

Scientific Opportunity with San Diego Biopharmaceutical – Ambrx, Inc.

Senior Scientist, Toxicology/Pharmacology

(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 Toxicologist/Pharmacologist 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 toxicokinetic (TK), drug metabolism (DM) and pharmacokinetic (PK) 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 Toxicology and DMPK functions:

- Design, outsource and manage non-GLP and GLP toxicology, safety pharmacology and DMPK studies in support of projects from discovery to early clinical development.
- Prepare study protocols and reports related to toxicology and DMPK 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 Toxicology and/or DMPK representative on multidisciplinary project teams.
- Contribute to regulatory submissions.
- Stay current with the latest toxicology trends and regulatory requirements.

Job Requirements:

- Ph.D. in Toxicology, Pharmacology or related discipline with at least 5-8 years, or MS/BS with 14+ years of drug discovery and development experience in the Pharma/Biotech industry.
- Experience in designing and conducting non-GLP and GLP toxicology and pharmacokinetic studies preferably with biologics for lead candidate selection and IND enabling studies is essential.
- Experience in authoring toxicology reports and nonclinical summaries for regulatory submissions.
- Experience in estimation of human equivalent dose (HED) and maximum recommended starting dose (MRSD) based on results from non-clinical studies.
- Experience selecting CROs and managing external contracts.
- Ability to independently interpret results from toxicology studies to help guide lead candidate design and selection.
- Ability to manage multiple projects simultaneously.
- Certification by the American Board of Toxicology (DABT) is a plus.
- 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, 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