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: **Director, Clinical and CMC Regulatory**
Location: **San Francisco, CA**

Job Description:
Allogene is seeking a Director of Clinical and CMC Regulatory to provide support for development and marketed products and provide product strategy and direction to research, clinical, and manufacturing / tech ops teams.

This individual will be responsible for assuring the regulatory strategy is aligned with Health Authority requirements and regulatory submissions are on time and high quality.

Responsibilities:

- As a member of the project teams, provide strategic Clinical and CMC regulatory guidance for global development and registration programs (e.g., INDs, CTAs, NDAs and MAAs).
- Assess and communicate Clinical and CMC regulatory requirements to ensure all development activities are in compliance with applicable regulations and guidelines.
- Primary regulatory representative (for assigned projects) at internal meetings as well as at meetings with regulatory agencies for all Clinical and CMC related issues.
- Compile, review, approve and submit CMC and marketing registration applications, supplements and variations. Respond to regulatory questions from various regulatory authorities, working in collaboration with SME's in Research, Clinical, Manufacturing, QC/QA, global supply chain and other business partners.
- Manage and ensure compliance with all reporting requirements, including annual and periodic reports.
- Manage contract staff and vendors as needed to support regulatory activities.

Requirements:

- Experience in filing regulatory submissions from early development to pre and post approval submissions and product lifecycle management in the area of Cell Therapy.
- Advanced scientific degree preferred. B.A./B.S. or higher degree (s) in the sciences, or health related field minimum, with 10-15 years regulatory experience.
- Established working knowledge of regulatory guidelines and regulations (US and international).
- Regulatory experience supporting both development projects and marketed products.
- First-hand knowledge and experience of FDA CMC regulatory submissions is essential
- Strong knowledge of eCTD elements and structure and regulatory writing skills
- 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.