

Clinical Supply Project Lead

Job ID
REQ-10011520
Giu 25, 2024
India

Sommario

About the role: The Global Clinical Supply (GCS) Clinical Supply Project Lead (CSPL) leads, represents, manages, and supports the Global Clinical Supply (GCS) project team and operates as single point of contact for clinical and technical teams across Development on clinical supply strategy. The CSPL ensures complete project oversight in GCS and retains accountability for project deliverables with operational and management responsibility for assigned activity. Leading and managing all project and local network activities and participates in cross-functional teams.

About the Role

Key responsibilities:

- Represents GCS/Technical Research and Development (TRD) to Global Clinical Team (GCT) and act as business partner to support and influence the decision-making process on the supply strategy and packaging design to be adopted in clinical trials.
- Represents GCS team in the TRD/CMC sub-team providing insights on clinical requirements and aligning clinical supply aspects with TRD/CMC sub-team.
- Aligns on early clinical study assumptions and provide early supply and financial forecast to support clinical development plan endorsement by development boards.
- Assesses clinical development plan scenarios, converts them into long term demand forecast to support long term supply and capacity planning for TRD/Novartis Operations (NO). As business partner to the clinical teams, drive GCS assessment to support unplanned clinical study requirements.
- Leads overall clinical supply strategy in alignment with clinical and technical requirements and constraints. Assess risks & opportunities and define strategies to ensure supply continuity and increase supply flexibility and responsiveness in case of new clinical study initiatives.
- Oversees the entire E2E supply strategy (from Drug Substance to clinical sites) and reviews the planning assumption adopted in the supply plans and forecasts. Drives the decision-making process in GCS to select the most effective supply set-up.
- Operates as first level of escalation and provide clear overview on issue, supply impact and mitigation plan to GCS management in case of supply risk / issue. Leads communication and manages stakeholder's expectations in case of escalation.
- Oversees and endorses strategy defined by GCS in collaboration with TRD/CMC sub-team regarding

substantial regulatory changes to ensure supply compliance.

- Leads, represents, manages and supports GCS sub-team in an indirect people management role. Assures GCS team works in agreement to the operating model, delivers results in alignment to the clinical project/study objectives and applies strategic mindset to optimize clinical supply strategy. Ensures KPI / Health Indicators are achieved and act as a role model for strong team spirit and behaviors of collaboration.
- Understands and proactively manages the interactions of project, network and/or platform related activities within and outside of GCS. Acts as ambassador for GCS in TRD and clinical environment.
- Ensures overall budget adherence of the financial resources allocated to the project in GCS. Acts as point of contact for GCS Finance department and TRD Planner, manages the budget allocated to the project and discuss variation that could require additional financial resources. Leads the cost assessment of packaging, distribution, booklet label and comparator activities in case of new clinical study initiatives.
- Provides to GCS on time info regarding portfolio changes to allow line function to perform forward looking resources planning and allocation.

Essential 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 knowledge of Drug Development processes
- Project management, good organization, and planning skills
- Knowledge of relevant regulations (e.g. Good Manufacturing Practice (GMP), Health, Safety & Environment (HSE) etc.).
- Demonstrates problem-solving and idea generation skills
- Good presentation skills and fundamental Leadership skills.
- Communication, negotiation, and interpersonal skills. Ability to work in interdisciplinary teams.

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