Clinical Supply Manager

Position Code: 23045-18B

Summary Description

The Clinical Supply Manager will be responsible for ensuring the clinical supplies needed for assigned Gossamer clinical studies are provided on time and in accordance with protocol and applicable regulatory requirements. This includes management and oversight of the planning, forecasting, sourcing, packaging, labeling, distribution and return of clinical supplies. The successful applicant will collaborate closely as a member of cross-functional study teams that include Project Management, Clinical Operations, and RA/QA.

Key Responsibilities

- Develop study specific Investigational Product Supply Plans and contribute to Pharmacy Manuals and supply related training/instructional materials
- Identify supply accountability tracking and ensure Master, Pharmacy, Subject Logs are appropriate
- Ensure appropriate documentation of IP supply activities is provided to the Trial Master File
- Manage supply planning/forecasting to ensure alignment with study activity and timelines
- Monitor inventory levels at sites through the life of a trial proactively avoiding potential issues
- Coordinate procurement, temperature excursions, product complaints and ensure expiry extensions are provided to depot/sites as needed to support continued use
- Collaborate with study team and vendors to assure proper distribution of supplies to study sites
- Manage return and destruction of clinical supplies, with proper documentation of all steps
- Serve as primary point of contact for third party packaging, distribution, and storage vendors
- Manage approval of the packaging and logistics service agreements and study specific plans
- Design/review/coordinate approval of investigational supply label text and proofs to meet specific country language(s), translations and regulatory requirements
- Liaise with appropriate parties to ensure adequate clinical study supply releases are obtained per applicable regulations (Qualified Person Release, Certificates of Analysis/Compliance, etc.)
- Work with cross-functional team to develop study-specific IXRS specifications and requirements documents providing IP management perspective
- Perform unblinded monitoring of IXRS inventory and functionality monitoring to assure resupply generation, etc. occur within defined specifications

Experience & Education

- Bachelor's Degree in health or life sciences or equivalent with 5-7+ years' experience in the pharmaceutical/ biotechnology industry and 3 years of international clinical supply experience
- Thorough knowledge of Good Manufacturing Practices (GMP), Good Clinical Practices (GCP), International Conference on Harmonization (ICH) Guidelines and other applicable global pharmaceutical regulations/guidelines/directives
- Experience with Interactive Voice/Web Response System (IXRS) design, implementation, user testing and monitoring
- Proficiency in Microsoft applications, collaborative platforms (e.g., SharePoint, eRooms, Drop Box, Skype for Business), Electronic Data Capture systems, and Inventory Management systems
- Ability to establish and meet multiple concurrent priorities and deadlines
- Willingness and ability to travel domestically and internationally as needed
- Effective organizational skills, verbal and written communication, ability to present in group settings, commitment to quality, and the ability to think critically and creatively