NOVARTIS

Global Labeling Manager

Job ID
REQ-10083187
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Индия

Сводка

-Provides the labeling/artwork strategy, regulatory intelligence and knowledge which are required to develop, market, and maintain products. Provides strategic labeling input and support for global development projects and/or marketed products. Reviews labeling change information, and ensures that it is supported by the data and consistent with the application. Supports and assists the development and participates in negotiations on later stage products with regulatory agencies on approval of label. Monitors, evaluates and recommends improvements to labeling processes, quality, systems tools and/or policies.

About the Role

Key Responsibilities:

- Serve as labelling lead for assigned products, developing and maintaining compliant global labelling documents (e.g., CDS, BPL, BSS, IFU) and major market labels (USPI/PPI/MG, EU SmPC/PIL and other priority countries).
  • Organize and lead ELTF meetings to align content and comments, as appropriate for level.
  • Collaborate with Global Labelling Directors / Associate Directors to ensure aligned, compliant, and competitive labelling content across assigned tasks. Flex on projects from Director or AD GL.
  • Conduct detailed research across competitor labels, global regulations and study information to support content development.
  • Prepare documentation supporting CDS changes and contribute to responses to Health Authority queries.
  • Ensure timely country implementation of labelling changes and compliance with CDS requirements.
  • Mentor newcomers and support readiness for audits, inspections and continuous improvement initiatives.
  • Maintain appropriate document quality and traceability (version control, references and rationale) to support governance requirements and audit readiness.
  • Development and maintenance of IPLs.

Minimum Requirements:

- Typically, 2 to 5 years' experience in Global Labelling, Regulatory Affairs, or related pharmaceutical development functions with demonstrated labelling drafting and maintenance experience.
- Working knowledge of core labelling concepts and major market formats (for example CDS, USPI, EU SmPC and PIL) and ability to apply internal standards and regulatory requirements.
- Ability to review and interpret clinical and safety information and translate into clear, consistent labelling text with appropriate referencing.
- Strong attention to detail and documentation discipline (version control, traceability, and rationale).
- Experience organizing and facilitating cross-functional meetings (for example ELTF) and managing actions to closure.
- Strong collaboration, communication, and prioritization skills; proactive issue identification and escalation.Continuous improvement mindset; experience supporting audits and inspection readiness activity
- Science-based BS or MS with demonstrated capability; advanced degree preferred

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

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.
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Дивизион
Development
Business Unit
Development
Место
Индия
Сайт
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

Accessibility and accommodation

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.

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