# Clinical Label Manager

Job ID
REQ-10008015
Oct 20, 2024
India

### About the Role

Your responsibilities will include, but are not limited to:

·Is responsible for generation/coordination of labels for IMP, medication list/randomization list/randomization schedules and ensures agreed landmarks, quality and costs are met. Is accountable for label compliance with respect to study design, pack design, pack material, analytical specifications of the IMP along with country specific regulatory requirements and Novartis standards of compliance.

·If nominated leads overall governance and/or maintains Phrase Library (validated repository of country specific regulatory requirement and translations of phrases in country specific languages). If nominated be a system owner for Systems managed by CLM team and lead/co-lead system enhancement initiatives as appropriate.

·If nominated be a qualified GMP line unit checker for label(s), as defined in SOP, drive culture of quality within the team. Leads investigations if certified in case of quality events/deviations or any non-Right First Time(RFT) cases when required.

·Keeps clear alignment with all the internal (e.g. Clinical Trial Supply Managers, Supply Chain Managers etc.) and external (e.g. external label service providers for specialized labels) partners for IMP label related activities. Is responsible for communicating challenges to internal and external customers and bring solutions to mitigate any risk(s). Leads as a subject matter expert/functional guide on label process during internal/external inspections.

·Is responsible for communicating challenges to internal and external partners and bring solutions to mitigate any risks on project level. Adapts priorities in response to changing needs. Knows when to act independently or when to call out issues. Support the Business owner by coordinating the vendor management and vendor performance.

·Manages all applicable finance activities, including grants, purchase orders (PO) and invoice approval for IMP labels, as applicable. Works closely with BPO (Business Process Owner) to define processes, identify and support initiatives for process improvement and simplification, deliver key functional objective(s) along with high quality standards and operational excellence when required.

·Be a mentor for the new CLM associates if nominated. Ensures colleagues know and use the appropriate processes and procedures and are aware of the risks of non-compliance. Supports Business Process Owner (BPO) to assess risks related to CLM and have robust process in place. Actively participates in projects, networks and/or forums. Acts as a role model for Novartis values and behaviors.

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

expertise

·Good knowledge about the Drug Development and clinical supply 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..

Why Novartis?

Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we

achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: https://talentnetwork.novartis.com/network

## 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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**Benefits and Rewards:** Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

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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