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 Manager, Document Management and Training
Location: San Francisco, CA

Job Description:
Allogene is seeking a Senior Manager, Document Management and Training to establish GxP compliant process and procedures for GxP document management and training. Must be able to work independently, and function as the company subject matter expert in relation to GxP document management and training practices.

Responsibilities:

- Develop and oversee document control procedures including the creation, routing, review, approval, distribution and archiving of new and revised controlled documents.
- Develop and oversee GxP training program including the maintenance of training records, and periodic reporting of training compliance.
- Assist in the design and implementation of Electronic Document Management System (EDMS) and Learning Management System (LMS).
- Manage document control processes and systems for GMP activities in compliance with internal procedures and policies as well as regulatory requirements.
- Manage the storage of incoming GxP documentation from contractors including batch production files, analytical product release and stability test results, raw data, and technical protocols and reports.
- Oversee the creation and management of document format and content templates.
- Ensure controlled documents are periodically reviewed for relevance and accuracy to ensure actual practices are reflected as defined in applicable procedures.
- Establish and maintain records management system including secure storage, retrieval, retention and destruction.
- Develop and deliver training and/or site guidance on document and records management roles, and processes.
- Identify and secure training resources as needed.
- Define resource requirements; assign resources to tasks; manage assigned team.

Requirements:

- Bachelor's degree preferred or minimum of 5-7 years of experience in a GMP related field within a biotechnology, biologics, or pharmaceutical manufacturing facility.
- Knowledge of quality systems and regulatory requirements (21 CRF Part 11/210/211).
- Minimum of 2-3 years of management experience.
- Strong knowledge of GMP, SOPs and quality systems as they relate to document management requirements.
- Excellent writing and editing skills.
- Works on multiple assignments in collaboration with various department system owners.
- Advanced skills with MS Office applications Word, Excel, Access, as well as Adobe Acrobat.

- Knowledge of EDMS, and LMS work environments as well as paper-based document management and training systems.
- 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.