CLINICAL TRIAL SUPPLY MANAGER – IRT SME

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Erkenningsnummer
VG. 1690/BO B-AB10.018.

The company is a clinical-stage biopharmaceutical company that is creating and developing a pipeline of differentiated antibody therapeutics. Their unique SIMPLE Antibody™ platform and suite of Fc engineering technologies combined with the complementary expertise of our people enabled us to build a clinical-stage portfolio of novel product candidates – tailored from discovery through development to address patient needs.

To further strengthen the Clinical Trial Supply (CTS) team we are looking for a talented **Clinical Trial Supply Manager** (CTSM) with **extensive IRT** experience. The CTSM represents product supply in the Clinical Study Teams and drives the development and execution of effective product supply strategies in close collaboration with various key stakeholders. Next to that the CTSM will be main point of contact for IRT related topics. This role provides an opportunity to design and implement effective processes within a fast-growing organization and reports to the Global Supply Chain Lead/IRT Lead.

KEY ACCOUNTABILITIES AND RESPONSIBILITIES:

IRT

- Together with IRT lead, serve as main link for IRT between the Clinical Trial Supply team, Clinical development, Data Management, Biostat and the IRT vendor
- Translation of study protocols into IRT user requirement specifications (URS)
- Drive and improve the IRT processes including: set-up and standardization of URS, User acceptance testing (UAT), system enhancements,...
- IRT vendors relationship management, and support with vendor selection and capacity management
- Act as escalation point for IRT related activities, e.g. issue resolution with IRT vendor

CTSM General

- Drives the development of tailored clinical trial supply strategies aligned with the relevant clinical trial protocol and in compliance with GxP requirements, local regulations and the company's processes;
- Creates and maintains complete and accurate clinical supply plan ('CTS Agreement') for clinical studies in alignment with protocol requirements, key study parameters and milestones, patient projections;
- Ensures availability of IMP for our patients in collaboration with our external stakeholders;
- Responsible for management of external clinical trial supply vendors and distributors:
    - Plan and coordinate the execution and release of IMP packaging runs
    - Support label and packaging design and blinding strategy development as necessary
    - Review distribution plan and monitor adherence
    - Create and maintain updated IMP demand planning;
- Manage potential unexpected challenges occurring related to supply chain activities (Temperature excursion, damaged material, unblinded situations, etc...);
- Represents CTS (Clinical Trial Supply) in the Clinical Study Team;

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- Drives the processes necessary for IRT set-up, conduct and close-out from a clinical trial supplies perspective;
- Develops and executes detailed clinical trial supply project plans in close collaboration with stakeholders;
- Drives the development of a study specific pharmacy manual and other relevant guides in close collaboration with Clinical Study Team and CMC team;
- Actively track drug inventory and visualizes active drug consumption versus projected forecast;
- Contributes to planning and organization of global product manufacturing activities;
- Responsible for collecting, registering and archiving information and documents in accordance with the applicable GxP guidelines for clinical studies (TMF, eTMF);
- Contributes as needed to CTS process development (label development, IRT, SOPs, ..);
- Responsible to consolidate, maintain and track the clinical trial budget.

DESIRED SKILLS AND EXPERIENCES

- Master's degree in a scientific discipline or equivalent through education and experience;
- Minimum 4 years' experience in field of clinical trial supplies;
- Extensive knowledge on IRT
- Knowledge of GxP regulatory requirements; Quality conscience attitude
- Excellent organization and planning skills;
- Strong communication skills and able to build relationship with internal and external stakeholders – team player with an analytical mindset and delivery-oriented focus;
- Flexible attitude in combination with a proactive mindset; Can do mentality;
- Working knowledge with MS Office package;
- Fluent in English – our working language.