Opportunity with San Diego Biopharmaceutical – Ambrx, Inc.

Vice President, Head of Biostatistics and Data Science

(Job: -21-20BA)

About Ambrx:

Ambrx®, Inc. is a 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™.

Job Description:

The Vice President, Head of Biostatistics and Data Science plays a key role on the cross-functional drug development team. This role reports to the Chief Medical Officer and will be responsible for leading all biostatistics workstreams for drug development programs and clinical trials, assets evaluations, regulatory interactions and submissions.

Primary Responsibilities:

- Draft statistical analysis plans, Data presentation plans, and statistical sessions of the study protocols for multiple programs and indications
- Partner with cross-functional teams to strategize development plans before and after data readouts
- Draft statistical sections of all regulatory submissions; provide input on drug development, submissions, and regulatory strategy from biostatistics perspectives
- Plays key leadership roles in the design of clinical trials, advising development team on endpoint selection, sample size, patient populations, data statistical analysis strategy, etc., flagging relevant issues and considerations as needed.
- Oversees in-house or CRO's biostatistics and programming activities on all data analysis, programming, tables/figures/lists outputs, data presentations, and data interpretations

Position Requirements:

- PhD in Statistics required
- 15+ years of hands-on pharmaceutical bio-statistical experience, with an emphasis on statistics, statistical programming, design and analysis of clinical studies
- Comprehensive knowledge of statistical analysis and regulatory requirements relating to clinical development of pharmaceuticals
- Advise on endpoint selections, with sample sizes and power evaluations
- Direct experience with development (NDA/BLA) is required
- Strong SAS programming skills; ability to review programming specifications
- Strong understanding of data management and respective systems
- Consistently able to produce quick, thorough, and accurate work
- Entrepreneurial spirit; willing to go above and beyond to manage multiple projects simultaneously and achieve key objectives in a fast-paced biopharma/biotech environment
- Natural collaborator who enjoys working on a cross-functional team
- Exceptional analytical, interpersonal, and communication skills