

Forty Seven, Inc. is a privately held, clinical-stage biotechnology company that is developing the next generation of transformational immune-oncology treatment. Forty Seven, Inc. is passionate to help patients defeat their cancer and are committed to the advancement of immuno-oncology through the engagement of new and complementary phagocytic pathways that enhance anti-tumor efficacy and selectivity.

## **TITLE: DIRECTOR, PHARMACOVIGILANCE**

### **POSITION SUMMARY**

This position will be responsible for the oversight and direction of drug safety and pharmacovigilance activities at Forty Seven including products under development and eventual marketed products. The scope of the position includes safety assessments and surveillance, compliant and timely regulatory authority reporting, risk identification and mitigation management, and communication of safety information. The individual will serve as the lead safety expert and ensure effective collaboration across various company departments, formulate and execute the safety strategy across all drug development phases and oversee the pharmacovigilance department at Forty Seven. This position will report to the Vice President of Clinical Development.

### **TASKS AND RESPONSIBILITIES**

- Oversee and contribute to the daily activities of the Forty Seven pharmacovigilance department including operations and personnel
- Responsible for oversight of global drug safety processes and drug safety deliverables
- Ensure timely and complete safety reporting for regulatory agencies
- Leads the periodic review of safety data and the development of signal management, safety surveillance and risk management plans for drug development programs throughout all life cycle activities
- Leads and coordinates the preparation of aggregate safety reports (e.g. DSURs, IND annual reports)
- Provides leadership and assists in the preparation of expedited and aggregated safety reports (e.g. 7/15-day Alert Reports, AOSEs)
- Leads the preparation and review of safety section(s) of IBs, protocols, informed consent forms, statistical analysis plans, clinical study reports, NDA/BLA submissions, ad hoc regulatory responses or others
- Collaborate with clinical development and regulatory affairs to develop a risk assessment plan for each development program, with continued monitoring throughout the development and life cycle activities for Forty Seven assets
- Perform signal detection and evaluation activities and prepare reports for emergent signal assessments

- Collaborate with academic institutions and corporate partners in order to ensure proper exchange of safety data
- Oversee and manage all CRO relationships and functions pertaining to pharmacovigilance activities in clinical trials
- Develop and maintain a pharmacovigilance regulatory inspection readiness plan

#### **PREFERRED BACKGROUND**

- M.D.,D.O., Pharm.D., M.S.N., or R.N. degree with over 8 years of pharmaceutical drug safety and pharmacovigilance experience and a minimum 2 years in leadership positions
- Pharmacovigilance experience in hematology and/or oncology
- Thorough understanding of all pharmacovigilance processes including serious adverse event collection and case processing
- Thorough understanding of the cross functional drug development processes (clinical development, operations, data management, biostats, and regulatory affairs) and context applicable to safety surveillance activities
- Strong experience working with and managing CRO/vendors
- Strong working knowledge of FDA and EMA regulations/ICH guidelines
- Experience in authoring periodic safety reports and regulatory documents (DSUR, PSUR, PADER, PBRER, IB, CSR, IND packages/annual reports, NDA/BLA, others)
- Willingness to be hands-on
- Ability to manage multiple tasks and prioritization skills, work in a collaborative matrixed team environment
- Ability to critically analyze scientific and clinical data and literature
- Excellent interpersonal and communication skills (written and verbal)
- Passionate about oncology drug development and working in an innovative therapeutic field

**LOCATION:** Menlo Park, CA

To apply, send resume to [careers@fortyseveninc.com](mailto: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.*