Master in Manufacturing of Advanced Therapy Medicinal Products

2025/2026

www.atmp-masterinmanufacturing.com

LIMITED CAPACITY!

Organized by:

Junta de Andalucía
Consejería de Salud y Consumo
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andalusian network
For the design & translation of
advanced therapies

International School for Postgraduate Studies

UNIVERSIDAD DE GRANADA

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SUMMARY

1. JUSTIFICATION

Advanced therapy medicinal products (ATMPs) are a particularly novel class of medicines and possibly constitute one of the most complex organizational and regulatory tasks that may be approached by clinical researchers in order to explore new therapeutic applications. ATMPs, including cell therapy, gene therapy and tissue engineered products, were classified as such by two European Directives (2003/63/EC and 2009/120/EC) and Regulation (EC) No. 1394/2007 of the European Parliament and of the Council, and represent a field with a constantly evolving regulatory landscape that scientists and regulators alike find difficult to navigate.

In May 2018, new Guidelines on Good Manufacturing Practice (GMP) specific to ATMPs came into force in Europe. These recent regulatory changes imply a transformation of the requirements for ATMP manufacturing and their application to human beings. Stem cell scientists should therefore be aware of the intricacies of GMP implementation before initiating full-fledged translational programmes, and also have at their disposal well trained technologists who will develop ATMPs at different laboratories and institutions - be it hospitals, academia or industry - within Europe.

The Master Degree in “Manufacturing of Advanced Therapy Medicinal Products” is founded upon the experience obtained from the training programme in manufacturing of ATMPs designed and set up in 2009 by the Andalusian Network of the design and translation of Advanced Therapies ***(1)*** and which, with the collaboration of the University of Granada, achieved Master Programme status in 2010. This Master is offered in English and is mainly, but not exclusively, focused on European students

The international Master’s Programme in the manufacturing of advanced therapy medicinal products is expected to cater to the needs of any European institution trying to implement ATMP Regulation. For this reason, it counted upon the participation, advice and support of European Medicines Agency (EMA) Experts.

1 - Cuende N, Izeta A. Clinical translation of stem cell therapies: a bridgeable gap. Cell Stem Cell. 2010;6(6):508-12

2. MASTER'S PROGRAMME FOCUS AND TARGET AUDIENCE

This Programme is quite unique in that it is not intended for biomedical students pursuing a Ph.D. in regenerative medicine or related subjects. In our opinion, there are plenty of postgraduate programmes at European universities that fill that knowledge area. As an alternative, the target audience for this pioneering Master's programme are the professionals presently working (or intending to do so) in Good Manufacturing Practice (GMP)-compliant facilities producing cell therapy, gene therapy or tissue engineered products for human use. In other words, we are targeting the technologists who will develop advanced therapy medicinal products (ATMPs) in different laboratories and institutions - be it hospitals, academia or industry - within Europe, such as:

- *Technical Directors or Qualified Persons of ATMP's Pharmaceutical Laboratories*
- *Manufacturing Managers of ATMP's Pharmaceutical Laboratories*
- *Quality Control Managers of ATMP's Pharmaceutical Laboratories*
- *Quality Assurance Expert of ATMP's Pharmaceutical Laboratories*

QUALIFIED PERSON (TECHNICAL DIRECTOR)

The qualified person is the main person responsible for managing the A.T. laboratory activities and for ensuring compliance with all GMP rules as well as for the budget implementation. This position, therefore, requires a high qualification, that is specifies in the 2001/83 European Directive ***(1)*** as follows:

> *"A qualified person shall be in possession of a diploma, certificate of other evidence of formal qualifications awarded on completion of a university course of study, or a course recognized as equivalent by the Member State concerned, extending over a period of at least four years of theoretical and practical study in one of the following scientific disciplines: pharmacy, medicine, veterinary medicine, chemistry, pharmaceutical chemistry and technology, biology. However, the minimum duration for the university course may be three and half years where the course is followed by a period of theoretical and practical training of a minimum duration of one year and including a training period of at least six months in a pharmacy open to public, corroborated by an examination at university level".*

MANUFACTURING MANAGER

The Manager of the Manufacturing Department must guarantee that products are manufactured and stored according to SOPs and GMPs ***(2)*** in order to obtain the required quality. He/she is responsible for ensuring that appropriate validations are achieved as well as the required initial and continuing training of the personnel of his/her department is carried out and adapted according to need.

