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: Quality Assurance Disposition Manager
Location: San Francisco, CA

Job Description:
Allogene is seeking a Quality Assurance Disposition Manager to oversee the disposition of GMP critical raw materials and products manufactured by our contract manufacturing partners, including review of executed batch records, approval of investigations, change controls and other associated quality documentation. Must be able to work independently and professionally in the execution of Allogene's supply chain responsibilities. Must be able to manage responsibilities in a fast-paced environment, meeting production objectives, while ensuring quality requirements are met. Will be able to design and develop core company QA policies and procedures with other quality leadership team members.

This position will report directly to the Senior Director of Quality Assurance.

Responsibilities:

- Work with CMOs to insure timely receipt and resolution of batch documentation for GMP materials.
- Review batch-related documentation, and ensure proper resolution of quality issues prior to batch disposition.
- Ensure all product-related deviations are initiated, investigated and properly addressed to assure product quality.
- Ensure associated CAPA's are initiated and resolved as needed.
- Review and approve change controls, as needed.
- Perform QA product disposition and lot closure.
- Ensure batch production files are organized and maintained.
- Authorize critical raw material and product shipments including release of material to clinical trial locations.
- Maintain metrics related to batch record review and product disposition in support of continuous improvement.
- Develop and improve company product disposition related work processes to improve their effectiveness.
- Train, manage, coach and mentor staff as needed.
- Engage with CMO partner staff to improve the performance and compliance of their internal policies and procedures.

Requirements:

- Bachelor's degree in related science or engineering field and minimum of 5-7 years of experience in GMP regulated biopharmaceutical manufacturing with preference for experience with gene and cell therapy products.
- Knowledge of quality systems and regulatory requirements including relevant US and EU guidelines.
- Minimum of 2-3 years of management experience.
- Direct experience with batch review and release of viral vector and or cell therapy product lots is preferred
- Excellent writing and editing skills.
- Works on multiple assignments in collaboration with internal and external customers.
- Advanced computer skills with MS Office applications Word, Excel, PowerPoint, as well as Adobe Acrobat.

- Ability to work in a fast-paced, start-up environment.
- Excellent problem-solving skills and ability to work with others to resolve conflict in order to meet objectives.
- 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.