



# PROFESSOR PAULA SALMIKANGAS

## CURRICULUM VITAE

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### Personal Details

Name: Paula Salmikangas  
Education: PhD

### Professional Experience

Current position:

- Member, NDA Advisory Board
- Adjunct Professor University of Helsinki, Faculty of Biological and Environmental Sciences, Department of Biosciences

Previous positions:

- 2003-2017: Research Professor and Senior Researcher (former) at Finnish Medicines Agency, Marketing Authorisations
- 2002 –2003: Senior researcher and group leader, Geneos Ltd
- 2001 –2002: Senior researcher, Folkhälsan Institute of Genetics and University of Helsinki, Department of Medical Genetics
- 2000: EMBO fellowship, Department of Cell Biology , University of Potsdam, Germany
- 1997- 2001: Researcher, Ph.D. student, University of Helsinki, Department of Pathology
- 1993-1997: Research Chemist, Helsinki University Central Hospital, Department of obstetrics and gynecology
- 1992-1993: Biologist (vicegerent), Helsinki University Central Hospital, Department of obstetrics and gynecology
- 1990-1992: Research Chemist, Helsinki University Hospital, Department of obstetrics and gynecology
- 1988-1989: Teacher and assistant, University of Oulu, Department of Biochemistry

## Area of Expertise

- Biochemistry, cell and molecular biology
- In-depth scientific and regulatory knowledge of biopharmaceuticals, especially ATMPs and CMC aspects of biomolecules, including clinical bioassays and immunogenicity
- Detailed knowledge of the European approval system including European Medicines Agency (EMA)
- CMC documentation requirements to support European Clinical Trial Applications (CTA) and Marketing Authorisation Applications (MAA)
- Regulatory aspects during Post-authorisation phase including variations and line extensions
- Legal, regulatory and scientific knowledge on ATMPs (cell and gene therapies and tissue engineering)
- Design of CMC development plans: Scientific and strategic aspects, comparability
- Biosimilars
- Medical Devices and combined products (devices and drugs)

### Scientific specialty

- Cell and molecular biology

## Major Representations

### As a Regulator:

- 2009-2017: Chairperson, Committee for Advanced Therapies, EMA and member of the EMA Scientific Coordination Board (Scicobo)
- 2015 – 2017: Finnish representative in the European Commission STAMP group
- 2009 – 2014: Member and Vice-Chair of the Committee for Advanced Therapies, EMA
- 2007 – 2012: Chairperson of Working Party on Cell-based Products (CPWP), EMA
- 2011 – 2012: Advisory Board Member for the Master's Training Program in Manufacturing of ATMPs, Andalusian Initiative for Advanced Therapies, Government of Andalusia, Spain
- 2007 – 2009: Member of Biologics Working Party (BWP), EMA
- 2005 – 2007: Member of Working Party on Cell-based Products (CPWP), EMA
- 2006 – 2007: National Expert of the EU Council Working Group on the Advanced Therapy Medicinal Product regulation
- 2005 – 2007: Member of Working Group 6 (Biological substances), Council of Europe

## **Associations**

- Editorial Board member, Human Gene Therapy Clinical Development
- Editorial Board member, Cell and Gene Therapy Insights

## **Publications**

The complete list can be provided upon request.