QUALITY CONTROL MANAGER

The Quality Control Manager ***(2)*** is responsible for approving or rejecting, as appropriate, all starting and packaging materials, intermediate bulk as well as finished products. He/she is also responsible for approving specifications, sampling instructions, test methods and any other

1 - Article 49, Directive 2001/83 of the European Parliament and of the Council of 6 November 2001 on the community code relating to medical products for human use
2 - EudraLex - Volume 4 Good manufacturing practice (GMP) Guidelines. Chapter 2 Personnel

quality control procedures. He/she must ensure that the required initial and continuing training of the personnel of his/her department is carried out and adapted according to need.

QUALITY ASSURANCE EXPERT

The Quality Assurance Expert is responsible for guaranteeing that the entire organized arrangements are carried out with the objective of ensuring that medicinal products are of the quality required for their intended use. Quality assurance, therefore, incorporates Good Manufacturing Practice ***(3)***.

Other potential attendees are professionals from diverse backgrounds who wish to update their knowledge related to any of our theoretical sections or who are seeking to enter the advanced therapy sector, or academic institutions and other public employees seeking to acquire a deep understanding of the sector that was once the preserve of the pharmaceutical industry.

THE UNIVERSITY-SPECIFIC DEGREES WE ARE OFFERING ARE:

- Master Degree in Manufacturing of Advanced Therapy Medicinal Products
  (1,500 hours / 60 ECTS)
- Specialisation Degree in Manufacturing of Advanced Therapy Medicinal Products
  (970 hours / 38.80 ECTS)

REQUIREMENTS FOR APPLYING TO THE DEGREES: STUDENT'S PROFILES

Applicants should hold a University Degree following at least 4 years of study or a Bachelor Degree with a Major or Specialism in the biomedical field (pharmacy, medicine, veterinary medicine, biology, biochemistry or biotechnology)

Applicants for the Master degree should also have acquired practical experience in cell culture.

3 - EudraLex - Volume 4 Good manufacturing practice (GMP) Guidelines. Chapter 1 Quality Management

3. OVERVIEW OF THE MASTER/SPECIALISATION DEGREE'S STRUCTURE AND METHODOLOGY

The Master degree will provide participants with the knowledge, skills and hands-on technical expertise necessary to face the challenges of manufacturing ATMPs for clinical use. This innovative master combines the general fundamentals of ATMP regulation with specific knowledge necessary to deal with the development of medicinal products of cell therapy, gene therapy and tissue engineering.

Both Degrees will include:

- ***Theoretical training*** *that is composed of 12 sections that will be completed online by students at their convenience, although with continuous support from instructors through a dedicated e-learning platform that will be available on a 24/7 basis. The case method will be used throughout the online activities promoting interaction and debate with professors and other students, creating strong and lasting relationships.*

The Master Degree will also include:

- ***3-week period of practical training*** *at Línea IAVANTE's (Fundación Progreso y Salud) headquarters in Granada, Spain. This will complement the acquired theoretical knowledge by making use of a fully equipped GMP facility specifically built for training purposes and dedicated expert tutors.*

- ***Supervised individual work*** *to compile a GMP facility dossier (site master file) as final project (dissertation) of the Master Degree.*

4. THEORETICAL CONTENTS

SECTION 1
An introduction to Advanced Therapies Regulation: bench to bedside roadmap:
1.1 A primer on regulation of advanced therapies in Europe: what is and what is not an Advanced Therapy Medicinal Product (ATMP)?
1.2 An introduction to ATMP development: roadmap

SECTION 2
Human embryonic and adult cells and tissues. Homeostasis, disregulation and disease:
2.1 Human cell and tissue diversity
2.2 Cell migration, communication, adhesion and histogenesis
2.3 Cell proliferation and differentiation
2.4 Cell progenitors and stem cells. The concept of stem cell niche
2.5 Principles of tissue repair and regeneration
2.6 Ageing, senescence and cell death
2.7 Oncogenesis, invasion and metastasis. Cellular hallmarks of cancer initiation and progression

SECTION 3
Cells with current and potential clinical application:
3.1 Committed cells
3.2 Adult stem cells: MSC & more
3.3 Pluripotent stem cells

SECTION 4
Methods for manufacturing of cell-based therapies:
4.1 Cell and tissue culture basics
4.2 Cell isolation, proliferation and differentiation
4.3 Cell culture quality control
4.4 Good Cell Culture Practice (GCCP)
4.5 Scalability strategies for cell manufacturing

SECTION 5
Viral vectors and gene therapy:
5.1 Viruses and viral vectors
5.2 Non-viral gene delivery
5.3 Methodological aspects of gene therapy
5.4 Advanced concepts in gene therapy
5.5 CAR-T cells
5.6 Upstream and downstream processes in gene therapy

SECTION 6
Tissue engineering for clinical application:
6.1 Tissue engineering: concepts, technology and applications
6.2 Biomaterials and nanotechnology
6.3 Tissue engineering models
6.4 Bioengineered organs

