Opportunity with San Diego Biopharmaceutical – Ambrx, Inc.

Vice President, Head of Regulatory Affairs and Quality Assurance

(Job: -22-20BA)

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 Head of Regulatory Affairs plays a key role in ensuring development and execution of regulatory strategies and plans to enable efficient global development of products in the portfolio. This role, reports to Chief Medical Officer, will provide ongoing analysis of regulatory risks and opportunities in the development programs and proposing innovative approaches to mitigate/resolve risks and leverage opportunities to the benefit of the company's development efforts. (S)he will also be accountable for effective regulatory submissions and communications/meetings with regulatory agencies, as well as developing the in-house and contracted infrastructure and capability to maintain compliance with all regulatory requirements applicable to the company's programs.

The Head of Regulatory Affairs will advise internal development functions such as Clinical, Medical, Nonclinical and CMC regarding regulatory impact of development decisions. (S)he will also be responsible for Quality Assurance to ensure quality systems and compliance are maintained. (S)he will support business development activities including assessing partnership/in-licensing/out-licensing opportunities, collaborate with strategic and government partners, and support government affairs/advocacy activities.

Responsibilities:

- Primary contact to regulatory agencies. Guide and/or lead regulatory agency interactions, including communications, contingency planning and meetings.
- Direct preparation of submissions (IND, CTA, BLA, MAA etc..) and approvals with regulatory authorities. Strategize, lead, and supervise the development of and submission of documents/ dossiers to regulatory agencies to achieve development goals; ensure on-time, high-quality and regulatory–compliant submissions.
- Provide regulatory leadership and support to project/program teams and Senior Management for all aspects of the development program (nonclinical, clinical, quality (CMC) and labeling.
- Responsible for Quality Assurance to ensure quality systems and compliance are maintained.
- Effectively communicate requirements and compliance obligations under laws, regulations, and guidance in the US and around the world.

- Provide support to regulatory reviews for due diligence initiatives, including opportunity and risk assessment.
- Contribute to the creation of the overall product development strategy and manage the development, monitoring and delivery of regulatory project plans throughout the life-cycle.
- Responsible for cost-effective management of the Regulatory Affairs department budget.
- Develop and maintain regulatory affairs infrastructure including development of departmental policies and procedures.
- Lead Regulatory Affairs and Quality Assurance group including both internal personnel and CRO; responsible for hiring and mentoring of staff.

Qualifications

- Experience supporting both early and late phase development, including development and filing of associated regulatory submissions (IND, CTA, BLA).
- Ability to drive meetings with various stakeholders: (i) senior management, (ii) regulatory agencies (iii) investors, (iv) expert advisors v) collaborators and vi) project teams.
- Ability to review, understand and explain the regulations and guidance documents to guide project teams.
- Experience managing and collaborating with outside partners/vendors.
- Ability to collaborate effectively with internal and external key stakeholders.
- Proven success in communicating to and negotiating with FDA and global health authorities
- Passion, self-starter, outcomes-oriented and innovative thinker. Entrepreneurial spirit to perform and deliver beyond job description
- Outstanding written, oral, organizational, and interpersonal skills are required for this highly collaborative role.
- Advanced degree in a scientific discipline (Ph.D. or PharmD) with at least 10 years of relevant regulatory experience is required.

To be considered as an applicant, please submit your resume/CV referencing the specific position of interest and position code 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.