



Position: Associate Director/Director, Cell Line and Upstream Process Development

Forty Seven Inc. is a privately held, clinical-stage biotech company that is developing the next generation of transformational immuno-oncology treatments.

This position is responsible for managing cell line and upstream process development and subsequent manufacturing of biological products at contract manufacturing organizations. Management of CMOs and CROs is a critical aspect of the job and will include frequent visits to the contractors depending on the intensity of the ongoing activities. The role involves significant cross functional collaboration with other functions, including downstream, analytical, quality assurance and regulatory.

Essential Functions

These may include, but are not limited to, the following; other duties may be assigned

- Manage and support cell line development, MCB manufacturing and release
- Manage and support upstream process development, scale-up, production and tech transfer of processes within or between CMOs.
- Ensure all experiments and activities are documented appropriately to ensure full traceability of work performed at the CMO/CRO.
- Contribute to preparation and submission of CMC portions of regulatory submissions and updates (IND, BLA, and post marketing commitments)
- Will design, manage and support process characterization studies and develop control strategies for process validation.
- Support process investigations and help determine root cause of excursions in clinical manufacturing.
- Ensure that all processes are in line with health, safety, environmental and quality requirements including regulations, policies, applicable guidelines and procedures.

Education & Experience

- PhD in Biochemistry / Biology / Chemical Engineering, with 10+ years of biological process development and manufacturing experience with a strong record of achievement; or BS/MS degree and 15+ years of relevant experience.
- Proven hands-on experience with mammalian bioreactors as well as centrifugation and depth filtration.
- Demonstrated experience in tech transfer of a process from development to manufacturing or between manufacturing sites.
- Previous team managing experience

Knowledge Requirements:



- Expert in mammalian cell line development; familiar with regulatory guidelines related to MCB manufacturing and release.
- Demonstrated, in-depth understanding of environmental, nutritional and mechanical factors influencing cell growth, productivity and longevity.
- Working knowledge of CMC regulatory requirements for biological pharmaceutical products at various stages of development
- Knowledge of quality systems and FDA/EU regulations as they relate to process / product development and manufacturing of biologics.

Other Information

- Position may require occasional evening and/or weekend commitment
- Position may require working with biological and/or chemical hazards
- Position may require occasional travel (~25%), domestic and international.

Location: [Menlo Park, CA](#)

Position type: [Full time](#)

To apply, send resume to careers@fortyseveninc.com and reference position description in subject line. Only candidates, no recruiters or agencies. We are an equal opportunity employer and value diversity at our company. We do not discriminate on the basis of race, religion, color, national origin, gender, sexual orientation, age, marital status, veteran status, or disability status.