



**Senior Scientist/ Scientist, cGMP Cell Line Development, Tech Transfer
Job Code 616YL**

Description

Fate Therapeutics is seeking two highly motivated individuals to join the Product Development team. This position will participate in Tech Transfer of iPSC cell banking platform from process development to manufacturing and facilitate strategic project execution and gap assessment. Ideal candidates will lead and participate in projects to transfer processes from development to manufacturing by collaborating cross-functionally with the iPSC Manufacturing, Process Development, and Project Management teams to ensure successful and timely process transfer. This is a full-time position reporting into the Cell Line Development group and is located at our corporate headquarters in San Diego, CA.

Responsibilities

- Author, review and approve validation documentation such as protocols & reports for PPQ, validation master plans, and comparability process validation testing.
- Support the execution of APV and engineering runs for iPSC MCB generation processes and train manufacturing staff as needed.
- Develop and implement scientifically sound validation plans, policies and procedures based on current regulations, industry standards and industry practices for MCBs.
- Participate in evaluation of new technology and process automation for introduction into GMP manufacturing.
- Evaluate various materials use in manufacturing processes and support the evaluation of new or alternate materials, material change either via supplier-initiated change or change control and ensure material readiness for introduction into GMP manufacturing.
- Initiate and support investigation, identification of root-causes and CAPAs at internal manufacturing sites, and external vendors in collaboration with QA. Lead resolution of critical manufacturing gaps, as needed.
- Support the development of a continued material onboarding plan for existing critical raw materials utilized for iPSC MCB manufacturing process.
- Collaborate with key suppliers/partners including iPSC Manufacturing, Quality, Supply Chain, Regulatory.
- Apply working knowledge of FDA and EMA guidance to procedures and processes
- Proactively identify process gaps and/or inefficiencies, perform root cause analysis, and propose solutions

Qualifications

- Education and work experience. Position depends on experience.
 - PhD in scientific discipline with 2+ years of biotech experience.
 - M.S. in a scientific discipline with minimum of 6+ years of biotechnology experience.
 - B.S. in a scientific discipline with minimum of 10+ years of biotechnology experience.
- Expertise in industry best practices, guidelines and regulations related to process validation (PDA/ICH/BPOG) and boards of health (FDA/ICH/EMA/PICS) is required
- Demonstrated knowledge of pharmaceutical manufacturing of biotechnology products, aseptic processing, cell culture, and process development
- Experience with the technology transfer of Biotech products
- Familiar with methods for technology transfer comparability assessments and process performance qualification



- Good understanding of material qualification and material testing requirements preferred

Working Conditions and Physical Requirements

- 100% on-site work at corporate headquarters in San Diego, CA
- Occasional evening and weekend work will be required.

For consideration send cover letter and curriculum vitae to: careers@fatetherapeutics.com and reference job 616YL.

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.