

# Paul Baldrick, PhD

Senior Director, Regulatory Strategy, Global Regulatory Affairs

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## Key Roles and Responsibilities

- ▶ Provide high-level scientific, regulatory and nonclinical strategy to support new product development and registration of small molecule pharmaceuticals, biotechnology products, vaccines and medical devices
- ▶ Ensure alignment across multiple geographic regions with regard to drug development and regulatory positions
- ▶ Liaise with regulatory authorities to promote strong relationships and effective interactions

## Areas of Expertise

- ▶ **Expert Data Review and Comment/  
Due Diligence/In-Licensing**
- ▶ **Regulatory Agency Interaction**
- ▶ **Nonclinical Study Package Design/Development  
Strategy, Including**
  - Toxicology and Safety Pharmacology testing
  - Line Extension/Excipient development
  - Preclinical Pediatric testing
  - Reproduction and Carcinogenicity evaluation
  - Biosimilar development

## Professional Highlights

- ▶ Professor (visiting chair for regulatory toxicology at the University of Lincoln, UK)
- ▶ More than 25 years in nonclinical drug development supporting new product development and registration
- ▶ Act as a signed expert for Expert Reports/Nonclinical Overviews for drug development/regulatory agency submission
- ▶ Member of the editorial board/associate editor for four industry journals
- ▶ Member of the Association of the British Pharmaceutical Industry (ABPI) Preclinical Drug Safety Expert Network
- ▶ Registered Toxicologist and Fellow of the British Toxicology Society
- ▶ Authored or co-authored more than 50 peer-reviewed journal publications and book chapters
- ▶ Led multi-function drug development group as Head of Toxicology, UCB Pharma, Belgium
- ▶ Was responsible for the development of several drug candidates as Senior Toxicologist/Project Lead, Fisons Pharmaceuticals, UK
- ▶ Joined Covance in 1998

## Education

- ▶ **PhD, Physiology**  
*University of Durham, UK*
- ▶ **BSc, Zoology**  
*University of Durham, UK*

## Publication Journals

- ▶ *Drug Discovery Today*
- ▶ *Drug Information Journal*
- ▶ *Food and Chemical Toxicology*
- ▶ *Journal of Applied Toxicology*
- ▶ *Regulatory Toxicology  
and Pharmacology*
- ▶ *Reproduction Toxicology*
- ▶ *Toxicologic Pathology*
- ▶ *Vaccine*

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