Global Labeling Manager

Job ID
REQ-10011593
Jul 01, 2024
India

Summary

Our Development Team is guided by our purpose: to reimagine medicine to improve and extend people's lives. To do this, we are optimizing and strengthening our processes and ways of working. We are investing in new technologies and building specific therapeutic area and platform depth and capabilities – all to bring our medicines to patients even faster. We are seeking key talent, like you, to join us and help give people with disease and their families a brighter future to look forward to. Apply today and welcome to where we thrive together! As Global Labelling Manager (GLM) you will be responsible for the maintenance of regulatory compliant, competitive, and up-to-date high quality and timely implemented core labelling documents (incl. Core Data Sheet (CDS)) and key country labelling (incl. US and EU) for assigned Novartis Innovative Medicines products. The assigned products will include higher complexity products and may include developmental programs. The RA GLM provides strategic and operational regulatory labelling input, working in close collaboration with Expert Labelling Task Force (ELTF) members in maintaining core labelling documents, key labelling, and for handling Health Authority or Country Operations labelling queries for assigned products.

About the Role

Key Accountabilities:

This role offers hybrid working, requiring 3 days per week / 12 days per month in our office.

As Global Labelling Manager, you will be responsible for:

- Maintaining regulatory compliant, competitive and up-to-date global labelling documents for assigned products, leading the ELTF to align on labelling strategy, labelling course of action and text.
- Representing Global Labelling in relevant sub-teams, researching and providing input about labelling topics across different markets, the competition, and regulations.
- Contributing to the creation of high-quality documents supporting changes to the CDS, USPI, EU SmPC and leading responses to labelling-related Health Authority queries.
- Leading the interaction with Country Organisations to ensure the timely implementation of labelling changes in local product information and ensuring consistency and compliance with the CDS.
- Representing Global Labelling during audits and inspections, as required.

Your experience:

- Bachelor’s degree in life science or pharmaceutical sciences. Advanced degree with the requisite experience is desirable.
- Experience in global labelling (incl. US and EU), or in related areas of the pharmaceutical industry or Health Authorities.
- Strong interpersonal, project management, communication, negotiation and problem-solving skills.
- Ability to lead cross-functional teams in a complex, matrixed work environment.
- Compliance and Quality mindset.

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of hard-working, 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

Commitment to Diversity & Inclusion:

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

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

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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
REQ-10011593

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