Clinical Supply Chain Manager (CSCM)

Job ID
REQ-10032615
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Italia

Sommario

The Clinical Supply Chain Manager partners with the Clinical Trial Supply Manager team to ensure continuous supply of Investigational Medicinal Product (IMP) for assigned clinical trials through effective monitoring and maintenance.
Has operational end-to-end responsibility for assigned supply activity. Provide team support for system set-up and smooth transactional execution between intercompany, intragroup and third party vendors.
Leads and manages demanding projects and network activities and participates in cross-functional teams.

About the Role

Major accountabilities:

- Being the Clinical Supply representative in Supply Chain meetings, drives IMP supply process ensures key project milestones are met.
- Creates and updates IMP supply plan on global project level, and ensures IMP delivery quantity/timeline.
- Assesses risks in the general set-up of the particular medication management strategy for a clinical trial. Actively contributes to the optimization of the general supply chain planning for development projects
- Reviews actual enrollment and inventory data. Updates the distribution plan based on actual recruitment/demand for ongoing studies
- Maintains overall supply plans, optimizing overage/drug usage, minimizing waste, allowing the flexibility to accommodate changing demand.
- Improve, maintain and track clinical supply orders and inventory through the IRT and processes in place; access data, reports and analyze against forecasts.
- Monitor and maintain correct system transactions related to order management processes according to defined business cases including the up-to-date status of the order at any point in time
- Prepare and ensure availability of all relevant documentations and approvals needed to guarantee steadily product flow
- Has key role at Supply Chain demand planning meetings, responsible for coordination of delivery of drug product and packaged goods according to plan.
- Contribute to define the strategy and to set-up of the clinical supply in the different countries according to the local regulation (e.g. IoR, proforma invoices)
- Oversees IMP orders according to supply plans to ensure timely and compliant shipment and delivery to investigator sites from order request through acknowledgement of receipt by the clinical site.
- Tracks shipment and release status and follows-up with distribution vendors and local hub/depot contacts.
- Point of contact with NVS GCS/CMO for comparator management: sourcing, procurement, clinical packaging and distribution

- Plans budget for associated external costs for clinical supply (AAA products, comparators and concomitant drugs) and issues related grants and purchase orders.
- Communicate and coordinate drug shipments with affiliates and vendors; review quotes, billing and invoices and follow-up as needed
- Liaise with Finance (BPA & Controller) for project cost tracking and phasing
- Aligns with CTSM on clinical supply to ensure that supply meets the changing demand on project level.
- Coordinates with CMC, in-licensing and QA partners to manage technical and quality issues to facilitate uninterrupted supplies; notify clinical teams of decisions and directions for disposal
- Actively contributes to SOP creation, revision and update.
- Keep updated on relevant cGMPs, GCPs and other regulatory requirements and ensure study management activities are aligned
- Contribute to the Quality/Technical/Supply/Service Agreements.
- Assist / author / implement SOPs.
- Perform other duties as assigned

General activities:

Ensures compliance of processes with regulations as well as Company internal procedures and GxP requirements. Actively participates in teams activities and fulfills all related tasks and responsibilities related to own discipline. Proactively communicates key issues and any critical topic in a timely manner to the appropriate management level and to/or any other relevant project team members. Interprets results, evaluate data, draw conclusions and report back to team and management. Gives guidance to team members. Provide coaching and technical training as subject matter expert or recognize technical expert. Act as mentor for junior and senior associates. Actively contributes to team goals. Monitors and reports performance measures to enable strategic objective to be met, or corrective action to be taken. Executes the activities part of the strategic plan.

Key Performance Indicators

- Accountability for quality, quantity and timelines for all assigned tasks/projects.
- Adherence to AAA/Novartis standards and Values & Behaviors, in particular, quality, ethical, health, safety, and environment standards (HSE), and information security standards (ISEC).
- Feedback from other team members/leaders.
- Refer to annual individual and team objective.
- Measurable contributions to increasing efficiency and productivity in the work related to assigned projects.

Job Dimensions

Subordinate Functions: N/A

Number of Associates: Direct: 0, Indirect: 0

Financial responsibility (where appropriate): Project cost tracking and phasing

Impact on the organisation (where appropriate):

Support own working unit and the broader departmental environment for on-time clinical trial drugs supply

Ideal Background (State the minimum and desirable education and experience level)

Education: Degree in science, engineering or equivalent

Languages: Fluency in English

Experiences:

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

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Innovative Medicines
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Job Type
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