Associate Director, Clinical Quality Assurance
Job Code 564YL

Description

Fate Therapeutics is seeking a motivated and talented Associate Director, Clinical Quality Assurance, to support Fate's Good Clinical Practice (GCP) and Good Pharmacovigilance Practice (GPvP) quality programs at Fate. The successful candidate will lead the execution of the compliance programs for Fate clinical studies, lead and perform routine and/or directed audits, and is a strong advisor/partner for Fate personnel on regulations, guidelines and best practices. This position requires an independent, proactive leader with a strong depth of understanding of the FDA and international regulations and guidance documents, and how they can be applied in a risk-based and appropriate fashion for a smaller company setting. Inspection management/readiness, 21 CFR Part 11 compliance, and training experience a plus. The ideal candidate must thrive in a fast-paced team environment and must have excellent attention to detail, communication, organizational abilities, and independent problem-solving skills. Candidates must have experience working in a GCP environment and have hands-on experience in electronic Quality Systems. This is a full-time position reporting to the Director, Quality Assurance, and is located at our corporate headquarters in San Diego, California.

Responsibilities:

- Leads the implementation and execution of GCP and GPvP compliance programs for the Fate clinical programs.
- Independently plans, leads, conducts, and concisely reports results of audits of clinical investigator sites, service providers and internal processes to ensure compliance with GCP guidelines, applicable regulations, company policies and procedures, and SOPs.
- Leads or participates in Systems Audits including development of audit plans and tools, managing audit conduct, and reporting the results.
- Works closely with the clinical operations teams to provide expert clinical compliance information, manage and identify issues, and support continuous improvement.
- Periodically assesses the adequacy of CQA Standard Operating Procedures, with the ability and experience to improve and develop key processes when tasked; Proactively able to identify gaps or deficiencies in processes and facilitate the remediation.
- Creates SOPs, training and internal audit programs for GCP.
- Works collaboratively with both internal and external clients, especially within the cross-functional clinical team environment, as an advisor to help guide GCP and GVP compliance.
- Leads or participates in Systems Audits including development of audit plans and tools, managing audit conduct, and reporting the results.
- Obtains audit responses from company functional areas or vendors and evaluates proposed CAPAs for adequacy if implemented successfully in accordance with company SOPs.
- Provides interpretation and guidance for internal and external customers on GCP related regulations / guidelines (FDA, ICH, EU, etc.) and company procedures and policies.
- Leads and models the quality issue management system at Fate; Assesses quality issues, works collaboratively to identify root cause, and determines/advises appropriate remediation strategies through the use of CAPAs.

- Promotes positive work environment by communicating with teammates clearly and collaboratively, provides support to other colleagues, and works in a fashion consistent with Fate values.
- Supports any regulatory inspections, should they occur and assists in audit readiness preparations.
- Supports other GxP functions as required.
- Contributes quality compliance data for metrical analysis.
- Supports the development and refinement of the Quality Systems by leading or participating in SOP authorship or review teams.
- Contribute to the development of continuous quality process improvements.

Qualifications

- Bachelor's degree and 7+ years experience in positions of increasing responsibility in clinical (GCP) quality assurance.
- 3-4 years of Good Pharmacovigilance Practice (GPvP) experience, with the ability and direct experience to help grow/develop a pharmacovigilance program.
- Significant experience leading external investigator site audits, vendor audits, clinical computerized systems audits, as well as internal process audits.
- Strong understanding and knowledge of US FDA regulations and guidance documents associated with GCP and GPvP, as well as the ICH E6 guidelines. Significant experience turning these regulations into real-world applications for a smaller company.
- Direct experience in the preparation and facilitation of regulatory inspections.
- Self-starter and leader who can anticipate issues and bottlenecks and resolve issues effectively with minimal oversight.
- Ability to communicate effectively with people in diverse and different settings.
- Strong verbal and written communication skills and ability to work with others and influence in a positive and collaborative manner.
- Ability to work independently, well organized, detail oriented, able to prioritize and complete activities in a timely manner, and manage multiple projects at one time.
- Self-motivated and willing to accept temporary responsibilities outside of initial job description.
- Good organizational, project management skills and ability to perform varied tasks in a functionally independent and consistent manner
- Strong technical writing skills.
- Able to independently develop and provide compliance related training programs, as tasked.
- 21 CFR Part 11 compliance auditing experience, and/or application to company processes, a plus, and data integrity knowledge and experience

Working Conditions and Physical Requirements

- Travel may be required (up to 25%)
- May require occasional evening and weekend work
- Subject to extended periods of sitting and standing, vision to monitor and moderate noise levels. Work is typically performed in an office environment, however there is consideration for a potentially mixed virtual/office situation. Car and plane travel may be a requirement of the role (see above).

The preceding job description indicates the general nature and level of work performed by employees within this classification. Additional and incidental duties related to the primary duties may be required from time to time.

For consideration send cover letter and resume to careers@fatetherapeutics.com and reference job code 564YL.

About Fate Therapeutics, Inc.

Fate Therapeutics is a clinical-stage biopharmaceutical company dedicated to the development of first-in-class cellular immunotherapies for patients with cancer. The Company has established a leadership position in the clinical development and manufacture of universal, off-the-shelf cell products using its proprietary induced pluripotent stem cell (iPSC) product platform. The Company's immuno-oncology pipeline includes off-the-shelf, iPSC-derived natural killer (NK) cell and T-cell product candidates, which are designed to synergize with well-established cancer therapies, including immune checkpoint inhibitors and monoclonal antibodies, and to target tumor-associated antigens using chimeric antigen receptors (CARs). Fate Therapeutics is headquartered in San Diego, CA. For more information, please visit www.fatetherapeutics.com.