SECTION 7
Good manufacturing practice (GMP) as applied to ATMPs:
7.1 Risk-based approach, personnel, premises, equipment, qualification and documentation
7.2 Starting and raw materials, seed lot and cell bank system, production, validation and quality control
7.3 Qualified person and batch release
7.4 Outsourced activities, quality defects and product recalls
7.5 Environmental control measures for ATMPs and for ATMP containing or consisting of GMOs
7.6 Product reconstitution after batch release
7.7 Automated production of ATMPs

SECTION 8
Quality, manufacturing and biosafety aspects in the regulation of ATMP development:
8.1 Biosafety issues related to cell and tissue donation
8.2 Characterization of ATMPs: potency, identity, purity, stability and comparability
8.3 Current methods in the quality control of ATMPs
8.4 Environmental monitoring programme
8.5 Genetically modified organisms. Contention levels

SECTION 9
Non-clinical and clinical aspects concerning the regulation of ATMP development:
9.1 An introduction to animal models of human disease. Genetic models
9.2 Good laboratory practice (GLP) implementation
9.3 ATMP non-clinical protocol design
9.4 Clinical trial design
9.5 Good clinical practice (GCP)
9.6 Risk based approach, risk management, drug safety and pharmacovigilance

SECTION 10
Investigational Medicinal Product Dossier (IMPD) and Common Technical Document (CTD):
10.1 Investigational Medicinal Product Dossier (IMPD)
10.2 Common Technical Document (CTD)

SECTION 11
Current implications and future perspectives in ATMP development:
11.1 Ethical issues related to advanced therapies
11.2 Intellectual property and industry right management in advanced therapies
11.3 Business model specificities according to product characteristics and worldwide perspective
11.4 Regulatory incentives for ATMP development

SECTION 12
Pharmaceutical Quality System:
12.1 Quality risk management
12.2 Quality management system and good documentation practices

DESCRIPTION OF THE CONTENTS FOR EACH THEORETICAL SECTION

SECTION 1

AN INTRODUCTION TO ADVANCED THERAPIES REGULATION: BENCH TO BEDSIDE ROADMAP

This section will try to provide students with arguments that will help them translate in regulatory terms the issues related to their particular therapeutic approach. Is it a medicinal product or not? If so, what kind of product is it? Is it an advanced therapy? Once classified, students should develop the abilities (roadmaps) to bring basic laboratory results to the bedside. The uncertain journey for the clinical translation of promising bench results will be here summarized for cell, gene and tissue engineered products. It will serve as an introductory chapter for subsequent sections that will approach specific issues in a more comprehensive manner.

SECTION 2

HUMAN EMBRYONIC AND ADULT CELLS AND TISSUES. HOMEOSTASIS, DISREGULATION AND DISEASE

This section aims to summarize key knowledge on cell and developmental biology that will be of use for professionals involved in the development of advanced therapy medicinal products. As one of the introductory modules, it is not expected to go into great detail in any of the subheadings. Rather, it should provide the students with some very basic materials to initiate or increase their understanding of human development both in homeostasis and disease, as well as their relationship to basic cell features such as migration, communication, proliferation, differentiation, etc. Importantly, it should provide the students with basic knowledge on cellular ageing, oncogenic transformation and cell death that will provide a theoretical basis for several quality control procedures that will appear later in the programme and in the students' professional life.

SECTION 3

CELLS WITH CURRENT AND POTENTIAL CLINICAL APPLICATION

Once the basic cell and tissue biology concepts have been summarized in Section 2, this module will introduce students to the cell therapy field by means of a historical overview of how cells have been introduced into the clinic. Use of keratinocyte and chondrocyte cultures is now extended practice worldwide. These have been grouped as "committed cells" and the lessons that we learned along the way to their clinical application will be of use to anybody intending to bring another cell type into human patients. A general introduction to stem cells is also expected to be included in this section, alongside an extended description of the decades-long effort concerning HSC characterization and their use in bone marrow transplantation improvement. Finally, pluripotent stem cells will be introduced as well as new approaches to generate tissues in the near future such as iPS cell technology or direct transdifferentiation of somatic cells.

SECTION 4

METHODS FOR MANUFACTURING OF CELL-BASED THERAPIES

This first methodological section will cover all aspects of basic cell culture laboratory. This methodological module is expected to cover cell culture techniques including those related to tissue specific stem cell isolation and analysis. It will provide the student with the theoretical basis to understand cell and tissue culture, with an emphasis on the importance of culture media, equipment, facility design, etc. GMP manufacturing will be covered later in the programme: basic knowledge of cells identity, sterility, virus safety and detection of replicant competent virus will be discussed as the main quality control in cell and gene therapy.

