Professor Beatriz Silva Lima
CURRICULUM VITAE

Personal details

Name	Beatriz Silva Lima
Education	PharmD, PhD

Professional experience

Current position

- Member, NDA Advisory Board
- Full Professor of Pharmacology and Pharmacotoxicology at the Universidade de Lisboa, Faculty of Pharmacy, and Head of the Department of Pharmacological Sciences
- Member of General Council of the Universidade de Lisboa
- Head of Research Group of Pharmacological Sciences of iMED.UL
- Independent consultant, silvalima preklinika limited, UK

Previous positions

- 2010- : Head of Department of Pharmacological Sciences of the Faculty of Pharmacy, Lisbon University
- 2008- : Faculty Director and/or member on several international courses on Nonclinical Safety Regulatory Science
- 2008- : Head of the Research Group of Pharmacological sciences of the iMED.UL (a research Institute of Medicines and Pharmaceutical Sciences, the Lisbon University)
- 2004: Full Professor of Pharmacology and Pharmacotoxicology at the University of Lisbon, Faculty of Pharmacy
- 1992: Auxiliar Professor of Pharmacology at the Faculty of Pharmacy,University of Lisbon.
- 1991: PhD in Pharmacology, Lisbon University, Portugal
- 1981: PharmD, Assistant Professor of Pharmacology at the Faculty of Pharmacy, University of Lisbon.
- 1980: PharmD, Assistant Professor of Toxicology at the Faculty of Pharmacy, University of Lisbon.
- 1980: Graduation in Pharmacy , University of Lisbon, Portugal

Areas of Expertise

- Preclinical drug development including non-clinical pharmacology, pharmacokinetics and toxicology for new medicinal products
- Biopharmaceuticals including gene and cellular therapies
- Mechanistic safety
- Regulatory strategies for biological products and emerging technologies

Major projects

As Regulator

- 1992-2012 Preclinical expert and member of the Board of Medicines of the Portuguese Medicines Agency (Infarmed)
- 1993-2012 CPMP/CHMP member, EMA
- 1996-2000 SWP member, EMA
- 2000-2012 Chair of SWP, EMA
- 2000-2012 SAWP member, EMA
- 2008-2012 CAT member, EMA
- 2007-2012: Co-deputy representing the European Commission on the ICH Expert Working Groups for M3 (R2), S6 (R1) and S1
- 2007: CHMP Rapporteur on the guideline addressing risk mitigation for First in Human clinical studies

As Academic

- Since 2010- Advisory Board of the IMI granted research projects, Safe-T, PANOPTES and stemBANCC
- Co-Responsible for module 2.2. on Regulatory Guidelines of the IMI training project SafeSciMet
- Since 2011- member of the stem cell working group of the European Partnership for animal alternatives (EPAA)
- Since 2012- member of the UK NC3Rs (Nonclinical replacement, reduction and refinement of animal in research) group.
- 2009 and 2012 integrated the panel of Reviewers of the FP7 research Grant Applications on Preclinical Development of Orphan Diseases.

Associations

Portuguese College of Pharmacists, Specialist on Regulatory Affairs, Portuguese Society of Pharmacology (member of IUPHAR), EUFEPS, DIA, ETS, New York Academy of Sciences

Publications

Publications / Conferences on basic science and nonclinical safety regulatory science aspects, including e.g. mechanisms of non-genotoxic carcinogenesis, Advanced Therapy medicinal products and Biomarkers.

The complete list can be provided upon request.