Dr. Jenny Sims BSc, PhD
CURRICULUM VITAE

Professional experience

Current position

- Member, NDA Advisory Board
- Independent consultant, Integrated Biologix GmbH, Basel, Switzerland

Previous positions

- 2008-2012, Head Translational Sciences and Safety, Novartis Biologics, Novartis Pharma AG, Basel, Switzerland
- 2007-2008, Head Biopharma Safety Assessment AstraZeneca / Cambridge Antibody Technology / MedImmune
- 2005-2006, Preclinical Director, Syngenta Biopharma
- 1999-2005, Head Project Safety Assessment, Preclinical Safety and Global Expert in Biotechnology, Novartis Pharma AG, Basel, Switzerland
- 1987-1999, Expert Preclinical Assessor, Medicines and Healthcare products Regulatory Agency (MHRA), London, UK

Area of Expertise

- Preclinical drug development including non-clinical pharmacology, translational PK-PD and safety assessment for new medicinal products, biopharmaceuticals (including gene and cellular therapies), biosimilars
- Immunogenicity risk assessment
- Nonclinical strategy and regulatory requirements to support European Clinical Trial Applications (CTA) and Marketing Authorisations Applications (MAA)
- Due-diligence evaluation

Major projects

As Regulator

- 1995-1999 UK delegate to CHMP Safety Working Party
- 1998-1999 EU Topic Leader for ICH M4(S)
- 1995-1997 EU Topic Leader for ICH S6
- 1997-1999: Co-Rapporteur for CHMP Note for Guidance on the Quality, Preclinical and Clinical Aspects of Gene Transfer Medicinal Products.
- 1995-1999: MHRA observer on UK Gene Therapy Advisory Committee (GTAC)

As Consultant

- 1999-2002: Industry (EFPIA) member for ICH M4(S)
- 2002-2004: Industry (EFPIA) member for ICH S8
- 2006-2007 UK industry review team post-Tegenero which recommended the MABEL approach for selecting starting doses for First in Human trials
- 2008-2011 Industry (EFPIA) Topic Leader / Rapporteur for ICH S6R(1)

Associations

- Eurotox Registered Toxicologist
- Member of BIO / Past Chair and current member of BioSafe Leadership Group
- Member of British Toxicology Society, British Society of Cell & Gene Therapy, TOPRA, American Association of Pharmaceutical Sciences

Publications

Publications and conference presentations on aspects of nonclinical PK-PD and safety assessment. The complete list can be provided upon request.