Senior Pharmacokineticist / Drug Metabolist (m/f)

Reporting to Head of PK

About AiCuris

AiCuris (name derived from 'anti-infective cures') is a pharmaceutical company focused on the discovery, research and development of novel antiviral and antibacterial agents for the treatment of severe and potentially life-threatening infectious diseases. AiCuris has its roots in Bayer's long history of successful anti-infective drugs. Spun out in 2006 AiCuris owns a broad portfolio of R&D programs, compounds and intellectual property. The research fields in question are human cytomegalovirus (HCMV), hepatitis C, HIV, herpes and bacteria. We will on the one hand take existing heritage of anti-infective projects further through clinical development (actual up to phase II) and has on the other hand a strong commitment to identify new drugs by in-house discovery research.

AiCuris is looking for a Senior Pharmacokineticist/ Pharmacometrician to work within translational development. This position will be responsible for leading the use of pharmacokinetics/pharmacodynamics within preclinical and clinical development, and ensuring the application of in-house skills and competencies, in particularly, for exploratory *in vitro, in vivo* and human studies up to and including Proof of Concept in man.

This position will be based at the company's headquarters in Wuppertal, Germany.

Tasks

He or she will be the resident expert for PK/PD analysis and will contribute to the integration of pre-clinical and clinical ADME, PK, pharmacology and toxicology to ensure an effective application of PK/PD analysis in early clinical development, guiding the selection of the optimal human dose, delivery and dosage regimen, based on prediction of pharmacokinetic properties in humans, i.e.

- Contribute to the proper pharmacokinetic characterization of AiCuris project compounds in preclinical and clinical studies, i.e. participate in the generation, analysis and reporting of ADME/PK data in preparation for clinical development and make recommendations on next steps and/or go-no go decisions.
- Assist in the selection of development compounds with regards to an optimal ADME/PK profile
- Ensure an efficient execution of regulatory ADME, PK and toxicokinetics studies necessary for IMPD generation with external resources.. Participate in preparation or review of the preclinical and clinical parts of regulatory documents, such as IB, IMPD.
- Ensure proper and effective information flows and collaboration between preclinical (pharmacokinetics, pharmacology, toxicology, pharmaceutical development), early clinical development and project management groups at AiCuris and partner organisations for all aspects of human and regulatory.
- Ensure the optimization of formulation activities for all development compounds with external resources and partners.
- Contribute to the definition, implementation and maintenance of new multidisciplinary ways of working in order to improve the efficiency and effectiveness of Aicuris' development.

Key Qualifications

- PhD in an appropriate area is mandatory, i.e. Pharmacology, Chemistry Toxicology, Biochemistry, or Mathematics. The successful candidate must have a minimum of at least 2 years professional experience in the fields of ADME/pharmacokinetics (PK) and/or pharmacokinetic-pharmacodynamic (PK/PD) relationships obtained within the pharmaceutical industry, CRO or academic environment. Such experience will ideally, encompass both preclinical and clinical drug development. An individual with experience of either and with a desire to further their career experience in the other will also be eligible.
- Knowledge, and ideally experience, of working with contract research organisations (CROs) in the area of ADME/PK study outsourcing.
- Good interpersonal skills, i.e. positive & constructive attitude, desire and ability to work in interdisciplinary teams and able to motivate and inspire his/her team members.
- Demonstrated ability to communicate information effectively to a variety of individuals in a manner that promotes interdisciplinary relationships.
- Proven skills in PK or PK/PD data analysis, predictive modelling and illustrative presentation of such data (including medical writing).
- Good organizational skills including the capability of setting priorities. Accuracy, detail-focussed without being a perfectionist, and able to maintain a complete overview over several projects.
- Ability to work in a project driven and result-oriented way, sometimes in pressured circumstances. Demonstrated ability to work independently and with self-motivation under tight timelines.
- An understanding of clinical development strategies and tactics, and regulatory requirements regarding ADME, PK and PK/PD analysis.
- Knowledge of working with specific software (MsOffice, Spotfire, WinNonlin,)

Technical skills

- Credible, in-depth knowledge and experience of the key disciplines of drug metabolism and pharmacokinetics/pharmacodynamics as applied to both drug discovery (lead optimisation to clinical candidate) and drug development. A clear understanding of the utility of pre-clinical and clinical data, in helping drive forward project goals are essential.
- Experience in the design, execution and reporting of ADME, pharmacokinetic (PK) and/or pharmacokinetic-pharmacodynamic (PK/PD) studies.
- Ability to present a well reasoned business case, and influence other R&D scientists and leaders to support cross functional implementation of new initiatives and projects.
- Ability to communicate effectively with internal and external opinion leaders.
- Ability to work in a matrix type environment.
- Knowledge of overall drug development process is an advantage.

Communication skills

- While the language of the company is German the business language of the company is English when English speaking colleagues are present. German language training may be provided, if requested, for those for whom German is not the first language.
- Demonstrated technical/medical writing proficiency
- Effective oral presentations and persuasive talent
- Expertise in design of documents and presentations: MS Word, MS Excel, PowerPoint, etc
- Ability to contribute to drug development plans

Problem solving

- Able to manage uncertainty.
- Able to work independently and to solve complex problems and multiple projects in a supervisory capacity.
- Able to see underlying or hidden critical issues (technical, scientific, human)
- Ability to apply innovative approaches for decision making in drug development
- Ability to manage multiple projects
- Has or can acquire an understanding of the complexities of clinical development

Interpersonal Skills

- High performer with a strong team-commitment. Must be a strong team player with abilities to work in a multicultural environment.
- Persuasive and diplomatic
- Self-motivated
- Innovative
- Remains calm and focused in times of challenge
- Welcomes working under pressured situations

We offer an exciting and challenging job in an expanding and innovative company with an excellent R&D portfolio and a highly motivated team exhibiting many years of Biotech and Big Pharma experience.

How to apply

To apply, please submit your full application inclusive your curriculum vitae and salary requirements via email or via letter post.

Contact

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