

GRADOCELL.

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PHARMA

**CRO and Regulatory Affairs
Advisory for Advanced Therapies**

GRADOCELL.

CONSULTING

**Technical Consulting and Quality
System Implementation for Advanced
Therapies.**

GRADOCELL.

MARKETING

**Marketing of devices and disposables
for Advanced Therapies and
innovative medicines.**



○ ABOUT US

Gradocell is a CRO and consulting firm founded in 2010 and focused on providing consultancy, regulatory affair services, training, technical advice and implementation of GMP guidelines for Advanced Therapy Medicinal Products and Innovative medicines.

Gradocell's clients include biotechnology companies and hospitals and academic laboratories.



OBJECTIVES

Our goal is to become the reference provider of specialized consultancy services to companies and academic laboratories needing to implement quality systems and develop clinical programs associated with investigational products based on cell and gene therapies, as well as advice and support regulatory processes required for the authorization and marketing of innovative biological medicines.

Gradocell, collaborates with companies, hospitals and research organizations in the development of these new therapies, ensuring compliance with the quality and regulatory standards



TEAM

Our team is formed by professionals that have gathered their expertise in pioneering the manufacturing and clinical development of advanced therapies now .

Our specialization and direct knowledge of the processes involved in the industrialisation of advanced therapies allows us to offer a unique service.



Rossana García: Founder CEO – Technical Advisor

26 years of experience in the pharmaceutical manufacturing and research (Pharmacia). Specialist in stem cell culture. 9 years service as Head of Production at TiGenix developing the manufacturing processes for its stem cell products.



Ana Torres : Quality Director

Expert in GLP and GMP implementation, responsible for the implementation of the quality systems at Cellerix where she was Head of Quality Assurance for 7 years.



Eva Martín: Senior technician in Regulatory Affairs

Expert in clinical drug development of advanced therapies. With over 7 years of experience in different biotech companies and CROs

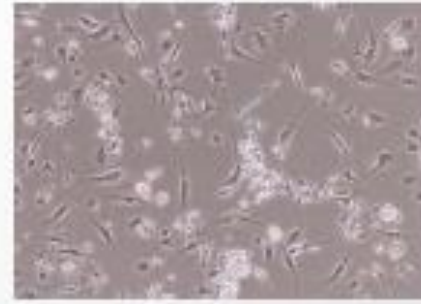
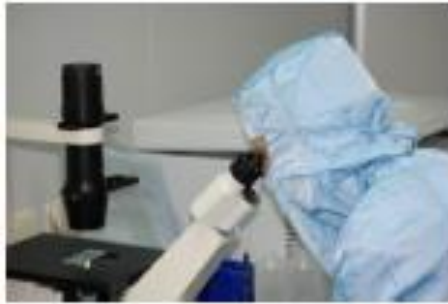


José L. Serrano: Head of Commercial Services

19 years of experience in marketing products and services in diverse industries and creating sales networks. Over 11 years developing new business in Iberia and Latin-America

EXPERTISE

- **Gradocell Consulting** : Manufacturing, control, validation, documentation, tech transfer and implementation of GMP regulations.



- **Gradocell Pharma**: Regulatory affairs, advice and support in elaboration of documentation for clinical trials and marketing authorizations.



- **Gradocell Marketing** : Iberian and Latin-American market needs identification and suppliers selection to serve customers in advanced therapy and innovative medicines field.

GRADOCCELL

○ GradoCell Consulting Services

- **Diagnosis, situation analysis and actions plans**

Targeted at clients facing the translation of R&D results to GMP processes.

- **Implementation of GMP in cell/gene therapy laboratories**

Targeted at clients needing advice, training and surveillance during the process GMP implementation.

- **Preparation for audits and regulatory inspections:**

We perform external audits, and define corrective and preventive plans to ensure success following formal inspections from the regulatory agencies.

- **Specialized technical consulting in cell and gene therapy processes:**

We advice and train your staff in all levels of the manufacturing process including: documentation preparation, design of facilities, selection of equipment, designing validation plans, etc... Our training is customized to your process and oriented to quality managers, manufacturing managers, production technicians, quality control managers and qualified person.



○ GradoCell Pharma Services

- **Management, evaluation and advice on the preparation of the clinical trial plan and documentation needed to advance your product to the clinic:**
 - Regulatory pathway design
 - Support for conducting scientific advice sessions with regulatory authorities to ensure proper protocol design.
 - Design of clinical protocols.
 - Evaluation of non clinical documentation.
- **Preparation of clinical trial documentation:**

Preparation of IMPD, Investigational brochure, Informed consent, CRDs, etc...



