Opportunity with San Diego Biopharmaceutical – Ambrx, Inc.

Scientist, CMC Bioassays
(Job: 37-16NA)

About Ambrx:

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 bioassay scientist to be a key member of the Translational Sciences team. The successful candidate will be primarily responsible for developing ELISA and cell-based potency assays for antibody drug conjugates (ADCs) and managing GMP CROs.

Responsibilities:

- Develop and pre-qualify cell-based potency assays and antigen binding ELISA methods.
- Apply Design of Experiments (DOE) to identify and optimize critical assay parameters.
- Set stage-appropriate systems suitability and acceptance criteria.
- Utilize PLA 3.0 software to perform parallel line analysis (equivalence testing).
- Interview GMP CROs, negotiate quotes, and perform audits to evaluate technical capabilities.
- Manage CROs to ensure bioassay methods are transferred and qualified within timelines for GMP lot release testing.
- CRO oversight to ensure stability sample testing occurs within specified time frames, new critical reagent lots are qualified for use, and any deviations, investigations, or CAPAs are resolved.
- Monitor bioassay performance and trend GMP DS and DP batch stability data**.**
- Represent bioassay function at project CMC subteam meetings.
- Perform non-GMP potency assay sample testing to support program needs.
- Write Development reports, memos, and relevant CMC sections for regulatory submissions.
- Present work and effectively communicate progress at meetings.

Requirements:

- Ph.D. (or MS) in Cell Biology or a related scientific discipline with >3 years of industry experience in the bioassay field. (title commensurate with experience)
- Extensive, hands-on experience in bioassay methods optimization, qualification, and validation.
- Prior experience auditing and managing GMP CROs for bioassay testing.
- Proficient at using JMP, Design of Experiments (DOE), and PLA 3.0 software.

- Knowledge of relevant ICH and USP chapters, GMP requirements, and industry best practices.
- Demonstrated capability to work with team members to troubleshoot and identify solutions.
- Prior experience working with ADCs or bispecific molecules is desirable.
- Ability to work effectively in a goal-oriented, fast-paced, matrixed team environment.
- Flexibility to contribute to other functional areas is desirable.

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