Opportunity with San Diego Biopharmaceutical – Ambrx, Inc.

Principal Scientist
Analytical and Formulation Development
(Job: 49-21BA)

Ambrx®, Inc. is an established biopharmaceutical company with a mission to deliver breakthrough protein therapeutics using an expanded genetic code. Unlike conventional conjugation techniques that create a mixture of suboptimal molecules, Ambrx technology combines site specific conjugation with proprietary linkers, payloads, and pharmacokinetic extenders to create a single molecular species that is optimized for safety, efficacy, and biophysical properties. We call this process Protein Medicinal Chemistry™.

The successful candidate will be a leader in analytical development for projects at various stages, especially at late phase clinical and BLA stages. As a senior member of this function, this individual should be able to maintain high standards of technical and quality excellence and will mentor and manage scientists and associates.

Major Responsibilities:

- Lead the efforts in developing and managing life cycle of analytical methods, ensuring that the projects are progressing as planned, process and products meet quality and regulatory requirements.
- Oversee biologics method qualification and validation at CDMOs to support PC/PV and manufacturing.
- Oversee raw materials testing, extractable and leachable studies; batch release and stability studies for mAbs, ADC/protein conjugates, and drug products; Reference Standards preparation and qualification.
- Oversee Comparability studies and clinical in-use Compatibility studies.
- Assist in gap analysis of CMC activities for BLA and develop plans to de-risk and manage studies to address the gaps.
- Write/diligently review development reports, SOPs, Test Methods, qualification and validation protocols and reports, etc.
- Author relevant CMC sections of IND, CTA, and BLA.
- Provide expertise, technical leadership, and assessment of product quality impacting OOS and OOT investigations.
- Participate in project teams to provide analytical support and coordinate resources for ongoing and new projects, from research to clinical stages.

Job Requirements:

- Ph.D. in Analytical Chemistry or related field with 12+ yrs. of relevant industrial experience in analytical development and characterization of protein therapeutics.
- Demonstrated leadership in staff and project management.
- Essential hands-on experience and in-depth knowledge in instrumentation and modern analytical chemistry techniques (HPLC assays, CE, peptide mapping, process residuals, and Compendial assays).
- Extensive experience with assay development, qualification, validation and tech transfer to CDMO to support early and late-stage development for proteins, protein conjugates, antibodies, and antibody-drug conjugates
- Experience with PTM characterization, CQA risk assessment, and biophysical assays is a plus.
- Experience with stability data evaluation, statistical analysis, DOE, and shelf-life projection preferred.
- Experience in GMP-compliance and Quality/Regulatory Assurance.
- Clear understanding of phase-appropriate regulatory requirement in CMC with significant experience in supporting late phase clinical development and commercialization, including authoring relevant CMC sections for IND, IMPD, and BLA submissions.
- Demonstrated ability to set clear and measurable goals for staff and prioritize tasks and resources to achieve superior work quality and efficiency.
- Excellent presentation, oral and written communication skills, be able to communicate effectively to senior management, cross-functional teams, and collaborators.

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.