Master in Manufacturing of Advanced Therapy Medicinal Products

2019 / 2020

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Organized by:

Junta de Andalucía

andalusian initiative for advanced therapies

Escuela de Posgrado

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 Initiative for 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 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 Managers of ATMP's Pharmaceutical Laboratories*

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,* ***specialisation as Qualified Person** (1,647 hours)*
- ***Master** Degree in Manufacturing of Advanced Therapy Medicinal Products,* ***specialisation as Manufacturing Manager** (1,559 hours)*
- ***Master** Degree in Manufacturing of Advanced Therapy Medicinal Products,* ***specialisation as Quality Control Manager** (1,559 hours)*
- ***Expert** Degree in **Quality Assurance** for Manufacturing of Advanced Therapy Medicinal Products (1,258 hours)*

> It is also possible to apply for one or more theoretical modules only.

REQUIREMENTS FOR APPLYING TO THE DEGREES: STUDENT'S PROFILES

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.

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

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".

Requirements for application for the Master in Manufacturing of Advanced Therapy Medicinal Products, specialisation as Qualified Person:

- *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 should demonstrate at least 6 months' experience in cell culture*

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.

Requirements for application for the Master in Manufacturing of Advanced Therapy Medicinal Products, specialisation as Manufacturing Manager:

- *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)*
- *It is preferable that applicants should also have acquired practical experience in cell culture*

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 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.

Requirements for application for the Master in Manufacturing of Advanced Therapy Medicinal Products, specialisation as Quality Control Manager:

- *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)*
- *It is preferable that applicants should have acquired practical experience in quality control in laboratories*

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2 - EudraLex - Volume 4 Good manufacturing practice (GMP) Guidelines. Chapter 2 Personnel

QUALITY ASSURANCE EXPERT

The Quality Assurance Expert is responsible for guaranteeing that the entire organised 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].

Requirements for application for the Expert Degree in Quality Assurance for Manufacturing of Advanced Therapy Medicinal Products:

- *Applicants should hold a University Degree following at least 4 years of study in the biomedical field (pharmacy, medicine, veterinary medicine, biology, biochemistry or biotechnology) or a Bachelor Degree with a Major or Specialism in biology, biochemistry or biotechnology*
- *It is preferable that applicants should have acquired quality assurance experience or training in quality systems management*

3. OVERVIEW OF THE PROGRAMME STRUCTURE AND METHODOLOGY

The 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 programme 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.

The programme will include:

A. *Theoretical training that is composed of 11 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.*

B. *A 1/3-week period of practical training (depending on the chosen degree) 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.*

C. *Supervised individual work to compile an investigational medicinal product dossier or a GMP facility dossier (site master file) as final project (dissertation) of the Master, depending on the chosen Degree.*

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

4. THEORETICAL CONTENTS

SECTION 1

An introduction to Advanced Therapies Regulation: bench to bedside roadmap:

- **1.1** *A primer on regulation of cell, tissue and gene therapies in Europe: what is and what is not an Advanced Therapy Medicinal Product (ATMP)?*
- **1.2** *An introduction to ATMP development: roadmap from a regulatory perspective*

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: from the embryo to the adult*
- **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** *Aging, 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 (chondrocytes, keratinocytes, dendritic cells...)*
- **3.2** *Adult stem cells*
- **3.3** *Pluripotent stem cells*

SECTION 4

Methods for manufacturing of cell based therapies:

- **4.1** *Cell and tissue culture basics*
- **4.2** *Stem cell isolation, proliferation and differentiation*
- **4.3** *Quality control of cell cultures in the basic laboratory*
- **4.4** *Good Cell Culture Practice (GCCP)*
- **4.5** *Scaling up and bioreactors*

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** *Manufacturing supply chain: upstream and downstream process 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 and 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 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** *Clinical trial regulation. Good clinical practice (GCP)*
- **9.6** *Risk based approach, risk management, IMP vigilance and pharmacovigilance*

SECTION 10

Investigational Medicinal 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** *Cells, tissues and vectors currently used in clinical trials: indications*
- **11.2** *Ethical issues related to advanced therapies*
- **11.3** *Intellectual property and industry right management in advanced therapies*
- **11.4** *Business model specificities according to product characteristics and worldwide perspective*
- **11.5** *Regulatory incentives for ATMP development: quality and non-clinical data certification for SMEs by EMA and orphan drug designation*
- **11.6** *Market and future perspectives in advanced therapies*

5. 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 yes, 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 summarised here 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 summarise key knowledge on cell and developmental biology that will be of use for professionals involved in the development of advanced therapy medicinal products. As an introductory module, 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 aging, 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 summarised in Section 2, this module will introduce the 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 at this point. This section is expected to summarise 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 enginee-

ring, 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 summarise 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 summarise many things and, thus, 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 summarise 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 a final section, 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 summarised so that the student may foresee alternatives that might impact their product development strategy in the not-so-distant future.

