Associate Scientist / Senior Research Associate, cGMP Cell Line Development (Compliance)
Job Code: 525MR

Description
Fate Therapeutics is seeking a highly motivated Compliance Associate Scientist or Senior Research Associate to assure adherence to standard operating procedures, GXP guidelines, and applicable regulations. The ideal candidate must thrive in a fast-paced team environment and must have excellent attention to detail, communication, organizational abilities, and independent problem-solving skills. Candidates must have experience working in a cGMP environment and have experience investigating and managing deviations, CAPAs, OOS. This is a full-time position reporting to the Manager, cGMP Cell Line Development and is located at our corporate headquarters in San Diego, CA.

Responsibilities
- Provide oversight and ownership of deviation, OOS, and change control records. Ensure records are properly initiated, investigated and resolved in accordance with established timelines and guidelines.
- Ensure CAPAs are initiated and resolved in a timely manner.
- Review batch-related documentation and ensure resolution of issues to release product.
- Provide support resolving in-process product, final product, environmental, facility and equipment and material issues.
- Ensure process control measures are in place and followed in iPSC master cell bank generation and working cells bank manufacturing.
- Review manufacturing production records and submit for approval.
- Draft, edit, and update procedures and forms as needed.
- Coordinate the packaging and shipping process of drug products to off-site facilities.
- In collaboration with Quality Assurance team, perform disposition of incoming materials, components, and banks.
- Maintain and be responsible for inventory of Quarantine and Released MCB, WCB, and parental cell banks.
- Enroll material under Quality Assurance guidelines for use by iPSC Product Development team.

Qualifications
- M.S. or B.S. degree in a scientific discipline with minimum of 4 years of biotechnology, clinical, or pharmaceutical experience is required. Position depends on experience.
- Experience with manufacturing investigations, deviations, and CAPA required.
- Experience with change control practices and strategies required.
- Working knowledge and ability to apply GMPs in conformance to U.S. and EU standards.
- Knowledge of equipment, facility, and utility IQ/OQ/PQ preferred.
- Good interpersonal, verbal and written communication skills are essential in this collaborative work environment.
- Must be able to work on multiple records simultaneously and demonstrate organizational, prioritization, and time management skills.

- Comfortable in a fast-paced company environment with minimal direction and able to adjust workload based upon changing priorities.
- Proficient in MS Word, Excel, Power Point and other applications.

Working Conditions and Physical Requirements

- Will require working with cells and cell lines of human and/or animal origin
- Occasional evening and weekend work will be required.
- 100% on-site work at corporate headquarters in San Diego, CA

The preceding job description indicates the general nature and level of work performed by employees within this classification. Additional and incidental duties related to the primary duties may be required from time to time.

For consideration send cover letter and curriculum vitae to: careers@fatetherapeutics.com and reference job 525MR.

About Fate Therapeutics, Inc.

Fate Therapeutics is a clinical-stage biopharmaceutical company dedicated to the development of first-in-class cellular immunotherapies for patients with cancer. The Company has established a leadership position in the clinical development and manufacture of universal, off-the-shelf cell products using its proprietary induced pluripotent stem cell (iPSC) product platform. The Company's immuno-oncology pipeline includes off-the-shelf, iPSC-derived natural killer (NK) cell and T-cell product candidates, which are designed to synergize with well-established cancer therapies, including immune checkpoint inhibitors and monoclonal antibodies, and to target tumor-associated antigens using chimeric antigen receptors (CARs). Fate Therapeutics is headquartered in San Diego, CA. For more information, please visit www.fatetherapeutics.com.