Director DMPK and Bioanalytics (m/f/d)

About Tubulis

The development of novel, effective and safe therapies for the treatment of cancer is one of the main challenges for modern medicine. We want to drive this process forward. The main goal of Tubulis is to become a leading company in the field of targeted therapeutics and antibody-drug conjugates (ADCs). With a strong team, our own technologies and innovative therapeutic concepts, we are ushering in a new era in the ongoing fight against cancer and share the vision of helping patients world-wide. Be part of a multidisciplinary and focused team, that works towards getting novel promising ADCs to patients with solid and hematological cancers.

Be part of our team

The Director DMPK and Bioanalytics will be part of an agile and highly efficient integrated R&D team being responsible for managing and overseeing all bioanalytical and DMPK activities for Tubulis' innovative ADC candidates. The incumbent will work closely with the research, preclinical and clinical organization as well as with CROs and consultants. Therefore, you must be highly adept at building and managing relationships across various functions, and positioning results with a deep scientific understanding as to how the findings relate to early lead selection through development.

Responsibilities

- Responsible for development, transfer and validation of highly sensitive and specific bioanalytical methods for quantitative analysis of candidate ADCs and any concomitant/interaction compound in the given project to support non-clinical and clinical studies
- Lead DMPK and bioanalytical strategies to generate decision-enabling bioanalytical data with skilled data interpretation to meet and answer project needs
- Technical monitoring during bioanalytical method development, validation, and sample analysis.
- Outsourcing and managing activities in DMPK and Bioanalytics (from proposal generation to report approval); resource and time planning, coordination and administrative management of studies with CROs
- Ensure validity, accuracy, relevance and completeness of scientific content in non-GLP and GLP non-clinical research and regulatory documents
- Ensure full compliance with the current global and local bioanalytical guidelines and GxPs
- Responsible for original writing, editing and review of documents or regulatory submission
- May represent the company as DMPK & Bioanalytical representative at meetings with regulatory bodies
- Attend appropriate scientific meetings and stay up to date with relevant scientific literature to maintain expertise
- Accountable for incorporating relevant recent advances in the field into non-clinical research

Requirements

- Ph.D. in Pharmacokinetics, Drug Metabolism, Biochemistry, or equivalent and a minimum of 5 years of relevant industry experience
- Knowledge of DMPK science inside a complex research and development setting in a biotech organization of pharmaceutical company
- Broad knowledge across pharmacokinetics, pharmacodynamics, ADME, and bioanalytics
- In depth knowledge in bioanalytical assay development to support non-clinical and clinical studies
- In depth understanding of the drug development process and of non-clinical development. Experience with ADCs is a plus
- Strong ability to manage multiple studies simultaneously and to be able to assist in troubleshooting when instrument or assay problems arise
- Experienced in authoring and providing regulatory guidance to team members on technical reports/ suitable for inclusion in registration dossiers
- Familiar with ICH, FDA and other regulatory guidance and regulations relevant to non-clinical research
- Excellent communication skills and proven ability to collaborate with interdisciplinary teams and CROs. German is a plus
- Excellent managerial and leadership skills. Must be highly organized and extremely analytical with strong problem-solving skills
- Ability to align activities with company objectives
- Able to work independently and work well in a team and in a fast-paced environment

We offer

Flat hierarchies and short decision-making processes; open corporate culture; possibility of mobile working; unlimited contract after probationary period; 30 days' vacation; strong team spirit; personal appreciation of values; multicultural and global team and high level of collegiality; regular team events; mobility allowance; GUV; pleasant office atmosphere; modern technology standard.

We look forward to receiving your application with details of when you can start and your salary expectations.
By email to career@tubulis.com – more information at www.tubulis.com