PAUL CHAMBERLAIN

CURRICULUM VITAE

Personal details

Name: Paul Chamberlain

Education: BSc (Hons) Applied Biology

Professional experience

Current position: Biopharmaceuticals & Immunogenicity Specialist, NDA Advisory Board (since September 2007)

Previous positions:

- Senior Director, Drug Development Programmes, MDS Pharma Services
- Head of Quality Control, Metris Therapeutics
- European Regulatory Specialist, Amgen
- Senior Scientific Officer, Biotechnology Department, Smith Kline Beecham UK

Area of Expertise

- Structure-activity and structure-immunogenicity relationships for biotherapeutics
- Early development planning for biopharmaceutical products
- Immunogenicity risk assessment
- Product quality control and comparability evaluation
- Analytical & bioanalytical method development & validation
- Regulatory strategy for US and EU
- Due-diligence evaluation and portfolio risk-analysis

Major projects

- Preparation of integrated summaries of immunogenicity for different product classes, including peptides, therapeutic proteins and Advanced Therapy Medicinal Products
- Preparation and review of CMC modules for IND & MAA dossiers, and for Scientific Advice Briefing Books, for different classes of therapeutic proteins and peptides, including full-molecule IgG mAbs, scFv, domain antibodies, mono-specific and bi-specific nanobodies and their chemical or radiochemical derivatives (including PEGylated conjugates)
- CMC & pre-clinical development for autologous and allogeneic stem cells and gene-modified, cell-based medicinal products, including CAR T-cells and therapeutic vaccines; also for liposomal delivery systems for tumour-associated antigens and probiotic investigational medicinal products for tissue healing applications.

NDA Group
Grove House, Guildford Road, Leatherhead, Surrey, UK KT22 9DF
Tel: +44(0)1372 860 610 Fax: +44(0)1372 860 611

- Representation of Sponsors in interactions with regulatory agencies, including FDA Advisory Committee meetings, to assess impact of undesirable immunogenicity on overall clinical benefit and risk
- Design, validation and implementation of bioanalytical assays (PK, ADA and biomarkers) for different product types, including trouble-shooting to minimise sources of bias in clinical samples
- Detailed reviews of suitability of full repertoire of analytical methods to support different stages of biopharmaceutical product development, including cell-based potency assays and physico-chemical methods
- Application of immunogenicity risk minimization tools to guide lead candidate selection
- Critical Quality Assessment for therapeutic proteins

Publications

Full list of publications available upon request.