Senior Global Program Safety Lead

Job ID
REQ-10024788

10月 04, 2024

Switzerland

摘要

-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

Primary Location: Basel, Switzerland

Alternate Location(s): Barcelona, Spain

Working model: Both locations have a hybrid working model (12 days per month in the office)

Closing date for applications: 18 October 2024

About this role:

Our Senior Global Program Safety Lead excels as a scientific safety leader within the Oncology Medical Safety organization.

Join us and you will make a significant impact on patients' lives and contribute to Novartis' overall success through robust safety evaluation expertise and medical innovation.

Key Responsibilities:

- **Safety Input and Team Participation:** Provide expert safety input to the clinical development program for assigned projects/products and actively participate in the Global Program Team (GPT), Global Clinical Team (GCT), and Clinical Trial Team (CTT). Responsible for managing safety issues from the formation of the GPT through Life Cycle Management.
- **Signal Detection and Safety Management:** Oversee overall signal detection, monitoring, evaluation, interpretation, and appropriate management of safety information, based on data from all relevant line functions, post-marketing data, and other sources.
- **Documentation and Record Keeping:** Ensure proper documentation, tracking, and record-keeping of medical safety activities for assigned compounds.
- **Regulatory and Professional Inquiries:** Respond to inquiries from regulatory authorities or healthcare professionals regarding safety issues.
- **Safety Strategy Preparation:** Lead the preparation of the safety strategy for health authority responses and collaborate with other project team members.
- **Departmental and Functional Goals:** Contribute to and often lead the development of departmental and functional/business unit goals and objectives.
- **Marketing Samples Distribution:** Manage the distribution of marketing samples, where applicable.

Key performance indicators:

- Timeliness and quality of safety analyses, interpretations, and presentation
- Compliance with internal and external regulations & procedures
- Compliance, consistency and quality of safety deliverables

Role Requirements:

- Medical Degree is required
- 10+ years of experience in Big Pharma
- 3 to 5 years Oncology experience.

Skills:

- Clinical Research.
- Clinical Trials.
- Functional Teams.
- Leadership.
- Medical Strategy.
- Process Safety Management.
- Regulatory Compliance.
- Risk Management.
- Safety Science.

Languages :

- Fluent English (both spoken and written) is mandatory.
- Additional languages are an advantage.

Why Novartis: Our purpose is to reimagine medicine to improve and extend people ' s lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

Commitment to Diversity and Inclusion:

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

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: https://talentnetwork.novartis.com/network

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

部门
Development

Business Unit
Innovative Medicines

地点
Switzerland

站点
Basel (City)

Company / Legal Entity
C028 (FCRS = CH028) Novartis Pharma AG

Alternative Location 1
Barcelona Gran V í a, Spain

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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