Job Title: Vice President, Head of Regulatory Affairs

Job Summary

Forty Seven Inc. is a privately held, clinical-stage biotech company that is developing the next generation of transformational immuno-oncology treatments. The Head of Regulatory Affairs will support this mission by overseeing all regulatory activities as well as developing and leading regulatory strategies for drug development and product registration within a growing organization. This individual will lead the company's Regulatory Affairs group and will report directly to the Chief Executive Officer.

In this role, the candidate will draw on extensive experience and strong leadership and organizational skills to develop and implement the global regulatory strategy for all company assets. This individual must possess outstanding communication skills as a contributor to the company's senior strategic leadership. She/he must work productively with cross-functional product teams, CROs, and ultimately health authorities to develop regulatory strategies that support the long-term development and registration of products. The successful candidate will take utmost care to nurture a strong Regulatory Affairs group within Forty Seven, Inc. This individual will mentor staff to ensure regulatory submissions meet US and global requirements (e.g., IN, CTA, health authority interactions) and company policies, and are delivered within agreed upon timelines. The ideal candidate should possess strong leadership skills, be self-motivated, and enjoy working in a dynamic, focused biotechnology environment.

Position Responsibilities

- Provide regulatory strategic leadership for all drug development projects, including but not limited, to health authority submissions, interactions and other regulatory requirements in line with corporate objectives and timelines
- Provide de-risking development strategies and evaluating opportunities to accelerate development
- Provide leadership, and when necessary, contribute hands on support to the regulatory team in managing, planning, coordinating, and preparing all documents submitted to FDA and ex-US health authorities in support of INDs, BLAs, MAAs, DMFs, CTAs, amendments, safety reports, and annual updates
- Develop budgets and resource forecasts for the Regulatory Team
- Lead, grow and mentor the regulatory team, with a focus on career development
- Lead all interactions with regulatory agencies
- Identify appropriate vendors and manage vendor relationships supporting regulatory activities
- Interpret and communicate regulatory expectations to internal and external stakeholders (including partners, CROs, CMOs, consultants, and contractors) in order to execute program objectives in compliance with applicable regulations

- Contributes to the strategic leadership and development of policies, procedures and best practices commensurate with the requirements of a rapidly growing company
- Lead and organize internal regulatory team meetings and corresponding actions

Education/Experience/Skills

- Minimum of ten years of experience in regulatory affairs within the biopharmaceutical industry
- Prior experience and success with filing BLAs/MAAs
- Experience with preparing regulatory documents including new INDs, safety reports, Investigator Brochures, DSURs, briefing packages and other regulatory submissions required
- Comfortable with setting strategies as well as taking a hands-on approach to all regulatory activities. Proven ability to de-risk clinical strategies in support of product development and registration
- Experience with both early and late stage oncology drug development
- Experience interacting directly with the FDA and other health authorities
- Knowledge of FDA regulations and EU CTA requirements required
- Strong leadership and communication skills and experience in working with multiple functional areas in a matrixed team environment required
- Possess outstanding mentorship skills and promote the career development of members of the regulatory group
- Experience with oncology or immuno-oncology biologics drug development is highly desirable
- Familiar with eCTD, e-publishing systems for preparing regulatory submissions a plus
- Self-motivated with experience in a fast-paced environment
- Advanced masters level or doctoral degree in a relevant scientific discipline preferred

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.