NOVARTIS

Clinical Trial Supply Manager

Job ID
REQ-10018499
Sep 03, 2024
India

About the Role

Major accountabilities:

- Represents GCS as a core member in the integrated Clinical Trial Team (iCTT); defines and advises the iCTT on the optimal clinical trial supply strategy in terms of, but not limited to, packaging design, technical and timeline feasibility, efficiency and risk management.
- Reviews overall clinical trial protocol/protocol amendments, provides inputs to develop optimal packaging design, clinical trial supply design and visit schedule.
- Creates and maintains complete and accurate clinical supply demand for assigned study in alignment with protocol requirements, key study parameters and milestones, patient projections, with appropriate overage and by using defined processes and systems.
- Creates and drives finalization of the packaging design (Clinical Packaging Request) and a comprehensive label strategy for all participating countries in the clinical trial.
- Defines clinical supply parameters for NIRT set up and initiates subsequent updates throughout the duration of the clinical trial
- Develops and executes a trial-level project plan together with all other relevant roles.
- Identifies, assesses and proactively communicates supply risks to all relevant stakeholders along with appropriate mitigation strategies to ensure supply continuity
- Collaborates with all relevant line function partners for country submission and approval timelines (including IND-IMPD amendment) to develop optimal supply strategy.
- Generates optimal distribution plans for investigational medicinal products (IMPs), jointly with partner functions. 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.
- Is responsible to consolidate, maintain and track the clinical trial budget with key stakeholders for overall GCS external cost (e.g. labels, packaging, distribution and comparators).
- Actively contributes to the GCS subteam as a full member. Ensures adequate, proactive exchange of relevant knowledge & information between the GCS sub team and the CTT.
- Fully supports, prepares the GCS PL to adequately address GCS-considerations at various cross-functional teams e.g. TRD sub team, ICT, etc.

Key performance indicators:

- Accountability for quality, quantity and timelines for all assigned tasks/projects
- GMP Compliance (number of deviations, technical issues, audit / inspection findings)
- Adherence to Novartis standards and Values & Behaviors, in particular, quality, ethical, health, safety,

and environment standards (HSE), and information security standards (ISEC).
- Refer to annual individual and team objective Unit KPIs. Cross-functional KPIs (if applicable)

Minimum Requirements:

· Degree in science, engineering or equivalent.

· >5 years of practical experience in chemical / pharmaceutical industry or > 3 years of experience in field of expertise

· Good expertise in related field. Good knowledge about the Drug Development process

· Basic project management , good organization and planning skills

· Knowledge of relevant regulations (e.g. GMP, HSE etc.) and Novartis specific standards.

· Demonstrates problem-solving and idea generation skills

· Good presentation skills; Fundamental Leadership skills.

· Very good communication, negotiation and interpersonal skills. Ability to work in interdisciplinary teams.

Role Requirements

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? https://www.novartis.com/about/strategy/people-and-culture

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Division
Development
Business Unit
Innovative Medicines
Location
India
Site
Hyderabad (Office)
Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular

Shift Work
No
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