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

TITLE: DIRECTOR, GMP QUALITY ASSURANCE

POSITION SUMMARY

Forty Seven, Inc. is a clinical-stage biotech company that is pioneering breakthrough solutions to advance the next generation of immuno-oncology treatments. The Director of GMP Quality Assurance will be an integral part of this mission, by providing strong leadership and strategic direction for our Quality organization as well as building and maintaining the Quality culture within the company.

In this role, the incumbent will draw on experience to build, manage, and maintain the company's QA department to ensure regulatory compliance of all internal GMP functions and external GMP service providers (e.g., CMOs). This individual will be responsible for ensuring the Quality of our clinical and commercial product produced by our manufacturing partners, applying phase-appropriate quality assurance for products in different stages of development.

The incumbent will have demonstrated strong technical knowledge and cGMP compliance, with respect to biologics development and commercialization. This individual must have demonstrated capabilities in execution of risk-based and compliant quality assurance, compliance programs and systems in support of the company infrastructure and external collaborations. The individual must have the ability to build a scalable Quality System, lead a Quality team, and prior experience leading internal/external audits. The individual will participate in cross functional project teams as a senior Quality representative and manage a team of consultants and contractors supporting Quality objectives.

TASKS AND RESPONSBILITIES

Build a Quality function, with requisite budget and resources to support company's product development, with a goal of product commercialization.

- Develop and maintain compliant quality system that adheres to US/EU regulatory expectations both internally and with respect to oversight of the company's suppliers.
- Responsible for ensuring that all investigational and potential commercial drug substances and drug products are manufactured in accordance with applicable regulations to support compliance with cGMPs and enable successful health authority filings and interactions.
- Responsible for timely review and release/disposition of drug substance/drug product/clinical trial lots to support company development goals.
- Lead the development of qualification and performance tracking measures, and oversee reviews of contract manufacturers and laboratories.
- Direct internal and external audits. Oversee GCP compliance with respect to clinical site and CRO audits
- Approve and issue specifications, and methods for drug substances and products
- Review and approve analytical/stability protocol, data and reports, maintain stability data base
- Review and approve IQ/OQ/PQ and validation protocols, tech transfers and reports, as applicable, for all manufacturing, testing, and packaging activities at all CMO's
- Serve as the QA representative on project teams. Work with CMC, non-clinical, clinical, regulatory, to ensure the appropriate document/data integrity for regulatory submission and PAI preparation.
- Support qualification/validation of GxP-related computer based systems; support process validation studies and tech transfer as needed
- Provide recommendations for corrective and preventative action to the functional area groups/teams
- Develop and maintain Quality documentation files, databases, and logs

PREFERRED BACKGROUND

- Minimum of 10 years' relevant experience within the biotech or pharmaceutical industry and minimum of 3 years of management experience.
- Candidate must have a proven track record working in a GMP compliant environment. Demonstrated ability to lead GMP operations. Applicant should also have experience in leading company activities to support internal audits and regulatory agency inspections.
- Experience with biologics drug development required. Oncology experience a plus.
- Understanding of phase appropriate QA requirements as relates to drug development is key.
- Experience with review of CMC sections in IND and CTD submissions
- Strong written/verbal communication skills and experience as part of a dynamic, fast-paced organization. Demonstrated ability to take initiative and to think strategically.
- Bachelor's degree in 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.