Director, Regulatory Affairs

Hinge Bio, Inc. is a privately-held biotechnology company leveraging its powerful GEM-DIMER™ platform to develop therapeutics that address the problems of resistance, inadequate efficacy, and side effects in the fields of inflammatory disease, cancer and infectious disease. GEM-DIMER™ technology is broadly applicable to all antibody-based therapeutics and antibody-based cellular therapies that would benefit from the ability to engage multiple targets with high affinity.

The GEM-DIMER technology uniquely enables (i) cooperative binding to disease targets allowing for orders-of-magnitude enhanced activity and (ii) greater degrees of multivalency and multispecificity than possible with conventional approaches, to produce molecules with entirely new functionality for superior safety and efficacy.

Hinge Bio is seeking a Director of Regulatory Affairs to lead regulatory strategy and the company's interactions with the FDA and other regulatory agencies. She/he will work closely with our scientific team and external advisors to build relationships with those agencies, help guide the development team to meeting the requirements for advancing therapeutic candidates into the clinic, and will lead the preparation and submission of IND-filings, coordinate regulatory aspects of clinical trials, and serve as the primary point of contact with regulatory agencies. The position provides the opportunity to join a creative, energetic and innovative research and development team. She/he will report to the company's Chief Development Officer.

The position is based at Hinge Bio's labs and offices in Burlingame, CA, with the expectation of regular on-site presence.

Job responsibilities

- Develop and execute regulatory strategies to support the advancement of GEM-DIMER candidates from preclinical to clinical stages, ensuring compliance with applicable regulations and guidelines.
- Lead the preparation, submission, and management of IND-filings and regulatory documentation for clinical trials, collaborating with cross-functional teams to ensure timely and high-quality submissions.
- Work closely with internal scientific teams to ensure timely and accurate reporting of scientific data necessary for regulatory filings.
- Serve as the primary point of contact for regulatory agencies, fostering strong relationships and effectively communicating with regulatory authorities to address questions, provide necessary information, and resolve issues.

Required qualifications:

- Bachelor's or advanced degree in life sciences, pharmacy, or a related field.
- 5+ years' experience in regulatory affairs within the biotech or pharmaceutical industry, with a focus on IND submissions and Phase I/II clinical trials.
- Demonstrated track record of successfully leading regulatory submissions, including IND applications and interactions with regulatory authorities.
- In-depth knowledge of FDA regulations, guidelines, and procedures relevant to drug development and clinical trials.

- Strong understanding of the drug development process, including preclinical, clinical, and regulatory requirements. Experience in autoimmunity and/or immuno-oncology preferred.
- Strong communication and interpersonal skills, with the ability to effectively collaborate and influence cross-functional teams and build relationships with regulatory authorities.
- Detail-oriented with excellent organizational, project management, and problem-solving abilities.
- Ability to work in a fast-paced, dynamic startup environment and adapt to changing priorities and deadlines.
- A ‘getting things done’ mentality, pro-active, enthusiastic and goal oriented.

Hinge Bio is an equal opportunity employer. All qualified applicants will receive consideration for employment without regard to race, color, religion, gender, gender identity, sexual orientation, national origin, disability status, protected veteran status, or any other characteristic protected by law.