Opportunity with San Diego Biopharmaceutical – Ambrx, Inc.

Scientist II / Sr. Scientist, Analytical and Formulations Development

(Job: 01-17BA)

Ambrx, Inc. is a biopharmaceutical company with a mission to deliver breakthrough protein therapeutics. Ambrx is based on a fundamental advance in protein biosynthesis that enables the company to genetically engineer proteins with new amino acid building blocks beyond the common twenty, enabling the biosynthesis of proteins with new physical, chemical and pharmacological properties. At Ambrx, we are dedicated to assembling and developing an exceptional team and a breakthrough technology to create the next generation of protein-based medicines.

Major Responsibilities:

We are currently seeking a highly motivated and innovative Ph. D level scientist to join our Formulation and Analytics group. The primary responsibilities of the scientist include:

- In collaboration with team members, design and execute overall formulation development strategies for Ambrx's therapeutic proteins to support toxicology and various clinical studies and commercial launch
- Carry out lab experiments to generate study results to support the formulation development of the programs. These include design of study protocols, set up of the formulation screening/stability studies, manage the development stability programs and generate study reports
- Participate in the interaction with CMO to support the fill-finish of GMP drug product for clinical supply. Prepare formulation report and technology transfer reports, participate in process transfer to CMOs for fill-finish of drug product, review manufacture batch records, and author documents for regulatory submissions
- Stay current on state-of-the-art scientific knowledge and practice in biological drug product development. Innovatively integrate new technologies into the work stream within the company
- Develop protocols for various stability studies including development stability study, IND stability study, long-term stability study, and use-time compatibility study etc. in collaboration with team members and external partners to support various programs in early and late stage development
- Perform statistical analysis to extrapolate and predict drug substance retest date and drug product shelf-life based on collected GMP stability data. Write interim and complete stability study report as appropriate
- Manage the internal long-term development stability program in collaboration with team members. Review, maintain and analyze the collected stability data.
- Author formulation development and stability sections of regulatory submissions

Qualifications

- Ph. D in Biochemistry, analytical chemistry, Pharmaceutics Sciences, or related fields with a minimum of 2 years of industry experience in biologic analytical /formulation development
- Must have in-depth understanding of the biophysical and biochemical degradation pathways for protein therapeutics in liquid formulation.
- Must have hands-on experience in formulation development of therapeutic proteins. Prior experience with monoclonal antibodies or Bi-specific proteins is a plus, and direct experience on ADC formulation and lyophilized formulation is highly preferred.
- Experience and knowledge in common analytical and formulation practices and procedures are required.
- Experience with SE-HPLC, cIEF, IEX-HPLC, CE-SDS, DSC, light scattering, and HIAC particle counting are required
- Good understanding of FDA and ICH guidelines associated with drug product development and drug substance and drug product stability assessment are required
- Familiar with selection of container/closure systems is required.
- Experience of GMP fill-finish of protein therapeutics is highly desirable
- Must have excellent scientific writing, communication, presentation, documentation, and organization skills.
- A team player with good people skills.