en español.
In the case of bilingual guides with discrepancies, the Spanish version will prevail.



1. Situación / Sentido de la Asignatura

Course Context and Relevance

1.1 Contextualización

Course Context

"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 Relación con otras materias

Connection 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 Prerrequisitos

Prerequisites

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

2. Resultados del proceso de formación y de aprendizaje (RD 822/2021) o competencias (RD 1393/2007)

Learning outcomes (RD 822/2021) or competences (RD 1393/2007)

Para los planes de estudio al amparo del RD 822/2021 deben completarse conocimientos o contenidos, habilidades o destrezas y las competencias.

Para los planes de estudio al amparo del RD 1393/2007 deben completarse las Competencias Generales y las Competencias Específicas.

For study programmes under RD 822/2021, it is necessary to specify knowledge or content, skills or abilities, and competences.

For study programmes under RD 1393/2007, General Competences and Specific Competences must be included.

2.1 (RD1393/2007) Competencias Generales

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) Competencias Específicas

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. Objetivos

Course 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. Contenidos y/o bloques temáticos****Course Contents and/or Modules****Bloque 1: "Cell Therapy and tissue engineering"****Module 1: "Cell Therapy and tissue engineering"**

Carga de trabajo en créditos ECTS:

*Workload in ECTS credits:***a. Contextualización y justificación****a. Context and rationale**

(Previously described in section 1.1).

b. Objetivos de aprendizaje**b. Learning objectives**

(Previously described in section 3).

c. Contenidos**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. Cell-based therapies in degenerative diseases: MSCs and their mechanisms of action.
- Lesson 11. Cell-based therapies in congenital haematological diseases (Fanconi anaemia).
- Lesson 12. Cell-based therapies 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 product of mesenchymal stem cells combined with a biocompatible matrix.
- Stability study of cellular products with different excipients at different time points.

d. Métodos docentes**d. Teaching and Learning 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. Plan de trabajo**e. Work plan**

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. Evaluación**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. Material docente**g Teaching material**

*Es fundamental que las referencias suministradas este curso estén actualizadas y sean completas. El profesorado tiene acceso, a la **plataforma Leganto de la Biblioteca** para actualizar su bibliografía recomendada ("Listas de Lecturas"). Si ya lo ha hecho, puede poner tanto en la guía docente como en el Campus Virtual el enlace permanente a Leganto.*

La Biblioteca se basa en la bibliografía recomendada en la Guía docente para adaptar su colección a las necesidades de docencia y aprendizaje de las titulaciones.

Si tiene que actualizar su bibliografía, el enlace es el siguiente,

<https://buc-uva.alma.exlibrisgroup.com/leganto/login?auth=SAML> (acceso mediante tus claves UVA). Este enlace te envía a la página de autenticación del directorio UVA, el cual te redirige a Leganto. Una vez allí, aparecerán, por defecto, las listas de lectura correspondientes a las distintas asignaturas que imparte ("instructor" en la terminología de Leganto / Alma). Desde aquí podría añadir nuevos títulos a las listas existentes, crear secciones dentro de ellas o, por otra parte, crear nuevas listas de bibliografía recomendada.

Puede consultar las listas de lectura existentes mediante el buscador situado en el menú de arriba a

It is essential that the references provided for this course are up to date and complete. Faculty members have access to the Library's Leganto platform to update their recommended reading lists. If they have already done so, they may include the permanent Leganto link both in the course syllabus and on the Virtual Campus.

The Library relies on the recommended bibliography listed in the course syllabus to adapt its collection to the teaching and learning needs of each degree programme.

To update your bibliography, please use the following link:

<https://buc-uva.alma.exlibrisgroup.com/leganto/login?auth=SAML> (access using your UVA credentials). This link takes you to the UVA directory authentication page, which will then redirect you to Leganto. Once there, the reading lists associated with the courses you teach will appear by default ("instructor" in Leganto/Alma terminology). From this platform, you can add new titles to existing lists, create sections within them, or alternatively, create new recommended reading lists.

You can browse existing reading lists using the search bar located in the top left menu, under the "Find Lists" option.

la izquierda, opción "búsqueda de listas".

