Interested Parties should contact:
Keith Ryan kryan@geneousbiomedical.com
508 359 4120

Position: Head of Regulatory Affairs
Location: Cambridge, MA
Reporting to: Chief Medical Officer

Our client is a well-funded, clinical-stage biopharmaceutical company advancing novel peptide technology to develop a new class of therapeutics for cancers and other diseases. Their goal is to use their proprietary drug platform to create first-in-class therapeutics that may be able to address historically undruggable targets.

Based on their robust preclinical data and early clinical data showing strong anti-tumor activity, they feel that their lead program can be developed into an effective monotherapy or combination therapy for a wide variety of solid and liquid tumors.

We are working with them to identify an experienced executive for a **Head of Regulatory Affairs.** This key leadership position will support all RA related activities required to progress their novel programs through preclinical and clinical development and to ensure alignment within the company and regulatory agencies.

This individual will be responsible for representing Regulatory Affairs in cross disciplinary areas and manage high-quality submissions to regulatory agencies. As Aileron develops clinical assets, there could be additional duties and responsibilities to this role, including the expansion and management of additional team members.

Responsibilities

- Represent Regulatory Affairs on project sub teams, especially Clinical and Nonclinical
- Provide regulatory strategy and guidance for teams (e.g., protocol reviews, report reviews, development plans)
- Responsible for preparing for regulatory agency meetings (e.g., Pre-IND, Type A, B & C, Pre-NDA/MAA/NDS, etc.)
- Prepare regulatory submissions including but not limited to INDs, CTAs, annual reports, NDAs, MAAs, briefing packages as well as orphan drug designation documents
- Write regulatory documents to support regulatory submissions
- Interacts with regulatory agencies
- Develop and implement strategy for timely submission and approval of pre-clinical submissions, applications for clinical trials, marketing applications, etc.
- Provide expertise in translating regulatory requirements into practical, workable plans.
- Coordinate with external publishing resources for on-time delivery of high-quality regulatory submissions to regulatory agencies
- Establish and maintain Clinical Trials.gov postings for supported studies
- Participate in regulatory intelligence gathering activities and maintain knowledge of US and EU regulatory requirements
- Ensure compliance with regulatory requirements and timely preparation of organized and scientifically valid applications.

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Qualifications and Experience

- Bachelor's degree in life sciences required; advanced degree preferred
- Minimum of 15 years' pharmaceutical industry experience with a minimum of 10 years in Regulatory Affairs

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- • Experience with the Oncology or Hematology divisions of FDA is a plus.
- • Experience as the lead regulator on BLA's & NDA's
- • Evidence of successful submissions to FDA (e.g., INDs, briefing packages)
- • Demonstrated evidence of writing of regulatory documents (e.g. eCTD Module 1, Module 2, briefing packages, etc.)
- • Knowledge of FDA, EMA and ICH regulations and guidelines a must
- • Knowledge of drug development
- • Excellent written and oral communication skills
- • Excellent interpersonal skills
- • Strong project management skills and drive for excellence

COMPENSATION

An attractive compensation package commensurate