SECTION 5

VIRAL VECTORS AND GENE THERAPY

At this point the student has acquired an understanding of cell biology issues from quite different points of view: basic cell biology, stem cells and their application to cell therapy, and associated methodology for standard cultures. It is, therefore, appropriate to introduce viruses and their use in gene therapy. This section is expected to summarize important facts concerning virus life cycles that will be of use later when virus vectors are discussed. Rather than introduce virology on a general basis, it is expected that the section will focus on viruses that are being developed into vectors in use in the clinical arena (AAV, AdV, retro and lentiviruses, etc.) both from the theoretical and the methodological point of view. While a general introduction to molecular biology techniques is clearly beyond the scope of this master, it is clear that all aspects of viral vector production should be touched upon (on a non-GMP basis: this will be dealt with later in the programme). Albeit less comprehensively, this section should also review non-viral gene delivery as well as "advanced concepts" such as gene targeting with custom-designed zinc finger nucleases, exon-skipping, RNAi, transposons and any other genetic modification technique that surpasses the "classical" faulty gene replacement approaches.

SECTION 6

TISSUE ENGINEERING FOR CLINICAL APPLICATION

Advanced therapies include tissue-engineered products (TEPs) which are generally composed of cells and biomaterials. Once the methodological aspects of cell culture and gene therapy are well studied, the programme switches its focus to TEPs, looking at these both from a theoretical and methodological standpoint. This module will start with the generalities of tissue engineering, and it is expected to focus more heavily on biomaterials since this is the first time these are introduced during the course. An overview of methodology associated with engineering particular tissues will be presented. Finally, this section will introduce two important issues that are not officially classified as advanced therapies yet which interact closely with them: that is the use of nanotechnology approaches and growth factor delivery in regenerative medicine which will be discussed within the framework of ATMP development.

SECTION 7

GOOD MANUFACTURING PRACTICE (GMP) AS APPLIED TO ATMPs

This section is arguably the most important in the programme since it includes many key issues in ATMP development and, thus, it is expected to be lengthy. During this section, we will describe Good Manufacturing Practice (GMP) as applied to ATMPs. While the generic GMP regulations, it is common knowledge that are easily accessible to anyone, we expect this section to explain them in a very clear manner by making use of specific examples (for example, a cellular product to be injected into the bloodstream).

SECTION 8

QUALITY, MANUFACTURING AND BIOSAFETY ASPECTS IN THE REGULATION OF ATMP DEVELOPMENT

Although general biosafety rules were introduced in section 4, this module will now examine biosafety issues related to donor selection, cell and tissue manipulation as considered specifically under transplant and pharmaceutical legislation. ATMP development will now be introduced from the point of view of the different aspects that characterize regulatory guidelines: quality, non-clinical and clinical. This section will first summarize typical quality aspects that should be defined for any ATMP: it is expected to explain full methodology of quality control of cellular products under GMP regulation (not to be confused with previous general quality control procedures for cells produced in a non- regulated environment). While these controls are very much product dependent, there are many that have been described extensively and that will be useful for the student in their professional activity on a daily basis. Although more extensive on cellular products, discussion should also include gene therapy product characterization and TEPs.

SECTION 9

NON-CLINICAL AND CLINICAL ASPECTS CONCERNING THE REGULATION OF ATMP DEVELOPMENT

This section will have to summarize many things and, thus, it is expected to introduce ideas for the student to develop further if interested. First, animal models of disease will be introduced as well as non-clinical protocol design. These two concepts are of great importance since they will impact on product development more than anything else, and, therefore, all available choices should be carefully considered. Implementation of good laboratory practice (GLP) is a must for these experiments to be considered under pharmaceutical legislation. Although normally done with specialist companies, it is important for the students to understand the issues related to GLP. The section will then move on to describe clinical trial regulation through good clinical practice (GCP) and, finally, the section will introduce investigational medicinal product (IMP) vigilance and pharmacovigilance.

SECTION 10

INVESTIGATIONAL MEDICINAL PRODUCT DOSSIER (IMPD) AND COMMON TECHNICAL DOCUMENT (CTD)

This section will summarize the structure of the investigational medicinal product dossier

(IMPD) and the common technical document (CTD). The IMPD will be always required to start a clinical trial. During this section, we will describe it as applied to ATMPs using specific examples not only related to this purpose but also to the difficulties usually encountered by independent researchers.