6. DESCRIPTION OF PRACTICAL MODULES

Depending on the chosen degree, the student will be offered a hands-on training stay of maximum 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

This module is compulsory for students registered on the Master Degree in Manufacturing of Advanced Therapy Medicinal Products, specialisation as Manufacturing Manager or as Qualified Person.

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

- *To produce an investigational cell therapy medicinal product according to GMP guidelines*
- *To recognise 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

This module is compulsory for students registered on the Expert Degree in Quality Assurance for Manufacturing of Advanced Therapy Medicinal Products and for those registered on the Master Degree in Manufacturing of Advanced Therapy Medicinal Products, specialisation as Qualified Person.

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

PHARMACEUTICAL QUALITY SYSTEM

This module is compulsory for students registered on the Master Degree in Manufacturing of Advanced Therapy Medicinal Products, specialisation as Quality Control Manager or as Qualified Person and for those registered on the Expert Degree in Quality Assurance for Manufacturing of Advanced Therapy Medicinal Products.

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

- *To manage the pharmaceutical quality system*
- *To design, plan, implement, maintain and improve a system which shall allow consistent delivery of products with appropriate quality attributes*

PRACTICAL MODULE 4

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

This module is compulsory for students registered on the Master Degree in Manufacturing of Advanced Therapy Medicinal Products, specialisation as Quality Control Manager or as Qualified Person.

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 generate and control relevant documentation.*
- *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*

7. MASTER'S DISSERTATION

Depending on the chosen degree, the students will have to complete an original final project or dissertation that will be supervised and evaluated.

Master Degree in Manufacturing of Advanced Therapy Medicinal Products, specialisation as **qualified person:**

- *Compilation of a site master file (GMP facility's dossier)*

Master Degree in Manufacturing of Advanced Therapy Medicinal Products, specialisation as **manufacturing manager:**

- *Fulfilment of the manufacturing aspects of an investigational medicinal product dossier*

Master Degree in Manufacturing of Advanced Therapy Medicinal Products, specialisation as **quality control manager:**

- *Fulfilment of the quality control aspects of an investigational medicinal product dossier*

Expert Degree in **quality assurance** for Manufacturing of Advanced Therapy Medicinal Products:

- *Fulfilment of some particular chapters of a site master file*

8. EDUCATION ADVISORY BOARD AND FACULTY MEMBERS

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

MEMBERS OF THIS BOARD:

AUSTRIA

Prof. Heinz Redl
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

FINLAND

Dr. Paula Salmikangas
Adjunct Professor University of Helsinki, Faculty of Biological and Environmental Sciences, Department of Biosciences. Member NDA Advisory Board. NDA Group AB. 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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Emeritus Professor of Pathology. University Medical Center. Johannes Gutenberg University

Prof. Dietger Niederwieser
Professor of Medicine, Head of the Division of Haematology & Medical Oncology. University Hospital Leipzig. Past President Worldwide Network for Blood & Marrow Transplantation. Past-president European Group for Blood and Marrow Transplantations

ITALY

Dr. Michele De Luca
Director Interdepartmental Centre for Stem Cell and Regenerative Medicine "Stefano Ferrari". University of Modena and Reggio Emilia. Full Professor of Biochemistry. University of Modena and Reggio Emilia. Scientific Director of Holostem Terapie Avanzate S.r.l.

