# Curriculum Vitae

## Personal information


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| Surname(s) / First name(s) | **TABERA FERNÁNDEZ, JAIME** |
| Address(es) | **MARINA 60, 5º 1ª, 08005 BARCELONA** |
| Telephone(s) | **0034 655 71 84 03** |
| E-mail | **jaime.tabera@gmail.com** |
| Place of birth | **Bilbao (Bizkaia)** |
| Nationality | **Spain** |
| Date of birth | **August 23rd, 1978** |
| Gender | **Male** |


## Work experience

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| Dates | **May 2009 - Today** |
| Occupation or position held | **Banc de Sang i Teixits (former Transplant Services Foundation-Hospital Clínic de Barcelona)**<br>Tissue Establishment and Advanced Therapies Unit<br>**Operations & Quality Manager – Barcelona Tissue Bank and ATMP Unit Hospital Clínic Barcelona** (May 2012 – Today)<br>**Deputy Qualified Person BTB** (May 2012 – Today)<br>**Supply Chain Manager BTB** (July 2010 – Today)<br>**Quality Assurance Manager BTB** (May 2009 – Today) |

## Work experience

- Production Manager of the Barcelona Tissue Bank and the ATMP Unit of the Hospital Clínic of Barcelona 2012-today
- Supply Chain Manager Barcelona Tissue Bank and the ATMP Unit of the Hospital Clínic of Barcelona 2010-today
- Global Quality System Manager (EU GMP, T&C EU Directives, ISO 9001) Barcelona Tissue Bank and the ATMP Unit of the Hospital Clínic of Barcelona 2009-today
- Member of the Advanced Therapies Strategic Committee of the Hospital Clínic of Barcelona 2013-today
- Coordinator of the European Project 'European Good Tissue Practices; Euro-GTPII' 2017-2019
- Expert in the European Project VISTART WP5b 2016-2018
- *Member of experts in the European Twinning* 'Strengthening the Institutional Capacity for Blood, Tissues and Cells' in Serbia 2018-2019
- Expert Mission in the Implementation of EU Legislation on Standards of Quality and Safety for Blood and Blood components in TAIEX MONTENEGRO – 2016
- Blood Safety Project in Ukraine organised in co-operation with the American International Health Alliance - 2016
- Consultant of the Atomic Energy International Agency for the Health Ministry of Uruguay - Octubre 2015
- *Member of experts in the European Twinning* 'Strengthening the Institutional Capacity for Blood, Tissues and Cells' in Croatia 2013-2016
- Member of experts in the '*Guide to the quality and safety of tissues and cells for human application' Council of Europe*
- Member of the European Project 'European Good Tissue Practices; Euro-GTPI' 2009-2011
- FIS Researcher in the project 'Anti-tumoral Immunotherapy using gene therapy based on CART19'
- IMP authorisation for Autologous peripheral blood differentiated adult T-cells expanded transduced with a lentivirus.
- IMP authorisation Dendritic Cells for the treatment of Multiple Sclerosis
- IMP authorisation Dendritic Cells for the treatment of metastatic colorectal cancer
- IMP authorisation Sclerocorneal Limbal Stem Cells for the treatment of ocular surface pathology
- IMP authorisation Dendritic Cells for the treatment of Crohn disease
- EU GMP certification (European Good Manufacturing Practices) Barcelona Tissue Bank and the ATMP Unit of the Hospital Clínic of Barcelona

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| Dates | **January 2003 – May 2009** |
| Occupation or position held | **Auditories Tecniques BCN (www.auditoriestecniques.com)** |
| | Services and assessment for pharmaceutical industry |
| | Auditor/Consultant |

**Consultant for the Quality Assurance/Technical Direction Department of Sanofi-Aventis Spain**

My collaboration was based on a GMP expert outsourcing where I developed functions as an external Quality Assurance and Deputy Qualified Person.

During this period I led the implementation of the Quality System required by the EU Good Manufacturing Practices for the centralized national drugs distribution.

Within my responsibilities scope was also the establishment of relationships with third party manufacturers (APIs and FPs) through quality agreements as a national and international level.

I also was in charge of the preparation of investigational medicinal drugs involved in clinical trials (double blinded labelling and packaging) according to Annex 13 of EU GMP and in collaboration with the Clinical Trials Units.

All those aspects and activities related to the requirements assigned to the role of a Qualified Person and a Quality Assurance Manager was part of my duties.

**GMP (manufacturing), GLP (pre-clinical studies), ISO 9001 (quality systems) audits for pharmaceutical laboratories**

As a main task I have performed national and international audits based on GMP, GLP and ISO9001 guidelines as senior auditor for pharmaceutical laboratories. These audits correspond to internal audits outsourced by the companies aiming to assess their regulatory status or preparing an inspection from competent authorities. Among the audited companies there are Spanish affiliates of multinational companies, Spanish companies and European companies.

**GMP and GLP trainer for pharmaceutical laboratories**

As a main task I have given technical courses related to the requirements of the Good Manufacturing Practices and Good Laboratory Practices for pharmaceutical laboratories.

**Equipment qualification and Processes validation for pharmaceutical laboratories**

As a main task I have participated in the configuration of Validation Master Plans and the execution of such VMP. The processes validation and the equipment involved qualification are the regular activities performed.