En la parte superior derecha de cada lista de lectura se encuentra un botón con el signo de omisión "•••" (puntos suspensivos), a través del cual se despliega un menú que, entre otras opciones, permite "Crear un enlace compartible" que puede dirigir o bien a la lista de lectura concreta o bien al "Curso" (asignatura). Este enlace se puede indicar tanto en el apartado "g. Materiales docentes" (y subapartados) de la Guía Docente como en la sección de Bibliografía correspondiente a la asignatura en el Campus Virtual Uva.

Para resolver cualquier duda puede consultar con la biblioteca de tu centro. [Guía de Ayuda al profesor](#)

In the top right corner of each reading list, you will find a button marked with an ellipsis "•••" (three dots). Clicking it opens a menu that includes, among other options, the ability to "Create a shareable link", which can point either to a specific reading list or to the entire course. This link can be included in section "g. Teaching Materials" (and its subsections) of the Course Syllabus, as well as in the Bibliography section of the course page on the UVA Virtual Campus.

If you have any questions, please contact your faculty library. [Guía de Ayuda al profesor](#)

g.1 Bibliografía básica

Required Reading

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 Bibliografía complementaria

Supplementary Reading

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 Otros recursos telemáticos (píldoras de conocimiento, blogs, videos, revistas digitales, cursos masivos (MOOC), ...)

Additional Online Resources (microlearning units, blogs, videos, digital journals, massive online courses (MOOC), etc.)

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. Recursos necesarios

Required 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. Temporalización

Course Schedule

CARGA ECTS ECTS LOAD	PERIODO PREVISTO DE DESARROLLO PLANNED TEACHING PERIOD
6.0	2 nd semester

5. Métodos docentes y principios metodológicos

Instructional Methods and guiding 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. Tabla de dedicación del estudiantado a la asignatura

Student Workload Table

ACTIVIDADES PRESENCIALES o PRESENCIALES o A DISTANCIA ⁽¹⁾ FACE-TO-FACE/ ON-SITE or ONLINE ACTIVITIES ⁽¹⁾	HORAS HOURS	ACTIVIDADES NO PRESENCIALES INDEPENDENT / OFF-CAMPUS WORK	HORAS 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 presencial <i>Total face-to-face</i>	45	Total no presencial. <i>Total non-face-to-face</i>	105
TOTAL presencial + no presencial <i>Total</i>			150

(1) Actividad presencial a distancia es cuando un grupo sentado en un aula del campus sigue una clase por videoconferencia de forma síncrona, impartida por el profesor. *Distance face-to-face activity refers to a situation in which a group of students, seated in a classroom on campus, attends a class via live videoconference delivered by the instructor in real time.*

7. Sistema y características de la evaluación

Assessment system and criteria

INSTRUMENTO/PROCEDIMIENTO ASSESSMENT METHOD/PROCEDURE	PESO EN LA NOTA FINAL WEIGHT IN FINAL GRADE	OBSERVACIONES REMARKS
Written exam	80%	Test and/or short questions.
Continuous assessment	20%	Includes participation in class, exercises to be delivered, practical work, etc.

CRITERIOS DE CALIFICACIÓN ASSESSMENT CRITERIA

- **Convocatoria ordinaria. First Exam Session (Ordinary)**
 - 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%)
- **Convocatoria extraordinaria^(*) Second Exam Session (Extraordinary / Resit) ^(*):**
 - 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.

(*) Se entiende por convocatoria extraordinaria la segunda convocatoria.

RECORDATORIO El estudiante debe poder puntuar sobre 10 en la convocatoria extraordinaria salvo en los casos especiales indicados en el Art 35.4 del ROA 35.4. "La participación en la convocatoria extraordinaria no quedará sujeta a la asistencia a clase ni a la presencia en pruebas anteriores, salvo en los casos de prácticas externas, laboratorios u otras actividades cuya evaluación no fuera posible sin la previa realización de las mencionadas pruebas."

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

(*)The term "second exam session (extraordinary/resit)" refers to the second official examination opportunity.

REMINDER Students must be assessed on a scale of 0 to 10 in the extraordinary session, except in the special cases indicated in Article 35.4 of the ROA: "Participation in the extraordinary exam session shall not be subject to class attendance or participation in previous assessments, except in cases involving external internships, laboratory work, or other activities for which evaluation would not be possible without prior completion of the aforementioned components."

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

8. Consideraciones finales

Final remarks

Use of Artificial Intelligence (AI): The use of AI tools for preparing assignments, reports, or any other assessable activity is strictly prohibited unless explicitly authorized. Such authorization applies only to the specific activity for which it was granted.