SECTION 11

CURRENT IMPLICATIONS AND FUTURE PERSPECTIVES IN ATMP DEVELOPMENT

ATMP development is a risky business and the socioeconomic implications must be considered before embarking on it. This module is expected to review different models that are being assayed worldwide for ATMP development. It will provide distinct points of view from academic, biotech and pharmaceutical stakeholders and also from funding bodies, patient associations, etc., providing the student with a general picture of what is needed for a putative therapy to actually reach the market. The current market will be analysed and main company profiles provided, learning both from success stories and major crashes. The section will then review intellectual property and industry right management in advanced therapies adopting a worldwide perspective. Finally, ethical issues related to advanced therapies are expected to be reviewed with an emphasis on the national differences at the European level.

As one of the final sections, the main content is expected to focus on marketed and close to market ATMPs and their development status worldwide. These are the success stories to build upon. Secondly, a comprehensive review on cells, tissues and vectors currently in use in clinical trials as well as a primer on the clinical indications being targeted will be provided. These data are always useful for our own product development and provide cases to support our own products. Finally, some speculation will be provided on next generation ATMPs (iPS? transdifferentiated cells? targeted mutation replacement?) and future perspectives in advanced therapies will be summarized so that the student may foresee alternatives that might impact their product development strategy in the not-so-distant future.

SECTION 12

PHARMACEUTICAL QUALITY SYSTEM

In this last section, students will learn to properly manage a quality system and how to use deficiency and change management tools for the correct traceability of the quality system. Likewise, specific risk analysis tools will be identified and students will work with two of them for an adequate management of risks in the processes.

5. MASTER DEGREE' S PRACTICAL MODULES

The student of the master degree will be offered a hands-on training stay of three weeks' duration in Granada, Spain. Students will make use of a fully equipped GMP facility built for training purposes and dedicated expert tutors.

PRACTICAL MODULE 1

MANUFACTURING PROCESS OF AN INVESTIGATIONAL CELL THERAPY MEDICINAL PRODUCT

The main objectives of this module are to learn how...:

- *To produce an investigational cell therapy medicinal product according to GMP guidelines*
- *To recognize the differences between cell culture for research and manufacturing of a cell product*
- *To co-work with the quality control dept. to comply with GMP guidelines*
- *To generate and control relevant documentation*
- *To carry out manufacturing validations and define manufacturing critical points*
- *To enter and exit a GMP facility and to keep it in good condition*
- *To master tissue engineering techniques*

PRACTICAL MODULE 2

SITE MASTER FILE AND HOW TO PASS INSPECTIONS TO BECOME AN AUTHORIZED MANUFACTURER

The main objectives of this module are to learn how...:

- *To prepare a site master file in ATMPs*
- *To successfully pass inspections to become an authorized manufacturer*

PRACTICAL MODULE 3

QUALITY CONTROL, ENVIRONMENTAL CONTROL, QUALIFICATION AND VALIDATION OF PREMISES AND EQUIPMENT

The main objectives of this module are to learn how...:

- *To control advanced therapy medicinal products according to GMP guidelines*
- *To culture cells for advanced therapy medicinal products*
- *To co-work with the manufacturing dept. to comply with GMP guidelines*
- *To carry out quality control validations*
- *To perform culture media and environmental control*
- *To master basic techniques in microbiology*
- *To practice endotoxins and mycoplasma test according to European pharmacopoeia*
- *To carry out sterility and growth promotion test*

6. MASTER'S DISSERTATION

Students of the master degree will have to complete an original final project or dissertation consisting of a compilation of a site master file (GMP facility's dossier) that will be supervised and evaluated. Finally, they will have to defend it in front of an Examining Board.

7. EDUCATION ADVISORY BOARD AND FACULTY MEMBERS

The Education Advisory Board took charge of supervising and reviewing all the theoretical contents of this Master's Programme.

MEMBERS OF THIS BOARD:

AUSTRIA

Prof. Heinz Redl
Founder and CEO. Trauma Care Consult. Director. Ludwig Boltzmann Institute for Experimental and Clinical Traumatology. Coordinator Austrian Cluster for Tissue Regeneration. Continental Chair- Europe of TERMIS. Associated Professor Technical University Vienna, Institute for Chemical Engineering

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Director of Biopharmaceuticals and ATMPs. NDA Group AB. Adjunct Professor University of Helsinki, Faculty of Biological and Environmental Sciences. Former Research Professor. Finnish Medicines Agency. Former Chair of the Committee for Advanced Therapies (CAT), EMA. Former Chair of the Cell Based Products Working Party (CPWC), EMA

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MEMBERS OF THE FACULTY:

The faculty members are mainly responsible for drawing up all the theoretical contents of the Master's Programme.