Dr. Maria Cristina Galli
Senior Researcher at Istituto Superiore di Sanitá. Co-Chair of the ATMP Platform EATRIS. Former Member of the Committee for Advanced Therapies [CAT], EMA. Former Chair of Gene Therapy Working Group, EMA

Dr. Martino Introna
Head Scientific Program Laboratorio di Terapia Cellulare e Genica "G. Lanzani". Department of Haematology. Ospedali Riuniti di Bergamo. Former Chair Legal and Regulatory Affairs Committee-Europe [ISCT]

Dr. Giovanni Migliaccio
Head of the section "Gene and Cell Therapy". Department of Cell Biology and Neuroscience. Istituto Superiore di Sanita, Rome. Scientific Director. EATRIS Amsterdam

PORTUGAL

Prof. Rui L. Reís
Vice-Rector/President for Research. University of Minho, Braga & Guimaraes. Director 3B's Research Group. Biomaterials, Biodegradables and Biomimetics. Dept. of Polymer Engineering, University of Minho. CEO of the European Institute of Excellence on Tissue Engineering and Regenerative Medicine. Portuguese Government Associate Laboratory ICVS/3 B's

Prof. Beatriz Silva Lima
Chair of the IMI [EU/EFPIA) Scientific Committee. Coordinator of the Pharmacological Sciences Research Group, Professor and Member of the Executive Board. IMED University of Lisbon. Member NDA Advisory Board. NDA Group AB. Former Member of the Committee for Advanced Therapies [CAT], EMA.Former Chair of the Safety Working Party [SWP). EMA

SPAIN

Prof. Cecilia Gómez-Salvago
Professor of Civil Law. Universidad de Sevilla

Prof. Jose López-Barneo
Professor of Physiology. Director of Instituto de Biomedicina de Sevilla (IBiS) Hospital Universitario Virgen del Rocio/CSIC/Universidad de Sevilla

THE NETHERLANDS

Dr. Ineke Slaper-Cortenbach
Head of the Cell Therapy Facility. Dpt. Clinical Pharmacy. UMC Utrecht

UNITED KINGDOM

Dr. Timothy Allsopp
Founder and Managing Director of Consilium Bio Ltd. Former Head of External Research. Neusentis Regenerative Medicine. Pfizer Ltd

Dr. Glyn Stacey
Director for the UK Stem Cell Bank. CEO of SSCBIO Ltd. Former Head of Division of Cell Biology and Imaging, NIBSC

Prof. Adrian Thrasher
Wellcome Trust Senior Clinical Fellow. NIHR Senior Investigator. Honorary Consultant Immunologist GOSH. Director of Centre for Immunodeficiency. Director of Gene Therapy Programme ICH/GOSH. UCL Institute of Child Health

U.S.A.

Dr. Gregory A. Bonfiglio
Founder and Managing Partner of Proteus LLC. Chairman of the Board of the Centre for Commercialization of Regenerative Medicine. RM Translation Center (Canada). Member of ISSCR. Member of ISCT

Prof. Jose Cibelli
Head of Cellular Reprogramming Laboratory, Michigan State University. Former Scientific Director LARCel-Seville

Prof. Pete Coffey
Professor Neuroscience Research Institute. University of California. Director of the London Project to Cure Blindness. Moorfields Eye Hospital. Professor at Institute of Ophthalmology. UCL

Dr. Michael C. Holmes
SVP & Chief Technology Officer. Sangamo Therapeutics, Inc. Former Vice President. Research. Sangamo BioSciences, Inc.

Dr. Jane S. Lebkowski
President of Research and Development at Regenerative Patch Technologies (California). Former President of R&D. Asterías Biotherapeutics. Advisor of BEAT Biotherapeutics Corp.

MEMBERS OF THE FACULTY:

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

Mr. Adrian Abbotts
Sales Manager. Cellgenix. Glasgow

Mr. Alexander Adan
Citometry applications specialist at Miltenyi Biotec. Madrid

Dr. Elisabet Aguilar
Process Improvement Manager. Andalusian Initiative for Advanced Therapies. Sevilla

Prof. Miguel Alaminos
Department of Histology. Faculty of Medicine. University of Granada. Granada

Dr. Jorge Alemany
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Mr. Arturo Argüello
Deputy Director. Technology Transfer Office. Fundación Progreso y Salud. Sevilla

Dr. Salvador Arias-Santiago
Qualified Person. Cell Production and Tissue Engineering Unit. Head of Dermatology. Hospital Universitario Virgen de las Nieves de Granada. Granada

Ms. Blanca Arribas
GMP Quality Manager. Production and Reprogramming Cell Unit of Seville. Sevilla

Dr. Pedro Baptista
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Dr. Karim Benabdellah
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Prof. Antonio Campos
Head of the Department of Histology. Faculty of Medicine. University of Granada. Granada

