

Regulatory Affairs Manager; Labeling

Job ID

REQ-10027723

Oct 29, 2024

India

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.

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>

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<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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