Scientific Opportunity with San Diego Biopharmaceutical – Ambrx, Inc.

Scientist/Senior Scientist, DMPK

(Job Code: 07-19BR)

Ambrx is a clinical-stage biopharmaceutical company enabling a new field of *protein medicinal chemistry*, using a technology that directs the incorporation of amino acids beyond nature's conserved set into biosynthetic proteins to produce high value biological products such as antibody-drug conjugates.

Ambrx is seeking an experienced and highly motivated DMPK scientist to be a key member of the Pharmacology group in our fast-paced and dynamic organization. The successful candidate will play a key role in setting safety pharmacology strategy, designing and executing drug metabolism (DM), pharmacokinetic (PK) and toxicokinetic (TK) studies and PK modeling to help progress novel protein therapeutics from preclinical research into IND enabling studies and early clinical development.

Primary Responsibilities:

Responsible for all aspects of DMPK and Toxicology functions:

- Design, outsource and manage non-GLP and GLP DMPK, safety pharmacology and toxicology studies in support of projects from discovery to early clinical development.
- Prepare study protocols and reports related to DMPK and toxicology studies.
- Interpret study results from toxicology in conjunction with DMPK and pharmacology studies to estimate therapeutic index.
- Perform PK/TK analyses as appropriate.
- Perform modeling and simulation for dose predictions (including first in human dose projections) and quantitative risk assessment of drug-drug interactions, conduct PK/PD modeling.
- Lead the development of early hypothesis-driven investigation into mechanisms of toxicity for the proactive management of potential safety liabilities.
- Communicate study status, timelines and data to key stakeholders.
- Collaborate and interface with other functional areas including biological, bioanalytical and translational sciences, in vivo pharmacology, clinical and regulatory teams to facilitate development and execution of study plans.
- Serve as DMPK and/or Toxicology representative on multidisciplinary project teams.
- Contribute to regulatory submissions.
- Stay current with the latest DMPK, toxicology trends and regulatory requirements.

Job Requirements:

- Ph.D. in Pharmacology or related discipline with at least 3-5 years of drug discovery and development experience in the Pharma/Biotech industry.
- Experience in designing and conducting non-GLP and GLP pharmacokinetic studies preferably with biologics for lead candidate selection and IND enabling studies is essential.
- Experience in authoring nonclinical DMPK summaries for regulatory submissions is required.
- Experience in estimation of human equivalent dose (HED) and maximum recommended starting dose (MRSD) based on results from non-clinical studies is essential.
- Experience selecting CROs and managing external contracts.
- Ability to manage multiple projects simultaneously.
- Knowledge of GLP regulations and relevant FDA, EMA, and ICH guidance documents is highly desired.
- Expertise in analysis of PK/PD data and PK modeling and simulation using Phoenix WinNonlin, NonMEM, MATLAB and contributions to PK/TK reports are desired.
- Experience working with ADCs, T-Cell engagers for oncology indications is preferred.
- Excellent time management, communication, organizational and collaborative skills.
- Ability to be a self-starter as well as work in an interdisciplinary team.

To be considered as an applicant, please submit your resume/CV referencing the specific position of interest to careers@ambrx.com Applicants whose qualifications and experience most closely match the requirements of the position will be reviewed. Candidates will only be contacted for evaluative discussions. Ambrx offers competitive compensation & benefits. EOE