Regulatory Affairs Manager; Labeling

Job ID
REQ-10027723
Okt. 29, 2024
Indien

Zusammenfassung

-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

Major accountabilities:

- Review and assess local country labels to identify deviations from the core labeling and propose topics for further cross-functional assessment during the periodic core labeling review process -Contribute to DRA activities regarding Novartis safety risk communications/portfolio stewardship activities having labeling impact for their assigned projects/products.
- Contribute to the creation of high quality documents supporting changes with internal and/or external experts including the preparation of responses to labeling related Health Authority queries -Ensure that key country label proposals which deviate from a proposed CDS or CDS amendment/update (e.g., US PI, EU SmPC) are brought to the attention -A seasoned, experienced professional with a full understanding of area of specialization; resolves a wide range of issues in creative ways.
- Networks with senior internal and external personnel in own area of expertise.
- Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable)

Key performance indicators:

- Adherence to Novartis policy and guidelines -Project & stakeholder feedback

Minimum Requirements:
Work Experience:

- Cross Cultural Experience.
- People Challenges.
- Functional Breadth.
- Project Management.
- Collaborating across boundaries.

Skills:

- Cross-Functional Teams.
- Detail Oriented.
- Labeling Documentation.
- Labeling Regulations.
- Operational Excellence.
- Regulatory Compliance.
- Safety.

Languages :

- English.

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

Abteilung
Development
Business Unit
Innovative Medicines
Ort
Indien
Website
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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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.

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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