# Clinical Label Manager

Job ID
REQ-10030736
Nov. 24, 2024
Indien

## Zusammenfassung

Contribute and execute labelling activities for clinical trial supplies (IMP) to ensure fulfillment of supply chain. Resulting in no stock outs /missed milestones and/or supply interruptions impacting patients due to label quality or availability. Has operational end-to-end responsibility for assigned supply activity (label related).

## About the Role

Your responsibilities include, but are not limited to:

• Is responsible for generation/coordination of labels for IMP, medication list/randomization list/randomization schedules and ensures agreed milestones, 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 Authority (RA) requirements and Novartis standards of compliance.
• Maintains Phrase Library (validated repository of country specific HA regulatory requirement and translations of phrases in country specific languages), if nominated.
• If nominated manages business administration activities of Labelling system and Randomization Re-porting Tool (RRT) and participate in system enhancement initiatives as appropriate. If required and qualified performs and documents GMP line unit checks of label(s) as defined in SOP. When required leads investigations if certified in case of quality events/deviations or any non-Right First Time (RFT) cases and notifies the Team Head or Deputy.
• 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) stakeholders for IMP label related activities. Act as subject matter expert on label process during internal/external inspections as required.
• Is responsible for communicating challenges to internal and external stakeholders and bring solutions to mitigate any risk(s). Support the Business owner by coordinating the vendor management and vendor performance when required. Manages all applicable finance activities, including grants, purchase orders (PO) and invoice approval for IMP labels, as applicable.
• Is able to describe the fundamental process and answer question regarding label process during internal/external inspections. Support SME's / SPOC / SU / BPM (Business Process Manager) to define processes, identify and support initiatives for process improvement and simplification when required.
• Actively participates in projects, networks and/or forums. Fulfill all related tasks and responsibilities related to own discipline. Be a mentor for the new CLM associates. Ensures colleagues know and use the appropriate processes and procedures and are aware of the risks of non-compliance as re-quired.
• Ensures execution according to quality, quantity, and timelines of all assigned activities. Adheres to and utilizes existing processes and procedures to achieve agreed outcomes in a consistent and disciplined way. Completely adheres to Novartis values and behaviors.

Role Requirements :

• 3 years of practical experience in chemical / pharmaceutical industry or > 2years of experience in field of expertise
• Apprenticeship or formal education in a logistical, technical, or related business area
• Basic knowledge of drug development and clinical supply process. Basic project management, good organization, and planning skills
• Good knowledge of HSE/GMP standards and processes. Problem-solving and idea generation skills
• Good presentation skills
• Fundamental Leadership skills.
• Good communication, negotiation, and interpersonal skills. Ability to work in interdisciplinary teams

**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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Functional Area
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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.

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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