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Dr. Francisco Martín Molina
Group Leader. Gene and Cell Therapy Research Group. Pfizer – University of Granada - Junta de Andalucía Centre for Genomics and Oncological Research (GENYO). Granada

Dr. Miguel Ángel Martín Piedra
Professor. Department of Histology. Faculty of Medicine. University of Granada. Granada

Dr. Francisco Javier Molina
Senior Postdoctoral Researcher. Gene and Cell Therapy Research Group. Pfizer – University of Granada - Junta de Andalucía Centre for Genomics and Oncological Research (GENYO). Granada

Dr. Pilar Muñoz Fernández
Postdoctoral Scientist. Gene and Cell Therapy Research Group. Pfizer – University of Granada - Junta de Andalucía Centre for Genomics and Oncological Research (GENYO). Granada

Dr. Daniela Celeste Profico
Qualified Person. Production Unit for Advanced Therapies. Institute for Stem Cell Biology, Regenerative Medicine and Innovative Therapies (ISBReMIT). IRCCS Casa Sollievo della Sofferenza. San Giovanni Rotondo

Ms. Blanca Quijano
Clinical Trial Manager. Andalusian Network for the Design and Translation of Advanced Therapies. Sevilla

Dr. Antonio Rodríguez Acosta
Qualified Person. Cell Production Unit. Hospital Regional de Málaga. Málaga

Dr. David Sánchez Porras
Research Assistant. Department of Histology. University of Granada. Granada

Dr. Natalia Sánchez Romero
Postdoctoral Fellow. Laboratory of Organ Bioengineering and Regenerative Medicine, GI and Hepatology Research Group - IIS Aragón

Dr. Mónica Santos
Head of Quality. Cell therapy unit. Hospital Reina Sofía. Córdoba

Dr. Joaquím Vives
Director of Research and Development Department. Blood and Tissue Bank. Xcelia. Barcelona

8. VENUE OF THE PRACTICAL MODULES

The Master in Manufacturing of Advanced Therapy Medicinal Products will provide participants with the knowledge, skills and hands-on expertise necessary to face the challenges of manufacturing ATMPs for clinical use. The student will be offered a practical training stay of three weeks' duration in Granada (Spain).

This practical training will take place in a fully equipped GMP facility just built for training purposes in the Advanced Multifunctional Centre for Simulation and Technological Innovation, CMAT, managed by Línea IAVANTE (Fundación Progreso y Salud) which belongs to the Andalusian Regional Ministry of Health and Comsuption.

This 140 m^2 **GMP** facility includes the following rooms:

- 1 STORAGE ROOM
- 1 CULTURE ROOM AND MICROSCOPES ROOM
- 1 QUARANTINE ROOM
- 1 GMP FACILITY ZONE consisting of:

    - *1 quality control room*
    - *2 production rooms classified grade B*
    - *1 cryogenic freezing room*
    - *And an ancillary area with changing rooms*

All premises are designed, adapted and maintained according to GMP guidelines to suit all operations carried out by students. Their layout and design aim to minimise the risk of errors and to allow effective cleaning and maintenance in order to avoid cross contamination, build-up of dust or dirt and any adverse effect on the quality of products.

Every student will be provided by the protective garments needed to work in a GMP facility.
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9. SELECTION CRITERIA

Decisions regarding admissions will be made according to date of submission of your application form as well as your CV.

Once students are accepted, they will receive an e-mail of confirmation together with details concerning the method of payment.

This Master's programme will be developed under the regulation of University of Granada

10. HOW TO APPLY

To apply for one of the degrees we are offering, you must satisfy the requirements for your chosen degree. The requirements are set out in this document.

Please, send an e-mail to Ms. Amaya García (amaya.garcia@juntadeandalucia.es) to receive the registration form or further information

Applications must be submitted before 27th of January 2025 at 14:00hrs (CET)

11. DIRECTORS AND COORDINATORS OF THE MASTER' S PROGRAMME

DIRECTORS OF THE MASTER´S PROGRAMME:

Dr. Fernando Campos
Professor. Department Histology. Faculty of Medicine. University of Granada. Granada

Dr. Gloria Carmona
Scientific Coordinator. Andalusian Network for the Design and Translation of Advanced Therapies. Fundación Progreso y Salud. Consejería de Salud y Consumo. Sevilla

COORDINATORS OF THE MASTER'S PROGRAMME:

Dr. Elisabet Aguilar
Process Improvement Manager. Andalusian Network for the Design and Translation of Advanced Therapies. Fundación Progreso y Salud. Consejería de Salud y Consumo. Sevilla

Ms. Amaya García
Executive Secretary. Andalusian Network for the Design and Translation of Advanced Therapies. Fundación Progreso y Salud. Consejería de Salud y Consumo. Sevilla

