Manager, Clinical Drug Supply
Job Code 315AM

Description

Fate is currently seeking a motivated Supply Manager to join our Technical Operations team. The successful candidate will be responsible for Investigational Product (IP) supply operations for multiple clinical trials and for managing the IP distribution process. The successful candidate will have excellent organizational and communication skills, a keen attention to detail and thrive in a team environment. This is a full-time position reporting to the Sr. Director of Manufacturing and QC and is located at our corporate headquarters in San Diego, California.

Responsibilities:

- Manages IP supply planning and timelines to ensure alignment with overall clinical development plan. Provides input to the development of IP-related study documents including protocols, study and pharmacy manuals as needed.
- Coordinates courier shipments and deliveries and manages the courier relationship. Oversees international shipments requiring customs paperwork for worldwide shipment of IP and clinical trial materials. Coordinates with international Qualified Person for release of IP for use.
- Responsible for working within established timelines of IP manufacturing, labeling, release, distribution and return/destruction, and/or helping to establish these timelines.
- Manages and tracks IP inventory; advises management team of potential shortages and makes recommendations for resupply activities based on usage trends and forecasting.
- Oversees IP shipment orders according to supply plans, or as requested by Clinical Trial Management team, to ensure timely and compliant shipment and delivery to investigator sites. Works with manufacturing to complete this activity and manages all aspects of the process.
- Works with cross-functional teams to develop specifications and user testing of Interactive Response Technologies (IRT) systems provided by 3rd party vendors. Leads effort for clinical supply management functionality; Monitors and manage clinical supply activities through IRT from study start-up through study closure; Ensures appropriate system documentation is transferred to TMF and inspection readiness as needed.
- Reviews drug return and destruction and administration records.
- Lead trouble shooting effort for investigational product shipment issues.
- Develop plans for supplying clinical study sites with ancillary supplies, either through in-house initiated supply or working with supply vendors as needed.

Qualifications

- B.S. / B.A. degree.
- Minimum 5 years related experience in a clinical stage biotech or pharmaceutical company with a minimum of 3 years of experience in clinical supply management.
- Extensive knowledge and experience developing and managing Interactive Response Technologies (IRT) such as IXRS.

- Knowledge of ICH/GCP and regulatory guidelines/directives. Disease/therapeutic area knowledge a plus.
- Effective problem-solving skills; Written and verbal communication and presentation skills in small and large group settings; Project management and organizational skills.
- Computer skills, with competency in MS Word and Excel.
- Study Tools including electronic system skills IVRS/IWRS, CTMS, EDC.
- Must work well in a team environment with admirable interpersonal and communication skills (written and verbal).

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.

For consideration send cover letter and resume to: careers@fatetherapeutics.com and reference job 315AM.

About Fate Therapeutics, Inc.

Fate Therapeutics is a clinical-stage biopharmaceutical company dedicated to the development of first-in-class cellular immunotherapies for cancer and immune disorders. 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 product candidates include natural killer (NK) cell and T-cell cancer immunotherapies, which are designed to synergize with well-established cancer therapies, including immune checkpoint inhibitors and monoclonal antibodies, and to target tumor-associated antigens with chimeric antigen receptors (CARs). The Company's immuno-regulatory product candidates include ProTmune™, a pharmacologically modulated, donor cell graft that is currently being evaluated in a Phase 2 clinical trial for the prevention of graft-versus-host disease, and a myeloid-derived suppressor cell immunotherapy for promoting immune tolerance in patients with immune disorders. Fate Therapeutics is headquartered in San Diego, CA. For more information, please visit www.fatetherapeutics.com.