Prof. Fernando Campos
Assistant Professor. Department of Histology. Faculty of Medicine. University of Granada. Granada

Dr. Xavier Cañas
Director of Scientific and Technical Services. Vall D' Hebrón Institut de Recerca. (VHIR) Barcelona

Ms. Ana Cardesa
Project Manager. Andalusian Initiative for Advanced Therapies. Sevilla

Ms. Gloria Carmona
Quality Assessment and GMP Facilities Coordinator. Andalusian Initiative for Advanced Therapies. Sevilla. Qualified Person. Production and Reprogramming Cell Unit. Sevilla

Mr. Carlos Casás
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Mr. Jesús Chato
Predoctoral. Department of Histology. University of Granada. Granada

Dr. Natividad Cuende
Executive Director. Andalusian Initiative for Advanced Therapies. Sevilla. Deputy Director. Andalusian Transplant Coordination. Sevilla

Dr. Massimo Dominici
Head of the Laboratory of Cell Biology and Advanced Cancer Therapies. University Hospital of Modena and Reggio Emilia. Italy. Chair. ISCT Presidential Task Force on the Use of Unproven Cellular Therapies. Vancouver

Mr. Daniel Durand
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Dr. Beatriz Fernández
Manufacturing Manager of LARCEL-CARTUJA. Production and Reprogramming Cell Unit. LARCEL. Sevilla

Dr. Daniela Ferrari
Adjunct Professor and Research Fellow. Department of Biotechnology and Biosciences. University of Milan-Bicocca. Milán

Dr. Miguel García
Scientific Director. Amarna Therapeutics S.L. CABIMER. Sevilla

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Prof. Cecilia Gómez- Salvago
Professor of Civil Law. University of Sevilla. Sevilla

Dr. María Elena González
Group Leader. Nanobiotechnology Area .Bionand. Málaga

Dr. Manuel Juan
Head of Immunotherapy Section. Immunology Service. Hospital Clinic. Barcelona. Director of Immunotherapy Platform. Hospital Sant Joan de Déu, Hospital Clinic. Barcelona

Dr. Manuel Jesús López
Professor of Public Law. Pablo de Olavide University. Sevilla

Ms. Fabiola Lora
Head of Clinical Operations and Pharmacovigilance. Andalusian Initiative for Advanced Therapies. Sevilla

Ms. María del Mar Macías
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PhD Student, Laboratory of Organ Bioengineering and Regenerative Medicine, GI and Hepatology Research Group - IIS Aragón

Ms. Ángela Ponce
Development and Translation Technician. Andalusian Initiative for Advanced Therapies. Sevilla

Dr. Isabel Portero
Founder and Director of BIOHOPE Scientific Solutions for Human Health. Madrid. Director. IMMPULSO Medical Sciences. Madrid. Department of Medicine. Universidad Complutense. Madrid

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

Dr. Ángel Ramírez
Molecular Oncology Unit. Department of Basic Research. Centro de Investigaciones Energéticas, Medioambientales y Tecnológicas (CIEMAT). Madrid

Dr. Alicia Rivera
Department of Cell Biology, Genetic and Physiology. University of Malaga. Málaga

Dr. Antonio Rodríguez
Head of Quality and Deputy Qualified Person. Cell Production Unit. Hospital Regional de Málaga. Málaga

Dr. Ana María Rodríguez
Department of Molecular Biology and Biochemistry. University of Malaga. Málaga

Mr. Antonio Ruiz
Quality Head and Deputy Qualified Person. Cell Production and Tissue Engineering Unit. Hospital Universitario Virgen de las Nieves. Granada

Dr. Rosario Sánchez-Pernaute
Scientific Coordinator. Andalusian Initiative for Advanced Therapies. Sevilla

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

Mr. Darío Sánchez
Quality Assurance Manager. Viralgen Vector Core SL. San Sebastián

Dr. Mónica Santos
Head of Production. Transfusion Centre of Cell and Tissue. Production and Reprogramming Cell Unit. Sevilla

Dr. César Trigueros
Chief Scientific Officer. Viralgen Vector Core SL. National institute for medical research. San Sebastián

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

9. 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. Depending on the chosen degree, the student will be offered a practical training stay of maximum 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 Regional Ministry of Health.

