

<p>UNIVERSITY OF GRANADA “MASTER IN MANUFACTURING OF ADVANCED THERAPY MEDICINAL PRODUCTS”</p> <p><i>Cell-based technologies: cell & gene therapies and tissue engineering</i> University-specific degrees of the University of Granada (Spain)</p> <p>2019 / 2020</p>	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	(€)