

"MASTER IN MANUFACTURING OF ADVANCED THERAPY MEDICINAL PRODUCTS"

Cell-based technologies: cell & gene therapies and tissue engineering

University-specific degree of the University of Granada [Spain]

Organized by the Andalusian Initiative for Advanced Therapies and
the University of Granada with the collaboration of the Lavante Foundation

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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.

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 Good Manufacturing Practice (GMP) implementation before initiating full-fledged translational programmes, and also have at their disposal well trained technologists that will develop ATMPs at different laboratories and institutions - be it hospitals, academia or industry - within Europe.

OBJECTIVE

The "**Master in manufacturing of advanced therapy medicinal products**" is founded upon a successful Spanish Master's programme that has been running at Lavante Foundation in Granada since 2009, promoted by the Andalusian Initiative for Advanced Therapies together with the University of Granada and with the collaboration of Spanish Medicines Agency [Agencia Española de Medicamentos y Productos Sanitarios- AEMPS].

This first international Master's Programme in the manufacturing of advanced therapy medicinal products will have a European focus and it is expected to cater to the needs of any European institutions trying to implement ATMP Regulation. For this reason, it will count upon the participation, advice and support of European Medicines Agency (EMA) experts.

DEGREES OFFERED:

1. **Master Degree** in Manufacturing of Advanced Therapy Medicinal Products, specialization as **Qualified Person** (1,630 hours)
2. **Master Degree** in Manufacturing of Advanced Therapy Medicinal Products, specialization as **Manufacturing Manager** (1,500 hours)
3. **Master Degree** in Manufacturing of Advanced Therapy Medicinal Products, specialization as **Quality Control Manager** (1,500 hours)
4. **Expert Degree** in **Quality Assurance** for Manufacturing of Advanced Therapy Medicinal Products (1,060 hours)

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

WHO SHOULD ATTEND?

The Degree is quite unique in that it is not intended for biomedical students pursuing a Ph.D. in regenerative medicine or related subjects. 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, such as:

- **Technical Directors or Qualified Persons of Pharmaceutical Laboratories**
- **Manufacturing Managers of Advanced Therapies**
- **Quality Control Managers**
- **Quality Assurance Managers**

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.



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 one-year 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 one-year programme will include:

THEORETICAL TRAINING 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. The main contents are:

- **Human embryonic and adult cells and tissues. Homeostasis, dysregulation and disease**
- **Cells with a current or potential clinical application (committed cells, adult stem cells and pluripotent stem cells)**
- **Basic methodology used in the cell culture laboratory**
- **Gene therapy vectors. Advanced concepts in applied genetics and virology**
- **Tissue engineering constructs and their clinical application**
- **An introduction to the regulation of advanced therapies: bench to bedside roadmap**
- **Quality and manufacturing aspects of the regulation in ATMP development (characterization of ATMP, current methods in the quality control of ATMPs and in environmental monitoring and quality issues in the EMA guidelines)**
- **Good manufacturing practice as applied to ATMPs and the investigational medicinal product dossier (IMPD)**
- **Non-clinical and clinical aspects concerning the regulation of ATMP development (animal models, ATMP non-clinical protocol design, good laboratory practice implementation, clinical trial regulation and good clinical practice, and non-clinical and clinical issues in the EMA guidelines)**
- **Biosafety issues and risk management as applied to ATMP development**
- **Current implications and future perspectives in ATMP development (business models, intellectual property, regulatory incentives, ethical issues, current indications and future perspectives)**

PRACTICAL TRAINING a 2/4 week period of practical training (for Master Degrees only) during the summer of 2012 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. The main contents are:

- **Basic methodology of cell and gene therapy**
- **Tissue engineering methods**
- **Manufacturing process of an investigational cell therapy medicinal product**
- **Quality control, environmental control, qualification and validation of premises and equipment**

Attendance at a weekend **INTERNATIONAL SYMPOSIUM** during the stay in Granada with key opinion leaders from academy, industry, regulatory agencies and other institutions sharing their real-world experiences, knowledge and expertise. It will provide the student with a deep understanding and a specialized view of advanced therapies as well as a broad networking base.

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.

CORPORATE COLLABORATORS

The Master in manufacturing of advanced therapy medicinal products will run in collaboration with a variety of organizations in the advanced therapy area, including several top research centres and regulatory bodies. Activities and projects will be developed, so as to simulate real situations in the management of such kind of advanced therapy manufacturing facilities. These activities will complement the Degree by providing the attendees with first hand exposure to best practices in the regenerative medicine field, and enabling them to apply the knowledge and skills developed in the programme to real-world situations.

→ **Further information is available on our website:**

www.juntadeandalucia.es/terapiasavanzadas/en/training

→ **or by e-mail request at:**

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