Forty Seven, Inc. is committed to the advancement of immuno-oncology through the engagement of new and complementary phagocytic pathways that enhance anti-tumor efficacy and selectivity.

TITLE: Vice President, Technical Development & Manufacturing

POSITION SUMMARY

Forty Seven, Inc. is a clinical-stage biotech company that is pioneering breakthrough solutions to advance the next generation of immune-oncology treatments. We are seeking a Vice President of Technical Development & Manufacturing that will be responsible for delivering high quality biologics for clinical and commercial use including establishing the CMC development plan and leading the execution of the plan for drug substances and drug products from pre-clinical through commercial development. The VP of Technical Development and Manufacturing will rely predominantly on external partners and contract manufacturing requiring CMC alliance activities as part of the global development of Forty Seven, Inc. and with partners. The position reports to the President & CEO.

TASKS AND RESPONSBILITIES

- Establish, manage and lead the technical development plan for drug substance and drug product from pre-clinical through commercial development including support for all regulatory interactions and files
- Develop an appropriate yet lean organization to oversee all pertinent CMC activities at Forty Seven Inc. including manufacturing support of the various program and product teams.
- Select third-party manufacturers working with Quality and Regulatory, negotiate effective supply/technical agreements. Identify contract analytical laboratory sites required to guide and support third party manufacturing relationships
- Full oversight of contract manufacturing, testing, packaging and labeling operations for the company's drug substance and drug product for development and commercialization. Act as primary liaison with contractor(s) on assigned projects. Guide external operations through all tech transfers, process and method development, optimization, qualification and validation of the activities related to all manufacturing operations
- Ensure adequate representation and participation in product development project teams via either directly or indirectly as CMC functional area representative
- Working with Quality Assurance, develop SOPs and guidelines related to the production, planning, disposition and management of CMP materials.
- Work with Regulatory, QA and Senior Management to ensure that all company policies are adhered to and all external manufacturing activities comply with relevant regulations
- Maintain knowledge of current best practices of biological manufacturing. Identify emerging trends and technologies and lead implementation/feasibility assessment, as appropriate
- Design and execute the development plan to support global submissions
- Prepare CMC regulatory filing sections (domestic and international) working with Regulatory and Quality
- Review and approve master and executed batch records from all manufacturing activities; analytical release testing, stability studies and investigations, as required
- Develop production plans to support preclinical, clinical, and commercial development and adjust plans as appropriate to meet corporate objectives
- Provides comprehensive project analysis to senior management as required in the form of reports or presentations as needed

PREFERRED BACKGROUND

- Minimum of 10 -15 years of biologic technical product/process development and/or commercial manufacturing experience in the pharmaceutical industry
- Leadership and managerial experience with a team of CMC development scientists and/or engineers (process chemists, analytical chemists, formulation scientists, technical operations), leading cross-functional projects, planning and delivering results within project deadlines. Participation in portfolio decision-making.
- Demonstrated ability to manage Contract Manufacturing Organizations (CMOs) spanning all phases of development including contract negotiation.
- Demonstrated expertise in manufacturing process characterization and validation, including taking a product through to commercial launch and life-cycle management. Experience with implementation of post-approval changes is preferred.
- Demonstrated understanding of US, EU, and ICH regulations and requirements.
- Demonstrated ability to build an efficient team and establishing effective relationships across global internal and external organizations, preferably with experience in a matrix environment. Experience working successfully with an external business partner (US, EU) is highly desirable.

EDUCATIONAL EXPERIENCE

- PhD in a relevant discipline
- A minimum of 10 years of experience in CMC project management, development, scale-up and clinical/commercial development and manufacturing in the biotechnology industry
- Experience in leading and direct management of research, process development, and manufacturing
- Extensive experience in leading biological process and analytical development
- Experience in achieving regulatory approval of new biologics

LOCATION: Menlo Park, CA

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.