Opportunity with San Diego Biopharmaceutical – Ambrx, Inc.

Principal Scientist, Analytical and Formulation Development
(Job: 02-19BR)

Ambrx is a biopharmaceutical company enabling a new field of *protein medicinal chemistry*, using a fundamentally new technology that directs incorporation of amino acids beyond nature's conserved set into biosynthetic proteins to produce high value biologics products. Ambrx is seeking a highly motivated scientist to be a key member of a fast-paced and dynamic organization.

The successful candidate will be a critical lead in the Analytical and Formulation Development group at Ambrx. As a senior member of this function, this individual should be able to maintain high standards of technical and quality excellence and will be involved in managing scientists and associates on a daily basis.

Responsibilities:

- Lead a sub-group in developing analytical methods/assays ensuring that the projects are progressing as planned, process and products meet quality and regulatory requirements.
- Work alongside the team to perform state-of-art analytical methods (mass spectrometry, peptide mapping including sequence variant, sequence liability and developability/manufacturability, and impurity characterization; disulfide mapping, glycan analysis, HPLC assays, CE, icIEF, biophysical assays etc.), formulation development, compatibility, forced-degradation, and stability studies.
- Develop and apply new technologies for complex protein molecules (including E. coli and CHO derived proteins/antibodies) and conjugates for research, process development, and clinical development.
- Oversee and perform assay development, qualification/validation and tech transfer to CMO/CRO to support clinical manufacturing, release and stability studies.
- Write and diligently review development reports, SOPs, qualification reports, analytical protocols etc.
- Provide expertise across functions in research, research transitioning to development and product development stages.
- Leading efforts in protein and protein conjugates testing and characterization, significant experience with monoclonal antibodies, ADC, bi-specifics, and PEGylated proteins highly preferred.
- Participate in project teams to provide analytical support and coordinate resources for new and ongoing projects, from research to clinical stages.

Requirements:

- Ph.D. in Analytical Chemistry or related field with 10+ yrs of relevant industrial experience in analytical development and characterization for proteins.
- Demonstrated leadership in staff and project management is required.
- Essential hands-on experience and in-depth knowledge in instrumentation and modern analytical chemistry techniques (LC/MS/MS, peptide mapping, PTM characterization, HPLC assays, CE, biophysical assays etc.) is absolutely required.
- Proven record in developing and applying new technologies for complex protein molecules, attention to detail in experimental design and data quality as well as excellent troubleshooting skills are required.
- Extensive experience with assay development, qualification/validation and tech transfer to CMO to support clinical manufacturing. Prior experience in GMP-compliance and Quality/Regulatory Assurance is required.
- Experience authoring CMC sections of IMPD/IND preferred.
- Demonstrated ability to set clear and measurable goals for staff and prioritize tasks and resources to achieve superior work quality and efficiency.
- Excellent oral, presentation, and written communication skills, be able to communicate effectively to senior management, corporate functions 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. EOE