



Keeping life
in mind.

Title: Senior Toxicologist
Reporting to: Head of Pharmacology Research (Research Department)
Job Location: Porto, BIAL Headquarters, Portugal

Company

Founded in 1924, BIAL's mission is to discover, develop and provide therapeutic solutions within the area of health. With products available in more than 50 countries throughout four continents BIAL's commitment is to contribute for the improvement of Human Health and the quality of life of people from all over the world.

With an experienced team of more than 900 highly-qualified specialized employees, of whom over 77% have higher education qualifications or PhDs, in recent decades BIAL has strategically focused on quality, innovation and internationalization.

BIAL is strongly committed to therapeutic innovation investing more than 20 percent of its annual turnover into research and development (R&D) within the neurosciences and cardiovascular fields. By the end of 2009, BIAL has launched the first drug of Portuguese patent, an anti-epileptic, already available in several European markets and in the US. At the end of 2016 BIAL launched a second medicine from its own R&D, a new treatment for Parkinson's disease. Already available in Germany, Italy, Portugal, Spain and in the United Kingdom, it will be introduced in the remaining European countries throughout the next years.

Currently representing around two thirds of its turnover, BIAL will continue to strengthen its international presence based on its own innovative medicines, particularly in the most important European pharmaceutical markets, namely Spain, Germany, United Kingdom and Italy, where the company is already present with its own affiliates.

Summary

A position is available within the Safety Pharmacology and Toxicology service, part of Pharmacological Research group (Research Department) at BIAL.

The selected candidate will be responsible for planning, overseeing, interpreting and reporting non-clinical Safety and Toxicology Studies for our early and late stage portfolio, with a focus on generation of regulatory enabling GLP study packages and contributing to regulatory documentation and interactions.

The successful candidate is expected to plan with adequate budgeting and timing to comply with the assigned department goals, design and monitor the non-clinical safety and toxicology studies conducted internally and externally both in a GLP and non-GLP environment followed by taking the responsibility of the interpretation, internal and external communication and reporting of non-clinical safety data generated.

Role/Responsibilities

- Designing, planning, monitoring and interpreting toxicity and safety pharmacology performed at CROs, ensuring presentation of data is accurate and supports the conclusions;
- Complying with the assigned timelines and department goals;
- Preparing and authoring integrative assessments of the non-clinical safety in regulatory documents (e.g. for IB, IND, IMPD, CTA, CTD, DSURs PSURs, briefing books);
- Providing responses to information requests from national and international agencies related to non-clinical safety studies;
- Identification of threats to the pre-clinical safety assessment plan, proposing options for resolution or mitigation of these threats, ensuring the implementation of appropriate adjustments to the toxicology strategy. Actively integrating multidisciplinary research and development project teams;
- Maintaining state of the art expert scientific, technical and regulatory knowledge in toxicology and safety pharmacology, liaising with key consultants and scientists in the field
- Interacting with competent authorities (e.g. FDA, EMA, CHMP), collaborations, partnership discussions, conferences, and scientific advisory board.

Qualifications/Requirements

- PhD-level education in toxicology, pharmacology, veterinary medicine or equivalent experience;
- Board Certification or proven qualification expertise;
- Minimum 10 years' experience in similar positions in the Biotech/Pharmaceutical Industry;
- Proven expertise in management and leadership of multiple parallel programs in a project matrix organization;
- Strong knowledge on the drug development process and of the regulatory environment regarding preclinical development of new drugs to support clinical development of all phases. Solid understanding of all GLP guidelines;
- Experience in authoring / reviewing of preclinical safety parts of regulatory documents (e.g. IB, IND, briefing books, NDA / MAA submission documents);
- Excellent understanding on how CRO's function and how to work and effectively communicate with them;
- Excellent understanding of pharmacological and toxicological mechanisms as the basis of developing safe medicines;
- Knowledge about SEND compliant documentation is desirable;
- Experience working with common toxicological species, especially primates, also experience in CNS/CV field will be a plus;
- Excellent command of English, both oral and written;
- Autonomous, motivated and reliable personality as well as a committed team player;
- Ability to interact successfully in a cross-functional team setting;
- Strong aptitude for solving problems requiring thorough technical and scientific assessment;
- Track record on supporting the development of clinical candidates;
- Strong writing and communication skills with a result driven character;
- Sense of urgency with analytical know-how and logical approach on problem solving;
- Desire and ability to work in a multi-disciplinary and team-focused environment;
- Excellent communication capabilities and good social skills are essential;
- A team player who thrives in a high-speed environment where autonomy, accountability and innovation are critical for success;
- Steady attitude to take accountability for all aspects related to the role;
- Solid computer skills, specifically in the most common IT systems of the field.

Salary and Benefits: Adequate to skills and experience; competitive package.