



MERCK

IT'S TIME TO LAUNCH

the next stage of your career.

Preclinical Safety Lead (all genders) (Req ID # 229743)

A career at our company is an ongoing journey of discovery: our around 58,000 people are shaping how the world lives, works and plays through next generation advancements in healthcare, life science and performance materials. For more than 350 years and across the world we have passionately pursued our curiosity to find novel and vibrant ways of enhancing the lives of others.

Your role:

You provide high quality expertise in preclinical safety (toxicology and safety pharmacology). You are accountable for the management of activities for marketed products and pharma development projects (small molecules and biologics) beginning at Exploratory Development (ED) through marketing authorization and life cycle management (LCM). You analyze results of in silico, in vitro and in vivo toxicology as well as of safety pharmacology studies and bibliographic data, put it into strategic perspective and compile preclinical safety assessments. You represent preclinical safety in internal and external groups and committees, e.g. LCM, Global Project or Product Alerts Teams. Furthermore, you ensure appropriate content of preclinical safety parts of all regulatory documents including clinical trial applications (IND/IMPDS), global marketing authorization applications (e.g. BLA/NDA) and other filings (e.g. AtO, RMP, DSUR, PBRER). You support the delivery of high-quality contributions to incoming requests from other Merck Biopharma functions and Health Authorities. Position to be filled in Darmstadt or Ivrea.

Who you are:

- Advanced scientific degree; DVM, PhD in life sciences e.g., Biology/Physiology
- Toxicology Board (ABT) certification or other relevant certification advantageous
- At least 5 years experience within a pharmaceutical project environment
- Detailed knowledge of preclinical toxicology and safety pharmacology, R&D and regulatory requirements
- Broad experience of health authority interaction like pre-IND meetings
- Very good project management, communication & analytical skills
- Fluent in English
- Highly motivated

What we offer: With us, there are always opportunities to break new ground. We empower you to fulfil your ambitions, and our diverse businesses offer various career moves to seek new horizons. We trust you with responsibility early on and support you to draw your own career map that is responsive to your aspirations and priorities in life. Join us and bring your curiosity to life!

Curious? Apply and find more information at <https://jobs.vibrantm.com>