Global Program Safety Lead

Job ID
REQ-10019287
Aoû 22, 2024
Suisse

Résumé

-Designs & develops safety surveillance strategy for products and approval. Responsible for the company's drug surveillance program including the necessary follow-up, risk assessment, and relatedness to product on adverse reaction reports, oversight of safety in clinical trials and post marketing programs. Participates in the resolution of any legal liability and complying with governmental regulations. Provides and contributes trending and safety signal detection and risk management assessment for the products' life cycle. Provides safety support to the clinical development teams.

About the Role

The **Global Program Safety Lead** successfully serves as scientific safety leader of the Medical Safety organization to improve patients' lives and impact on overall Novartis results through robust safety evaluation expertise and medical innovation. Ensures optimal patient safety for assigned compounds, is responsible for the integration, analysis, and interpretation of internal and external safety information from all sources through lifecycle management.

Your key responsibilities, but not limited to;

- Providing expert safety input to the clinical development program for assigned projects/products and be an active member of the Global Program Team (GPT), Global Clinical Team (GCT) and Clinical Trial Team (CTT).
- Responsible for safety issue management from formation of Global Program Team (GPT) through Life Cycle Management.
- Develop and is responsible for key internal Novartis safety documents: reviews these documents regularly and updates as required (e.g. when significant new information received). Ensures that these, and all other project-related safety documents, are consistent in safety messages.
- Own the safety strategy and document it in the corresponding documents (e.g. dSPP, SSPT) and leads the production of the medical safety deliverables (e.g. DSUR, PSUR, RMP) for the assigned products.
- Responsible for overall signal detection, monitoring, evaluation, interpretation and appropriate management of safety information, based on information from all relevant line functions, post-marketing data, and other sources. To this end, constitutes and runs the Safety Management Team (SMT). Ensures that this team appropriately and timely reviews all medical safety data from various sources (e.g. pre-clinical, clinical trial data post-marketing, literature) throughout the development and post-approval process.
- Responsible for documentation/tracking/record keeping of the assigned compounds medical safety activities.
- Responsible for initial development and ongoing maintenance of safety information in Core Data Sheet

(core global labeling), including addressing safety issues optimally in all project/product labeling indications.

- Responsible for responses to inquiries from regulatory authorities or health care professionals on safety issues. Leads the preparation of the safety strategy for health authority responses and strategy, in collaboration with other project team members.
- Ensuring safety information is communicated/escalated to HPS/MPH, HMS HYD and/or EU Qualified Person in a timely fashion.
- Facilitate involvement of external experts (e.g. authors of white papers, members of trial- specific data safety monitoring boards, ad-hoc support for HA meetings, etc.)
- Preparing and presents safety issues to internal Novartis Boards and other meetings as required. Provides relevant input for SMT/SMB, GPT, GCT and CTT meetings as needed
- Initiate and maintains productive cross-functional Medical Safety collaborations with colleagues within CMO&PS and those from other functions, e.g. Clinical Development and Medical Affairs, Regulatory Affairs, Medical Information, Biostatistics, Quantitative Safety & Epidemiology, Clinical Pharmacology, QA, BD&L and NIBR, as well as externally with expert panels and other scientific contacts.

Languages:

Fluent in spoken and written English. Understanding in another major language (e.g. French, German, Spanish) desirable

Education:

Medical Degree or equivalent (preferred), PhD, PharmD or equivalent graduate level health care professional degree required. Specialty Board certification desirable.

Useful additional degrees: Post graduate degree in Pharmaceutical Medicine; Master of Public Health in Epidemiology (or equivalent)

Why Novartis?

766 million lives were touched by Novartis medicines in 2021, and while we’re proud of this, we know there is so much more we could do to help improve and extend people’s lives.

We believe new insights, perspectives and ground-breaking solutions can be found at the intersection of medical science and digital innovation. That a diverse, equitable and inclusive environment inspires new ways of working.

We believe our potential can thrive and grow in an unbossed culture underpinned by integrity, curiosity, and flexibility. And we can reinvent what's possible, when we collaborate with courage to aggressively and ambitiously tackle the world’s toughest medical challenges. Because the greatest risk in life, is the risk of never trying! Imagine what you could achieve here at Novartis!

Commitment to Diversity & Inclusion:

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

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 diversity.inclusion_ch@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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

Division
Development
Business Unit
Innovative Medicines
Emplacement
Suisse
Site
Basel (City)
Company / Legal Entity
C028 (FCRS = CH028) Novartis Pharma AG
Alternative Location 1
Espagne
Functional Area
Recherche & Développement
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

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

iframe{ width: 100%; margin-top: 3rem; } @media screen and (max-width: 767px){ iframe{ height: 30vh !important; } } @media screen and (min-width: 768px){ iframe{ height: 34vh !important; } }
Job ID
REQ-10019287

Global Program Safety Lead

Apply to Job

safety-lead

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://talentnetwork.novartis.com/network
3. https://www.novartis.com/careers/benefits-rewards
4. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Basel-City/Global-Program-Safety-Lead_REQ-10019287-1
5. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Basel-City/Global-Program-Safety-Lead_REQ-10019287-1