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| Dates | **October – December 2002** |
| Occupation or position held | **Auditories Tecniques BCN (www.auditoriestecniques.com)** |
| | Services and assessment for pharmaceutical industry |
| | Trainee |
| | Equipment qualification |

## Education and training

- Speaker in the Spanish Inspectors Seminar for Tissue Establishments – March 2016
- New Annex 15 of the EU GMP (ASINFARMA) – February 2016
- Speaker Workshop Cleanroom Management EATB SPLIT-October 2015
- 23rd congress of the EATB, Lund (Sweden) October 2014
- I International Symposiyum on Cell and Gene-Based Therapies – Granada – June 2012
- Speaker at the 6th World Congress of Tissue Banking – Barcelona – November 2011
- Speaker at XX Symposium of SEGCIB – Sevilla – October 2011
- Advanced Good Manufacturing Practices. Barcelona – January 2011
- Speaker at CIBER-BBN: I+D in Advanced Therapies; Regulatory Affairs. Barcelona - October 2010
- Advanced Therapies Workshop: Biological contamination risks in a Cell Factory. Barcelona – November 2009
- Good Laboratoy Practices. Barcelona – March 2009
- Workshop: "Samples managing". SEGCIB – Barcelona, November 2008
- Good Manufacturing Practices in the 21st century. Barcelona – November 2008.
- Good Laboratory Practices: Diverse points of view. Barcelona – June 2008.
- Good Clinical Practices (10h). Auditories Tecniques – Barcelona, May 2008
- Article in Farmespaña Industrial Magazine "News in Good Manufacturing Practices: Annex 2: Biological medicinal products manufacturing (May-June 2008)
- XVII Symposium of GLP, GMP, GCP and Validation of Computerised Systems (SEGCIB) Barcelona – April 2008
- Auditor Leader IRCA ISO 9001:2000. SGS-Barcelona, February 2008
- 5ª Symposium Good Manufacturing Practices. Generalitat de Catalunya – December 2007.
- Course "Good Manufacturing Practices in Cosmetic Industry" (Auditories Tecniques BCN). Barcelona, November-2007.
- Workshop "Risk Management in Quality Systems", SEGCIB, Barcelona, November 2007.
- Article FARMESPAÑA INDUSTRIAL Magazine (March-April 2007): "Audit of labelling process for clinical assays medicinal products".
- Speaker at XVI Symposium of SEGCIB – Pamplona – March 2007
- Course "Good Laboratory Practices in the 21st century" (Auditories Tecniques BCN), Barcelona, February-2007
- Workshop; Computerised systems audit, SEGCIB, Barcelona, December 2006.
- XV Symposium Good Laboratory Practices (GLP), Good Clinical Practices (GCP) and other quality rules. SEGCIB Madrid–March 2006.
- Symposium of Assessment and Audit of Pharmaceutical Industry Suppliers (Auditories Tecniques BCN) – March 2006

## Education and training

- XIV Symposium of SEGCIB. Barcelona - April 2005.
- Management of GMP Processes (Auditories Tècniques BCN) – February 2005
- Calibration in chemical and biological laboratories (Auditories Tecniques BCN) – February 2004
- Calibration (Auditories Tecniques BCN) - 2003
- Good Distributing Practices (GDP) (Auditories Tecniques BCN) - 2003
- GLP rules training (Auditories Tecniques BCN) - 2003
- *Internal Audits training (Auditories Tecniques BCN) – 2002*

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| Dates | **January – December 2012** |
| Title of qualification awarded | **Master in Manufacturing of Advanced Therapy Medicinal Products, specialization as Qualified Person (1630 horas)** |
| Name and type of organization providing education and training | University of Granada |
| Dates | **January – December 2002** |
| Title of qualification awarded | **Master in Pharmaceutical Products Manufacturing (1240 horas)** |
| Name and type of organization providing education and training | Institut Univ. de Ciencia i Tecnologia (Mollet del Valles) *(www.iuct.com)* |
| Dates | **1996 – 2001** |
| Title of qualification awarded | **Biochemistry Degree** |
| Name and type of organization providing education and training | Basque Country University (www.upv.es) Nº Colegiado 21679-C |

## Publications

Co-author HAEMATOL/2018/191924 entitled "Pre-clinical development of a novel anti-CD19 chimeric antigen receptor" 2018

Abstract co-author 23rd Congress of the European Hematology Association EHA, Title: Production of ARI-0001 cells (A3B1:CD8:4-1BB:CD3z CAR19 cells) in patients with CD19+ relapsed/refractory B-cell malignancies using the CliniMACS Prodigy System. 2018

Abstract co-author Phase II randomized trial of autologous tumor lysate dendritic cell vaccine (ADC) plus best supportive care (BSC) compared with BSC, in pre-treated advanced colorectal cancer patients. ASCO annual meeting June 2015

Abstract co-author Cancer Inflamation and Immunity Cell Symposium June 2015

Regulatory Issues in Cell-Based Therapy for Clinical Purposes. Casaroli-Marano RP, Tabera J, Vilarrodona A, Trias E. In: Cell-Based Therapy for Retinal Degenerative Disease. Zarbin M & Casaroli-Marano RP Editors. Dev Ophthalmol. Basel, Karger, 2014, vol 53, chapter 15: in press.

Co-author of the *'Guide to the quality and safety of tissues and cells for human application' 1st Edition 2013, Council of Europe*

Article in Farmespaña Industrial Magazine (May-June 2008): *"News in Good Manufacturing Practices: Annex 2: Biological medicinal products manufacturing"*

Article in Farmespaña Industrial Magazine (March-April 2007): *"Audit of labelling process for clinical assays medicinal products"*

## Other Skills

ASSOCIATIONS

Member of the European Association of Tissue Banks

Member of the Research Quality Assurance Spanish Association (Sociedad Española de Garantía de Calidad en Investigación SEGCIB) since 2003.