Annex I
TUITION FEES

www.atmp-masterinmanufacturing.com

UNIVERSITY OF GRANADA **"MASTER IN MANUFACTURING OF ADVANCED THERAPY MEDICINAL PRODUCTS"** **Cell-based technologies: cell & gene therapies and tissue engineering** **2025 / 2026**	**MASTER** DEGREE IN MANUFACTURING OF ADVANCED THERAPY MEDICINAL PRODUCTS **(1,500 hours / 60 ECTS)**	**SPECIALISATION** DEGREE IN MANUFACTURING OF ADVANCED THERAPY MEDICINAL PRODUCTS **(970 hours / 38.80 ECTS)**	FEES FOR EACH INDIVIDUAL MODULE (€)
THEORETICAL MODULES			
1. An introduction to advanced therapies regulation: bench to bedside roadmap			**400**
2. Human embryonic and adult cells tissues. Homeostasis, disregulation and disease			**400**
3. Cells with current and potential clinical application			**400**
4. Methods for manufacturing of cell-based therapies			**400**
5. Viral vectors and gene therapy			**400**
6. Tissue engineering for clinical application			**400**
7. Good Manufacturing Practice (GMP) as applied to ATMPs			**400**
8. Quality, manufacturing and biosafety aspects in the regulation of ATMP development			**400**
9. Non- clinical and clinical aspects concerning the regulation of ATMP development			**400**
10. Investigational Medicinal Product Dossier (IMPD) and Common Technical Document (CTD)			**400**
11. Current implications and future perspectives in ATMP development			**400**
12. Pharmaceutical Quality System			**400**
PRACTICAL MODULES			
1. Manufacturing process of an investigational cell therapy medicinal product			**3,200**
2. Site master file and how to pass inspections to become an authorized manufacturer			**700**
3. Quality control, environmental control, qualification and validation of premises and equipment			**2,800**
FINAL PROJECT			
Compilation of a site master file			
MASTER/SPECIALISATION DEGREES' FEES (€)	**8,500**	**4,500**	**(€)**

REGISTRATION DEADLINE

Applications must be submitted **before 27th of January 2025 at 14:00 hrs (CET)**

Please, send an e-mail to Ms. Amaya García (amaya.garcia@juntadeandalucia.es) to receive the registration form or further information.

SCHOLARSHIP

A scholarship will be granted for one of the students who best complete the Master Degree. After completing the degree, he/she will be offered six-month period pay job in one of our laboratories in Andalusia (Spain). Applicants must have a valid Spanish residence permit.

Decisions regarding this scholarship will be made under criteria of the Direction of the Master's programme.

Annex II
CALENDAR

www.atmp-masterinmanufacturing.com

1. THEORETICAL MODULES (ON-LINE TRAINING)

2025

	Tuesday	Wednesday	Thursday	Friday	Monday
FEBRUARY	4	5	6	7	10
	SECTION 1: SELF-STUDY				
	11	12	13	14	17
	SECTION 1: CASE AND TEST				
	18	19	20	21	24
	BREAK				
	25	26	27	28	3
	SECTION 2: SELF-STUDY				
MARCH	4	5	6	7	10
	SECTION 2: SELF-STUDY AND CASE				
	11	12	13	14	17
	SECTION 2: CASE AND TEST				
	18	19	20	21	24
	BREAK				
	25	26	27	28	31
	SECTION 3: SELF-STUDY				
APRIL	1	2	3	4	7
	SECTION 3: SELF-STUDY AND CASE				
	8	9	10	11	14
	SECTION 3: CASE AND TEST				
EASTER BREAK					
APRIL	22	23	24	25	28
	BREAK				
	29	30	1	2	5
	SECTION 4: SELF-STUDY				
MAY	6	7	8	9	12
	SECTION 4: SELF-STUDY AND CASE				
	13	14	15	16	19
	SECTION 4: CASE AND TEST				
	20	21	22	23	26
	BREAK				
	27	28	29	30	2
	SECTION 5: SELF-STUDY				

This calendar is subject to change as deemed appropriate by the Direction of the Master's programme in order to accommodate circumstances beyond its control

	Tuesday	Wednesday	Thursday	Friday	Monday
JUNE	3	4	5	6	9
	SECTION 5: SELF-STUDY AND CASE				
	10	11	12	13	16
	SECTION 5: SELF-STUDY AND CASE				
	17	18	19	20	23
	SECTION 5: CASE AND TEST				
	24	25	26	27	30
	BREAK				

