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Clinical Trial Supply Manager

Job ID
REQ-10034114
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Italie

Résumé

Clinical Trial Supply Manager (CTSM) defines and executes an optimal clinical trial supply strategy for a clinical trial including effective risk management to ensure supply continuity to patients.
The CTSM is the GCS single point of contact at trial level for the integrated CTT (Clinical Trial Team). The CTSM is responsible for clinical trial supply deliverables within GCS and all other relevant associated sub-functions, maintaining Quality and Compliance through all activities.
Has operational end to end responsibility for assigned activity. Leads and manages all project and local network activities and participates in cross-functional teams.

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 and other related documents (e.g. Pharmacy manuals), 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 (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 management of expired clinical supplies.
- Is responsible to consolidate, maintain and track the clinical trial budget with key stakeholders for overall

GCS external costs (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.

Ideal Background:

Education (minimum/desirable):
Degree in science, engineering or equivalent

Languages:
Fluency in English

Experience/Professional requirement:
1. Good expertise in related field (>4 years of practical experience)
2. Good knowledge about the drug development process
3. Basic project management skills
4. Good organization and planning skills
5. Knowledge of relevant regulations (e.g. GCP, GMP, GDP, etc.)
6. Demonstrate problem-solving and idea generation skills
7. Experience using IRT systems and document management systems
8. Very good communication, negotiation and interpersonal skills
9. Ability to work in interdisciplinary and cross-cultural teams

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Job Type
Full time
Employment Type
Regular
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