Position: Associate Director/Director, Drug Product 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 will lead drug product development activities, and will be responsible for formulation development, stability, drug product fill and labelling/packaging. 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 drug substance process, analytical, quality assurance and regulatory.

This position will lead drug product development activities, and will be responsible for formulation development, stability, drug product fill and labelling/packaging. 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 drug substance process, analytical, quality assurance and regulatory.

Essential Functions

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

- Develop strategic phase-appropriate drug product development plans; responsible for drug product fill/finish process, product quality and compliance; providing PIP support in drug product manufacturing at CMOs.
- Manage day-to-day activities of multiple projects to meet aggressive development timelines and support manufacturing of clinical materials
- Serve as the subject matter expert in formulation, container closure system and drug product fill/finish.
- Oversee CMC clinical supply task
- Manage the company's stability programs at CROs/CMOs by reviewing protocols, raw data, performing trend analysis and guiding OOS/OOT investigations
- Author, review and/or approve analytical related documents, including COAs, SOPs, protocols, method development reports, analytical qualification/validation reports, stability and other technical reports
- Author and review analytical and characterization sections of Regulatory submissions (i.e. IMPD/INDs), and responses to Regulatory agency questions.

Education & Experience

- PhD in life Sciences or relevant field with a minimum of 10 years of relevant industry experience, or MS with a minimum of 15 years of relevant industry experience.
- Strong preference for at least 3 years of experience managing outsourced formulation development and drug product fill/finish at contract organizations

- Broad, and in-depth expertise in mAb formulation development
- Extensive experience with drug fill/finish process and solid knowledge of cGMP practices.
- Experience with sterile, parenteral /injectable products
- Experience in setting process and product specifications
- Experience in designing and evaluating stability programs
- Direct experience preparing and reviewing CMC documentation for regulatory filings and inspections required.
- Experience meeting/interacting with FDA (and/or other Regulatory bodies) a strong plus.
- Experience in early-stage development and small company environment is a plus
- Experience in project management and team facilitation skills preferred

Knowledge Requirements:

- Expert in formulation development; familiar with regulatory guidelines related to stability program and drug product shelf life.
- Demonstrated, in-depth understanding of drug product fill/finish process and related GMP guidance.
- Working knowledge of CMC regulatory requirements for biological pharmaceutical products at various stages of development
- Previous team managing experience

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.