Immutep is hiring:

Clinical Trial Supply Manager (m/f/d)

Company:

We are Immutep, an emerging international biotechnology company developing immunotherapeutic products for cancer and autoimmune diseases. With operations based in Australia, USA, Germany and France; Immutep is dedicated to bringing innovative treatment options to market for patients. The company is publicly traded on the ASX and NASDAQ.

Location:

- Berlin, Germany; office based, 75-100 % negotiable, or
- remote with 10 % presence in the Berlin office

Summary:

Our lead candidate, the LAG-3 based recombinant protein eftilagimod alfa, is currently undergoing pivotal clinical trials in cancer on a global scale. You will work closely with the Senior Director of Manufacturing to define and execute an optimal clinical trial supply strategy for Immutep's clinical study pipeline, ensuring supply continuity to patients. Your responsibilities include establishing and managing the depot network and distribution to clinical sites, determining label and kit design, forecasting the demand for the investigational product and ancillary supplies, ensuring on-time supply of study medication and ancillary materials to clinical sites, and overseeing the final return and destruction process.

Job description:

- Generates study specific Request for Proposals (RFP) based on study assumptions, decision-making to final vendor selection as well as contract negotiation (Master Service Agreements, Work Orders and Change Orders).
- Establishes and monitors global network of regional and global depots to distribute investigational product, comparators and ancillary supplies to countries and study sites in assigned clinical trials.
- Coordinates timely and compliant importation and supply of investigational product, comparators and ancillary supplies into regional and global depots.
- Manages the inventory levels and product expiry.
- Develops and maintains complete and accurate clinical supply demand forecast for the assigned study in alignment with protocol requirements, key study parameters, and patient projections, with appropriate overage.
- Determines labelling and clinical kit design and a comprehensive label strategy for all participating countries in the clinical trial.
- Identifies, assesses and proactively communicates supply risks to all relevant stakeholders along with appropriate mitigation strategies to ensure supply continuity.
- Generates optimal distribution plans for investigational products, jointly with partner or vendor.
- Triggers and tracks shipments of IMPs from central depot to regional hubs and local depots.
- Develops, maintains and executes an optimal resupply strategy with proactive planning, appropriate lead-time and replenishment quantities to ensure compliance and continuity of clinical supplies, including proactive expiry management of clinical supplies.

- Manages and provides support in establishing of IWRS or IRT system of blinded and open label trials.
- Creates and updates budgets for studies including packaging and labeling costs, storage and distribution costs, and comparator and ancillary material costs for assigned clinical studies.
- Strives for cost optimization and manages KPIs for the assigned procurement categories.
- Closes collaboration with the Manufacturing team as well as Clinical Operations, Quality Assurance and enabling functions such as Legal and Finance.
- Participates in management reviews of process performance, product quality and the quality management system.
- Provides requested input on forecast of annual budgets.
- Provides requested input to Product Development Plans and Portfolio Review.
- Represents the Company at external conferences and meetings.

Skills/Experiences/Qualifications:

Essential:

- Post graduate degree in natural / life sciences / engineering background.
- At least 5 years of practical experience in pharmaceutical industry or >3 years' experience in supply chain management.
- Experience in clinical trial supplies leading global studies preferably with biologics.
- Strong project management skills paired with good communication skills in cross functional project teams.
- English Language skills.
- Good working knowledge of using Microsoft office programs.

Desirable

- Experience in vendor selection/management.
- Profound knowledge in pharmaceutical procurement, specifically Clinical Trial Supply Services such as CMOs and CROs.
- Good negotiation skills.
- Strong understanding on the Drug Development process.
- Previous experience in supervising, mentoring or training colleagues and setting objectives is an advantage.
- Knowledge of relevant regulations and guidelines (GMP, GDP, GCP).

Job expectations:

- Multifunctional interesting tasks in the emerging field of immune therapeutics.
- Be part of the development of a "first in class" drug.
- Highly motivated and energetic international team.
- Competitive compensation.

Expected start date:

- 1st Jan 2025

If you are interested in this challenging career opportunity, please send your CV, certificate of employment, salary expectations, application letter and your earliest possible entry date to the following e-mail address (confidentiality is of course guaranteed):

hr-germany@immutep.com

Privacy Statement for Applicants