

RA Global Labelling Manager - (80-100%*)

Job ID
REQ-10048431

4月 14, 2025

Switzerland

摘要

Development is guided by our purpose to reimagine medicine to improve and extend people's lives. As a Global Labeling Manager, you will be responsible for maintenance of regulatory compliant, competitive, and up-to-date high quality and timely implemented core labeling documents (incl. Core Data Sheet (CDS)) and key country labeling (incl. US and EU) for assigned Novartis Innovative Medicines products. The assigned products may include higher complexity products and may include developmental programs. You will provide strategic and operational regulatory labeling input, working in close collaboration with Expert Labeling Task Force (ELTF) members in maintaining core labeling documents, key labeling, and for handling Health Authority or Country Operations labeling queries for assigned products.

About the Role

Your Key Responsibilities:

- Maintaining regulatory compliant, competitive and up-to-date global labeling documents for assigned products, leading the ELTF to align on labeling strategy, labeling course of action and text.
- Represent global labeling in relevant sub-teams, researching and providing input about labeling topics across different markets, the competition, and regulations.
- Contribute to the creation of high-quality documents supporting changes to the CDS, USPI, EU SmPC and leading responses to labeling-related Health Authority queries.
- Lead the interaction with Country Organizations to ensure the timely implementation of labeling changes in local product information and ensuring consistency and compliance with the CDS.
- Contribute to Global Labeling management and continuous improvement initiatives.
- Review and comment on emerging internal and external guidelines and regulations on labeling topics.
- Represent Global Labeling during audits and inspections, as required

Role Requirements:

Essential Requirements:

- Bachelor ' s degree in life science or pharmaceutical sciences. Advanced degree with the requisite experience is desirable.
- Extensive experience (2-3 years) in global labeling (incl. US and EU); alternatively extensive experience (5 years) 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.

Location: Basel, Hybrid working requirement 3 days / 12 days per month in office.

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>

Commitment to Diversity & Inclusion:

We are committed to building an outstanding, inclusive work environment and diverse teams representative of the patients and communities we serve.

*Restrictions on flexible working arrangements may apply and will be discussed at interview if applicable

Accessibility and accommodation:

Novartis is committed to working with and providing reasonable accommodation to all individuals. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to receive more detailed information about the essential functions of a position, please send an e-mail to inclusion.switzerland@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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部门

Development

Business Unit

Innovative Medicines

地点

Switzerland

站点

Basel (City)

Company / Legal Entity

C028 (FCRS = CH028) Novartis Pharma AG

Functional Area

Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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