

Position Title: Project Manager Senior)

Department: Toxicology

Ipsen is an innovation-driven international specialty pharmaceutical group with over 20 products on the market and a total worldwide staff of nearly 4,200. Its development strategy is based on a combination of specialty products, which are growth drivers, in targeted therapeutic areas (oncology, endocrinology and neurology), and primary care products which contribute significantly to its research financing. The location of its four Research & Development centres (Paris, Boston, Barcelona, London) and its peptide and protein engineering platform give the Group a competitive edge in gaining access to leading university research teams and highly qualified personnel. More than 800 people in R&D are dedicated to the discovery and development of innovative drugs for patient care. This strategy is also supported by an active policy of partnerships. In 2008, Research and Development expenditure was about €183 million, close to 19% of consolidated sales, which amounted to €971 million while total revenues exceeded €1 billion.

Primary Purposes of Position:

Define, establish and sign-off the content of the preclinical safety studies to be performed from theselection of a lead candidate to registration.
Ensure that toxicology dossiers of Ipsen products are designed and conducted in compliance with international regulatory requirements and internal Ipsen procedures for clinical evaluation and regulatory registration.
Responsible for the quality and adequacy of the tabular and written summaries and prepare in a timely fashion of data and documents (non-clinical part of IB, CTX, IMPD, IND, Briefing documents, Expert reports etc..) of high quality for submission to Regulatory Authorities

Main Duties to be performed:

- Contribute to the optimisation of preclinical development plans of products: identifying toxicology pre-requests, proposing toxicology development plan, communicating with all other functional areas involved in projects
- Interface with Contract Research Organization (CRO). Ensure high quality of the studies and reports from CROs on schedule, time and budget. Identify and select CROs, facilitating scientific follow-up of Ipsen involved functional units, reviewing study documents and reports to ensure accuracy and compliance with internal and external regulatory requirements.
- Contribute to the assessment of the safety of products: a) communicate relevant toxicology information to the project teams b) participate to the writing of the toxicology part of regulatory documents c) prepare documentation for experts
- At an expert level: Master a discipline (Reproductive toxicology, Immunotoxicology, Toxicokinetics, Toxicogenomics, Pathology....) within preclinical safety and serve as expert to project teams for issue resolution and derisking strategies

Specifics of Position:

- Broad scientific knowledge of the toxicology science (genotoxicity, reproductive toxicology, general toxicology, investigational toxicology)
- Transversal thinking and awareness is an asset ie understanding of the multiple factors playing a direct or indirect role in the research and development of molecules as well as on regular regulatory review and approval of the submitted information
- Complementary expertise in a specific toxicology discipline: reproductive toxicology, immunotoxicology, toxicokinetics, toxicogenomics....)

Education:

- Ideal: Doctorate level in Toxicology plus DVM or Pharm D or MD or PhD. Board certification (ABT or ACVP) is a plus.
- Minimum: Doctorate level in Toxicology plus DVM or Pharm D or MD or PhD.

Linguistic Skills:

- Languages: English (writing, speaking)

Experience:

- Ideal: 10 years in Pharmaceutical Industry
- Minimum: 7 years in Pharmaceutical Industry

If you would like to be considered for this role, please contact Carol Bieber
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