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:*

    I. *1 quality control room*
    II. *2 production rooms classified grade B*
    III. *1 cryogenic freezing room*
    IV. *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.

10. SELECTION CRITERIA

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

Due to limited capacity, priority will be given to those applicants wishing to study for one of our

Master full degrees rather than those who apply for individual modules only. Once students are accepted, they will receive an e-mail of confirmation together with details concerning the method of payment.

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

11. HOW TO APPLY

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

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

Applications must be submitted **before 20th of January 2019 at 14:00hrs (CET)**

12. DIRECTORS AND COORDINATORS OF THE MASTER' S PROGRAMME

DIRECTORS OF THE MASTER´S PROGRAMME:

Dr. Natividad Cuende
Executive Director of the Andalusian Initiative for Advanced Therapies. Junta de Andalucía

Prof. Antonio Campos
Head of the Histology Department. University of Granada

COORDINATORS OF THE MASTER'S PROGRAMME:

Ms. Gloria Carmona
Quality Assessment and GMP Facilities Coordinator. Andalusian Initiative for Advanced Therapies. Junta de Andalucía

Ms. Ángela Hernández
IT Platform Technician. Andalusian Initiative for Advanced Therapies. Junta de Andalucía

Ms. Amaya García
Executive Secretary. Andalusian Initiative for Advanced Therapies. Junta de Andalucía

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
University-specific degrees of the University of Granada (Spain)

2019 / 2020

	MASTER DEGREE IN MANUFACTURING OF ADVANCED THERAPY MEDICINAL PRODUCTS, SPECIALISATION AS **QUALIFIED PERSON** **(1,647 hours)**	**MASTER** DEGREE IN MANUFACTURING OF ADVANCED THERAPY MEDICINAL PRODUCTS, SPECIALISATION AS **MANUFACTURING MANAGER** **(1,559 hours)**	**MASTER** DEGREE IN MANUFACTURING OF ADVANCED THERAPY MEDICINAL PRODUCTS, SPECIALISATION AS **QUALITY CONTROL MANAGER** **(1,559 hours)**	**EXPERT** DEGREE IN **QUALITY ASSURANCE** FOR MANUFACTURING OF ADVANCED THERAPY MEDICINAL PRODUCTS **(1,258 hours)**	**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, dysregulation 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**
PRACTICAL MODULES					
1. Manufacturing process of an investigational cell therapy medicinal product	■	■			**3,200**
2. Site master file and how to pass the mandatory inspections to become an authorized manufacturer	■			■	**700**
3. Pharmaceutical quality system	■		■	■	**700**
4. Quality control, environmental control, qualification and validation of premises and equipment	■		■		**2,800**
FINAL PROJECT (not applicable for students registered in some modules only)					
Compilation of a site master file	■				
Fulfilment of manufacturing aspects of an investigational medicinal product dossier		■			
Fulfilment of quality control aspects of an investigational medicinal product dossier			■		
Fulfilment of some specific chapters of a site master file				■	
MASTER/EXPERT'S DEGREES FEES (€)	**9,000**	**7,500**	**7,500**	**5,000**	**(€)**

TUITION FEE DISCOUNT SCHEMES

(The following discount offers cannot be combined with each other)

Applications must be submitted **before 20th of January 2019 at 14:00hrs (CET)**

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

EARLY BIRD DISCOUNT

Apply by 25th November 2018 and you will take advantage of a **25% discount** off on the tuition fee.

TUITION FEE DISCOUNT FOR THE UNEMPLOYED

We offer a **30% discount off** on the tuition fee for the unemployed. To take advantage of this discount you must be able to submit a copy of an unemployment statement from your national public employment agency or service.

TUITION FEE DISCOUNT FOR ANDALUSIAN PUBLIC HEALTH SYSTEM AND UNIVERSITY OF GRANADA'S EMPLOYEES

We offer a **30 % discount off** on the tuition fee for those working for the Andalusian Public Health System or the University of Granada. To take advantage of this discount you must be able to submit a copy of a signed statement from the management of your centre.