SUMMER BREAK

SEPTEMBER	16	17	18	19	22
	SECTION 6: SELF-STUDY				
	23	24	25	26	29
	SECTION 6: SELF-STUDY AND CASE				
	30	1	2	3	6
	SECTION 6: CASE AND TEST				
OCTOBER	7	8	9	10	13
	BREAK				
	14	15	16	17	20
	SECTION 7: SELF-STUDY				
	21	22	23	24	27
	SECTION 7: SELF-STUDY				
	28	29	30	31	3
	SECTION 7: SELF-STUDY AND TEST				
NOVEMBER	4	5	6	7	10
	BREAK				
	11	12	13	14	17
	SECTION 8: SELF-STUDY				
	18	19	20	21	24
	SECTION 8: SELF-STUDY				
	25	26	27	28	1
	SECTION 8: SELF-STUDY				
DECEMBER	2	3	4	5	8
	SECTION 8: SELF-STUDY AND TEST				
	9	10	11	12	15
	BREAK				

CHRISTMAS BREAK

This calendar is subject to change as deemed appropriate by the Direction of the Master's programme in order to accommodate circumstances beyond its control

2026

	Tuesday	Wednesday	Thursday	Friday	Monday
JANUARY	13	14	15	16	19
	SECTION 9: SELF-STUDY				
	20	21	22	23	26
	SECTION 9: SELF-STUDY AND CASE				
	27	28	29	30	2
	SECTION 9: SELF-STUDY AND CASE				
FEBRUARY	3	4	5	6	9
	SECTION 9: CASE AND TEST				
	10	11	12	13	16
	BREAK				
	17	18	19	20	23
	SECTION 10: SELF-STUDY				
	24	25	26	27	2
	SECTION 10: SELF-STUDY AND TEST				
MARCH	3	4	5	6	9
	BREAK				
	10	11	12	13	16
	SECTION 11: SELF-STUDY				
	17	18	19	20	23
	SECTION 11: SELF-STUDY AND CASE				
	24	25	26	27	30
	SECTION 11: CASE AND TEST				
EASTER BREAK					
APRIL	7	8	9	10	13
	BREAK				
	14	15	16	17	20
	SECTION 12: SELF-STUDY				
	21	22	23	24	27
	SECTION 12: SELF-STUDY AND TEST				
	28	29	30	1	4
	BREAK				

This calendar is subject to change as deemed appropriate by the Direction of the Master's programme in order to accommodate circumstances beyond its control

2. MASTER DEGREE'S PRACTICAL MODULES
(ON-SITE TRAINING IN A FULLY EQUIPPED GMP FACILITY GRANADA, SPAIN)

<table>
<tr><th></th><th>Monday</th><th>Tuesday</th><th>Wednesday</th><th>Thursday</th><th>Friday</th></tr>
<tr><td rowspan="6">MAY</td><td>11</td><td>12</td><td>13</td><td>14</td><td>15</td></tr>
<tr><td colspan="5">QUALITY CONTROL, ENVIRONMENTAL CONTROL, QUALIFICATION AND VALIDATION OF PREMISES AND EQUIPMENT</td></tr>
<tr><td>18</td><td>19</td><td>20</td><td>21</td><td>22</td></tr>
<tr><td colspan="5">MANUFACTURING PROCESS OF AN INVESTIGATIONAL CELL THERAPY MEDICINAL PRODUCT</td></tr>
<tr><td>25</td><td>26</td><td>27</td><td>28</td><td></td></tr>
<tr><td colspan="2">MANUFACTURING PROCESS OF AN INVESTIGATIONAL CELL THERAPY MEDICINAL PRODUCT</td><td colspan="2">SITE MASTER FILE AND HOW TO PASS INSPECTIONS TO BECOME AN AUTHORIZED MANUFACTURER</td><td></td></tr>
</table>

3. MASTER'S FINAL PROJECT. To be carried out by each student individually from 29th May to 29th June 2026. To be submitted on the 29th of June 2026 and defended in front of an Examining board in July.

This calendar is subject to change as deemed appropriate by the Direction of the Master's programme in order to accommodate circumstances beyond its control

CONTACT DETAILS

Ms. Amaya García
Executive Secretary
amaya.garcia@juntadeandalucia.es
www.atmp-masterinmanufacturing.com

Address:
Red Andaluza de diseño y traslación de Terapias Avanzadas
Fundación Pública Andaluza Progreso y Salud
Avd. de Américo Vespucio nº 15, Edificio S-2
41092 Isla de la Cartuja (Sevilla)
Tel. [+34] 955 04 83 66
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Master in Manufacturing of Advanced Therapy Medicinal Products 2025/2026

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Consejería de Salud y Consumo
Fundación Progreso y Salud

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