



Dr. Julia Dunne MA(Oxon), FRCP, Hon.FRCPCCH

CURRICULUM VITAE

Professional experience

Current positions

- NDA Medical Advisor
- NDA Advisory Board Member

Previous positions

- 2012-2014 Group Manager Special Populations Group, Medicines and Healthcare products Regulatory Agency (MHRA), UK
- 2008-2012 Scientific Adviser, Office of Pediatric Therapeutics, Food and Drug Administration (FDA), USA
- 2003-2007 Head of Special Populations Unit, MHRA, UK
- 2001-2003 Detached National Expert, Pharmaceuticals unit, European Commission, Brussels
- 2000-2001 Acting Group Manager, Licensing Group I, Medicines Control Agency (MCA)
- 1996-2000 Head, New Chemical Entities Unit, MCA
- 1994-6 Senior Medical Assessor, New Chemical Entities Unit, MCA
- 1992-94 Detached National Expert, Pharmaceuticals Unit, Directorate General for Enterprise European Commission, Brussels:
- 1989-1992 Senior Medical Assessor, New Chemical Entities Unit, MCA
- 1978-1984 Consecutive clinical posts in internal medicine in London Teaching Hospitals and Post-graduate Medical Centres

Areas of Expertise

Twenty five years of experience in regulatory affairs from drug development to post-marketing, including assessment of paediatric investigation plans, applications for orphan drug designations, clinical dossiers of marketing authorisation applications and pharmacovigilance and risk management plans. Expert at risk:benefit evaluations. Direct involvement in developing European legislation, including the Paediatric Regulation.

Major projects

- UK delegate to PDCO, EMA
- UK delegate to PRAC, EMA
- CHMP delegate to COMP, EMA
- UK delegate to CHMP, EMA
- Chairman European Council Working Party on the Paediatric Regulation (Regulations (EC) Nos 1901/2006 and 1902/2006)
- Rapporteur for European Guideline on Paediatric Pharmacovigilance
- Management Board Member, UK Medicines for Children Research Network
- Co-editor Pediatric Drug Development 2nd edition
- EU rapporteur for ICH guideline on Paediatric Medicine Development
- Co-led FDA cross-divisional working group on extrapolation of efficacy from adults to the paediatric population

Associations

- Royal College of Physicians (London UK), Royal College of Paediatrics and Child Health (Honorary)

Publications

- Extrapolation of efficacy from adults to the paediatric population; globalisation of paediatric clinical trials