SCHOLARSHIP

A scholarship will be granted for one of the students who best complete one of our Master's degree. After completing the degree, he/she will be offered six-month period pay job in one of our laboratories in Andalusia (Spain). 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)

2019	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	MONDAY
FEBRUARY	5	6	7	8	11
	SECTION 1: SELF-STUDY				
	12	13	14	15	18
	SECTION 1: CASE AND TEST				
	19	20	21	22	25
	BREAK				
	26	27	28	1	4
	SECTION 2: SELF-STUDY				
MARCH	5	6	7	8	11
	SECTION 2: SELF-STUDY AND CASE				
	12	13	14	15	18
	SECTION 2: CASE AND TEST				
	19	20	21	22	25
	BREAK				
	26	27	28	29	1
	SECTION 3: SELF-STUDY				
APRIL	2	3	4	5	8
	SECTION 3: SELF-STUDY AND CASE				
	9	10	11	12	15
	SECTION 3: CASE AND TEST				
	16	17	18	19	22
	EASTER BREAK				
	23	24	25	26	29
	SECTION 4: SELF-STUDY				
MAY	30	1	2	3	6
	SECTION 4: SELF-STUDY AND CASE				
	7	8	9	10	13
	SECTION 4: CASE AND TEST				
	14	15	16	17	20
	BREAK				
	21	22	23	24	27
	SECTION 5: SELF-STUDY				
	28	29	30	31	3
	SECTION 5: SELF-STUDY AND CASE				

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

2019	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	MONDAY
JUNE	4	5	6	7	10
	SECTION 5: SELF-STUDY AND CASE				
	11	12	13	14	17
	SECTION 5: CASE AND TEST				
	18	19	20	21	24
	BREAK				
	25	26	27	28	1
	SECTION 6: SELF-STUDY				
JULY	2	3	4	5	8
	SECTION 6: SELF-STUDY AND CASE				
	9	10	11	12	15
	SECTION 6: CASE AND TEST				
	SUMMER BREAK				
SEPTEMBER	3	4	5	6	9
	SECTION 7: SELF-STUDY				
	10	11	12	13	16
	SECTION 7: SELF-STUDY				
	17	18	19	20	23
	SECTION 7: SELF-STUDY AND TEST				
	24	25	26	27	30
	BREAK				
OCTOBER	1	2	3	4	7
	SECTION 8: SELF-STUDY				
	8	9	10	11	14
	SECTION 8: SELF-STUDY				
	15	16	17	18	21
	SECTION 8: SELF-STUDY AND TEST				
	22	23	24	25	28
	BREAK				
	29	30	31	1	4
	SECTION 9: 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

2019	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	MONDAY
NOVEMBER	5	6	7	8	11
	SECTION 9: SELF-STUDY				
	12	13	14	15	18
	SECTION 9: SELF-STUDY AND CASE				
	19	20	21	22	25
	SECTION 9: CASE AND TEST				
	26	27	28	29	2
	BREAK				
DECEMBER	3	4	5	6	9
	SECTION 10: SELF-STUDY				
	10	11	12	13	16
	SECTION 10: SELF-STUDY AND TEST				
2019 | 2020	***CHRISTMAS BREAK***				
JANUARY	14	15	16	17	20
	SECTION 11: SELF-STUDY				
	21	22	23	24	27
	SECTION 11: SELF-STUDY AND CASE				
	28	29	30	31	3
	SECTION 11: SELF-STUDY AND CASE				
FEB	4	5	6	7	10
	SECTION 11: CASE AND EST				

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. PRACTICAL MODULES
(ON-SITE TRAINING IN A FULLY EQUIPPED GMP FACILITY IN GRANADA -SPAIN)

2020	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY
MARCH				5	6
				MANUFACTURING PROCESS OF AN INVESTIGATIONAL CELL THERAPY MEDICINAL PRODUCT for manufacturing managers and qualified persons	
	9	10	11	12	13
	MANUFACTURING PROCESS OF AN INVESTIGATIONAL CELL THERAPY MEDICINAL PRODUCT for manufacturing managers and qualified persons				
	16	17	18	19	20
	QUALITY CONTROL for quality control managers and qualified persons				
	23	24	25	26	
	PHARMACEUTICAL QUALITY SYSTEM for quality control managers, quality assurance experts and qualified persons		SITE MASTER FILE AND HOW TO SATISFACTORILY PASS EUROPEAN INSPECTIONS for quality assurance experts and qualified persons		

3. MASTER'S FINAL PROJECT

To be carried out by each student individually from March to May 2020. It must be submitted before the 15th of May 2020 and will be assessed before the 30th of June 2020

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

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19 / 2020

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andalusian initiative for advanced therapies

Escuela de Posgrado

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