Manager, Clinical Supplies

Remote

Summary

Reporting to the Senior Director, Clinical Supplies, the Manager, Clinical Supplies will be responsible for the adequate and timely provision of Investigational Medicinal Product (IMP) to our clinical sites; spanning all aspects of the supply chain from secondary packaging and labeling through to returns and destruction. In addition to study drug supply, the role shall oversee non-CRO vendors that may be contracted for specialized central study services and supplies (labs, ECG, imaging etc.).

Responsibilities

- Ensure clinical trial protocol elements of clinical supplies are operationalized effectively and meet delivery requirements, with consistency of processes and documentation across multiple studies
- Manage clinical supplies distribution and receipt of Investigational Medicinal Product (IMP) to all clinical sites, including coordination with internal and external stakeholders as necessary, and including raising appropriate import and export documentation as required for global clinical trials.
- Support drug supply delivery timelines throughout the duration of a clinical trial with finished product packaging and labeling of IMP, coordinating with QA, Technical operations and Regulatory Affairs as required.
- Monitor clinical supply inventory using both manual and automated tools (IVRS/IRT) and adjusting IMP distribution plan accordingly. Monitor expiry dating of IMP.
- Oversee vendors from start-up to close-out including vendor selection, budget negotiation process and contracting, and ensure study budgets are managed to plan and scope
- Manage the provision of all clinical supplies including finished product packaging and labeling, distribution, drug returns and accountability, and coordinate with internal and external stakeholders as necessary
- Work collaboratively with other departments for the creation and approval of product labeling
- Participate in design and implementation of interactive response technology (IRT) systems
- Ensure pharmacy manuals, laboratory manuals, lab specification documents, requisition forms and any other associated documentation are developed with quality and within pre-specified timelines
- Selection and management of vendors for the supply of centralized services such as clinical trial supply companies, specialty labs, central ECG or imaging or other suppliers
- Coordinate the provision of lab kits to sites and tracking of samples back to labs, delivery of test results and sample storage/destruction as required by protocol
- Work closely with Clinical Project Managers and other internal stakeholders to ensure timely and adequate supply to all clinical trial sites
- Tracking and management of shipment temperature data for IMP and of laboratory samples through entire chain of custody
- Contribute to and/or conduct investigator training sessions as required
- Development of SOPs and evaluation of tools to support outsourcing oversight and study processes
- Other related duties as assigned
Qualifications and Requirements

- Bachelor’s degree in a relevant field and at least five years Clinical Operations experience including experience with supply chain management
- Previous experience within a pharmaceutical/clinical laboratory facility coordinating sample logistics would be an asset
- Demonstrated ability to effectively negotiate contracts and financial terms
- Knowledge of global regulatory requirements for the shipping of IMP and human samples
- Strong understanding of CFR and ICH guidelines, regulations and guidelines governing conduct of clinical studies
- Well organized with strong technical skills, solid written and verbal communication skills, computer skills, and proven ability to multitask
- Excellent leadership and interpersonal skills with an ability to effectively work within a multidisciplinary team and to effectively manage multiple vendors
- Self-starter who works with a sense of urgency and acts as a good team player working with other disciplines
- Adaptability, flexibility, independence and resourcefulness to roll-up-sleeves and multi-task in order to thrive in small company environment

How to Apply

To apply for this role, please submit your CV and cover letter in PDF format to hr@sierraoncology.com. Please indicate the position title in the subject line of your email. We thank you in advance for your interest in Sierra. We will contact you directly should we wish to arrange a meeting to discuss this position further.