Forty Seven, Inc. discovers, develops, manufactures and commercializes immuno-oncology therapies to help patients defeat their cancer.

**TITLE: SENIOR MANAGER, REGULATORY AFFAIRS**

**POSITION SUMMARY**

In this role, the incumbent will draw on past experience and strong organizational skills to coordinate and lead regulatory submissions based on US and global requirements (e.g., IND, CTA, health authority interactions). This individual will apply strong communication skills to work productively with cross-functional product teams, CROs, and health authorities. The successful candidate will not only manage the compilation of regulatory documents included in submissions, but also work closely with colleagues to develop strategies that support the long term regulatory strategy guiding products in development (e.g., pediatric strategies and optimal clinical development pathways). The candidate will ensure regulatory activities are in compliance with regulations, health authority guidelines, and corporate policies/procedures, all within agreed upon timelines. The ideal candidate should be self-motivated, enjoy working in a fast-paced environment and take leadership of delegated activities.

**TASKS AND RESPONSIBILITIES**

- Represents regulatory function for specific drug development project teams with responsibility for developing or contributing to regulatory strategies, submissions, and requirements in line with corporate objectives and timelines
- Leads the planning, coordination, and preparation of documents that are submitted to FDA and ex-US health authorities, in support of INDs, NDAs, DMFs, CTAs, amendments, safety reports, and annual updates
- Responsible for interactions and contact with regulatory agencies and supports formal meetings
- Collaborates with Drug Safety and CROs, to ensure timely submission of safety reports to regulatory health authorities
- Interprets and communicates 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 development and review of Regulatory SOPs, procedures, and company best practices to support a rapidly growing company
- Supports internal regulatory team meetings and corresponding actions
- Maintains adherence to corporate policies and regulatory requirements

**PREFERRED BACKGROUND**

- Minimum of five years of experience in a regulatory affairs function within the biopharmaceutical industry.
- Experience with biologics drug development is preferred. Oncology/immune-oncology experience highly desirable.
- Knowledge of FDA regulations required; EU CTA requirements desirable.
- Demonstrated experience with preparing new INDs, and deliverables for health authority interactions.
- Familiar with eCTD, e-publishing systems for preparing regulatory submissions is desirable;
- Strong communication skills and ease with working on cross-functional teams.
- Self-motivated with experience in a fast-paced environment.
- Bachelor's a life science or relevant discipline. Advanced degree 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.*