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: **Senior Director, Quality Assurance**
Location: **San Francisco, CA**

Job Description:
Allogene is seeking a Senior Director of Quality Assurance to lead the Quality Assurance function. This position will require active engagement and strategic vision for the QA role in the company. The position will be responsible for building a company quality management system and providing direction and decision making with regard to quality operations. Role will entail operating in a fast-paced, highly dynamic environment with key company work partnerships including both internal and external stakeholders. Excellent communication skills and demonstrated ability to work well with others will be essential.

Responsibilities:

- Provides Quality functional leadership including hiring and managing a professional, high performing quality assurance staff designed to meet the technical and compliance requirements of a growing company.
- Establishes a quality management system designed to facilitate development of Allogene's product portfolio and maintain cGMP compliance.
- Provides company guidance with respect to regulations, guidelines, and emerging inspectional trends.
- Performs and or oversees quality operations including lot disposition, deviation management, and supplier management.
- Develops and implements annual quality plans, departmental goals, action plans, and budgets.
- Independently reports quality metrics to executive management through Management Review process.
- Drives continuous improvement utilizing quality tools such as lean, six sigma, and risk management.
- Internally collaborates with research, clinical, process development, and manufacturing groups.
- Externally collaborates with contract service providers and corporate partners in support of supply chain objectives.
- Ensures cGMP training program is effective and followed by staff involved in GMP operations.
- Approves or oversees review and approval of process and method validation, qualifications and validation reports, change control documents, and technical reports.
- Other duties as assigned.

Requirements:

- At least 12 years in a technical role in quality assurance, manufacturing, QC or quality engineering with demonstrated manufacturing plant experience with at least 5 years in a related management role.
- Bachelor's degree in Engineering, Chemistry or biological sciences required. Advanced degree preferred (education or training in cell culture and gene therapy a plus), ASQ Auditor certification, ASQ Quality Engineer certification preferred.
- Lean or Six Sigma certification (preferred but not required).
- Experience in medical device or pharmaceutical bio-pharmaceutical field required.

- Extensive working knowledge of quality system requirements such as US FDA GMP, EMA, and ICH guidelines and have a proven track record of successfully implementing these requirements.
- Knowledge of fundamental quality engineering principles such as process capability, process control, and structured problem solving, including root cause investigations.
- Proficient in MS Word, Excel, Powerpoint, Visio, Project, and statistical software.
- Demonstrated ability to successfully interact with regulatory health authorities at inspections (prior experiencing leading inspections is preferred).
- Ability to effectively work in a fast-paced, start-up environment, while dealing with ambiguity.
- 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 relationship building, conflict resolution, and 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.