NOVARTIS

Clinical Label Manager

Job ID
REQ-10030736
Nov 24, 2024
India

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

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

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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Job ID
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