NOVARTIS

Clinical Trial Supply Manager

Job ID
REQ-10087112
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Индия

Сводка

-This is a universal job description meant to capture some of the primary duties of this role that are common across functions or divisions. It is not intended to represent all of the specific responsibilities of the position. -Has operational end to end responsibility for assigned supply activities. Leads and manages projects of different complexity and local network activities and participates in cross-functional teams. -Produces, packages and manufactures drugs to be used in clinical trials. Responsible for distribution, warehousing, transportation, packaging, randomization, blinding, and labeling of material for clinical trials in conformity with guidelines of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), Good Clinical Practice (GCP), and Good Manufacturing Practice (GMP). -Has operational end to end responsibility for assigned supply activity. Leads and manages demanding projects and network activities and participates in cross-functional teams.

About the Role

Major Accountabilities

- Represents GCS as a core member in the Clinical Trial Team (CTT); defines and advises the CTT 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 IRT 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 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 sub team 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.

Minimum Requirement

- > 5 years of practical experience in clinical supplies within the pharmaceutical industry
- Strong operational excellence with high attention to detail. Advanced project management, good organization, and planning skills
- Broad technical knowledge in appropriate Supply Chain systems used for forecasting and demand planning (minimum 3 years of expertise with SAP). Data & Digital savviness with high learning agility
- Knowledge of relevant regulations (e.g., GMP, HSE etc.)
- Master’s or Doctorate in life sciences (or MBA with bachelor’s degree, or equivalent experience in life science)

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

Benefits and Rewards: Learn about all the ways we’ll help you thrive personally and professionally.
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Business Unit
Development
Место
Индия
Сайт
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

Accessibility and accommodation

Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.india@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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