Allogene Therapeutics is a biotechnology company with a mission to catalyze the next revolution in cancer treatment through the development of allogeneic chimeric antigen receptor T-cell (CAR T) therapy directed at blood cancers and solid tumors. Founded and led by former Kite Pharma executives who bring unrivaled clinical development acumen in cell therapy, Allogene is well-positioned to further the potential of allogeneic cell therapy for patients.

Allogeneic CAR T therapies are engineered from cells of healthy donors and stored for "off-the-shelf" use in patients. This approach eliminates the need to create personalized therapy from a patient's own cells, simplifies manufacturing, and reduces the time patients must wait for CAR T treatment. The Allogene portfolio includes 16 pre-clinical T cell therapy assets and UCART19, an allogeneic CAR T therapy currently in Phase 1 development for the treatment of acute lymphoblastic leukemia (ALL). Through its notable partnerships, Allogene leverages pioneering technology platforms, including TALEN® gene editing technology, to progress its portfolio of immuno-oncology therapies. Allogene, with headquarters in San Francisco, California, is a Two River portfolio company formed with one of the largest Series A financings in biotechnology from an investment consortium which includes TPG, Vida Ventures, BellCo Capital, the University of California Office of the Chief Investment Officer, and Pfizer. For more information, please visit www.allogene.com, follow @AllogeneTx on Twitter and LinkedIn.

Position: Head of Regulatory Affairs
Location: San Francisco, CA

Job Description:
Allogene is seeking a Head of Regulatory Affairs to provide regulatory leadership in support of the development programs at Allogene. This includes the development and implementation of regulatory strategy, ensuring timely preparation, review and submission of documents to regulatory authorities, and maintaining compliance with applicable regulatory requirements. The ideal candidate for this role is an individual who is excited to take on new challenges in a fast-paced and dynamic start-up environment.

This position will report directly to the Chief Medical Officer.

Responsibilities:
- Develop and implement regulatory strategy.
- Represent the regulatory function on cross-functional development teams.
- Provide regulatory guidance and strategy including identifying and assessing regulatory risks.
- Plan, prepare, and review submissions to regulatory authorities including FDA, EMA and other national authorities to support the conduct of clinical trials and approval of marketing applications (IND, CTA, BLA, MAA).
- Lead regulatory activities for assigned projects in line with US, European, ICH, and other applicable requirements to ensure compliance.
- Manage the regulatory aspects of products and projects including achievement of timelines and deliverables.
- Ensure that regulatory documents are accurate, complete and verifiable, and confirm compliance with regulatory requirements.
- Monitor, analyze, and disseminate intelligence on regulatory matters that may affect ongoing development programs.
- Prepare meeting requests, briefing documents, coordinate and prepare teams for meetings, and interface with regulatory authorities; be primary liaison with regulatory authorities for day-to-day interactions.
- Coordinate and prepare responses to requests for information from regulatory authorities.
- Train and mentor other regulatory affairs personnel.
- Other duties as assigned.

Requirements:
- PhD or PharmD in a scientific discipline preferred along with at least 7 years of experience in industry related Regulatory Affairs (or BS/MS with at least 10 years of relevant experience).
- Knowledge and understanding of global regulations and guidelines.
- Previous experience in the preparation and submission of regulatory documents.
- Previous experience in attending and leading a team to prepare for major health authority interactions (e.g., FDA pre-NDA/BLA, EOP2 meetings, advisory committee meetings and/or EU oral explanations/scientific advice, etc.).

- Must be able to collaborate and work with other departments such as Clinical, Commercial, Finance, Research & Development, Manufacturing, and Supply/Purchasing.
- Ability to work in a fast-paced, start-up environment.
- Strong attention to detail with the ability to multi-task and handle multiple responsibilities simultaneously.
- Excellent organizational skills and an ability to prioritize effectively to deliver results within reasonably established timelines.
- Ability to work independently and as part of a team.
- Strong interpersonal skills including verbal and written communication are essential in this collaborative work environment.
- Candidates must be authorized to work in the U.S.

As an equal opportunity employer, Allogene Inc. is committed to a diverse workforce. Employment decisions regarding recruitment and selection will be made without discrimination based on race, color, religion, national origin, gender, age, sexual orientation, physical or mental disability, genetic information or characteristic, gender identity and expression, veteran status, or other non-job related characteristics or other prohibited grounds specified in applicable federal, state and local laws. In order to ensure reasonable accommodation for individuals protected by Section 503 of the Rehabilitation Act of 1973, the Vietnam Era Veterans' Readjustment Act of 1974, and Title I of the Americans with Disabilities Act of 1990, applicants who require accommodation in the job application process may contact careers@allogene.com for assistance.

For more information about equal employment opportunity protections, please view the 'EEO is the Law' poster.