○ Gradocell Marketing Services

- Identification of the regulatory framework affecting the new products to be introduced in the market.
- Advising our partners on roadmap for the introduction of a new product in the Iberian and Latin American markets.
- Assistance in designing documentation and actions for product disclosure and advertising.
- **Sales operations:**
 - Objectives definition
 - Sales execution
 - **Sales and market reporting**
- **Sales team selection when specific actions are necessary**

○ GradoCell Client Portfolio

- **GradoCell Pharma** has developed important projects in different hospitals and companies providing **scientific advice, clinical trial design, clinical and preclinical evaluations, IMPD and monitoring** of cell therapy clinical trials:
 - **Hospital Universitario Virgen de Arrixaca (Murcia):**
 - Preparation of IMPD and Monitoring of “ ENSAYO CLÍNICO EN FASE I/II DE UTILIZACIÓN DE MEMBRANA AMNIOTICA PARA LA EPITELIZACIÓN DE GRANDES HERIDAS”
 - Monitoring of “ENSAYO CLÍNICO EN FASE I/II SOBRE UTILIZACIÓN DE CÉLULAS MADRE DE MÉDULA ÓSEA AUTÓLOGAS EN PACIENTES CON ESCLEROSIS LATERAL AMIOTRÓFICA
 - **Hospital Universitario de Salamanca:**
 - Monitoring of “ENSAYO CLÍNICO FASE I/II DE TRATAMIENTO DE LA FUGA AÉREA POSTOPERATORIA TRAS RESECCIÓN PULMONAR EN PACIENTES DE RIESGO ELEVADO, MEDIANTE LA ADMINISTRACIÓN DE CÉLULAS MESENQUIMALES AUTÓLOGAS.”
 - Monitoring of “ENSAYO CLÍNICO EN FASE II DE TRATAMIENTO DE CITOPENIAS POSTRASPLANTE ALOGÉNICO CON INFUSION SECUENCIAL DE CÉLULAS MESENQUIMALES ALOGÉNICAS EXPANDIDAS IN VITRO.”
 - Monitoring of “ENSAYO CLÍNICO EN FASE I/II NO ALEATORIZADO PARA EL TRATAMIENTO DE LA OSTEONECROSIS DE LA CABEZA FEMORAL MEDIANTE LA ADMINISTRACIÓN DE CÉLULAS MESENQUIMALES AUTÓLOGAS

○ GradoCell Client Portfolio

- **Hospital Universitario La Paz:**
 - Preparation of IMPD and Monitoring of “ENSAYO CLÍNICO FASE IIa PARA CONOCER LA SEGURIDAD DEL TRATAMIENTO DE LA ISQUEMIA CRÍTICA NO REVASCULARIZABLE DE MIEMBROS INFERIORES MEDIANTE CÉLULAS TRONCALES MESENQUIMALES
- **Hospital Puerta de Hierro de Madrid:**
 - Preparation of CRD for clinical trial for use of mesenchymal stem cells in spinal cord injury.
- **Coretherapix, SLU:**
 - Evaluation of documentation of IMPD for a cell therapy product aimed at cardiovascular regeneration
- **Praxis Pharmaceuticals, SL:**
 - Evaluation of documentation of CTD for a cell therapy product aimed at severe burn treatment.
- **Viscofan Naturin, GmbH:**
 - Preparation of IMPD for clinical trial for use of mesenchymal stem cells in cardiovascular regeneration.



○ Gradocell Client Portfolio

- **Gradocell Consulting** is carrying out projects related to **the implementation of GMP** in cell therapy units in :
 - Hospital de Cruces de Barakaldo
 - Hospital Virgen de la Arrixaca in Murcia.
 - Hospital Puerta de Hierro.
 - Faculty of Medicine (Universidad San Pablo-CEU)
 - CIEMAT.
 - ViveBiotech.
 - Equicord Ymas.
- **Internal Audits** in Tigenix, SLU, Regennia SL, 3P Biopharmaceuticals SL., Inbiomed, ViveBioTECH , Pharmacell, Ltd., Banco de tejidos y Terapia Celular de Medellín (IPS univ Antioquia)
- **Training** : preparation of didactic material and teaching of Master in Advanced Therapies: (Andalusian Initiative on Advanced therapies, ESAME, CEU San Pablo, Univ. Fco. De Vitoria))
- **Feasibility study**: of the proposed construction of a production facilities for gene therapy medicines in **Fundación Medina**.
- **Technical Advice** in production of cell based and human plasma derivated products in **Clinica Dermatológica Ercilla and Regenia,SL, ViveBiotech,SLU**
- **Technology transfer** of a production process of cell therapy product to a CMO:Coretherapix SLU , Viscofan Naturin GmbH, Equicord Ymas, Genetrix, Praxis Pharmaceuticals, ViveBioTECH etc..

○ Gradocell is a member of

- **ASEBIO** - Association of the Spanish Biotechnology Industry.
- **Madrid Science Park:** The main science park and incubator in the Madrid region.
- **Madrid Network**, a public-private partnership involving large and small companies, universities and research centers to foster innovation in the Community of Madrid.
- **Madrid Biocluster**, aimed at consolidating a competitive biotechnology business sector in the Madrid region.
- **European Society for Gene and Cell Therapy:** leading organization committed to support scientists and clinicians involved in basic and translational research on gene transfer and clinical applications of gene and cell therapy



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