

Global Program Safety Lead

Job ID
REQ-10036817
Jan 16, 2025
Switzerland

Summary

Global Program Safety Lead – RLT

Primary Location: Basel, Switzerland (80-100%)

Alternate Location: Barcelona, Spain

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

Note: Novartis is not able to offer relocation support for this role. Please only apply if one of these locations is accessible for you.

About this role:

Our Global Program Safety Lead excels as a scientific safety leader within the Oncology Medical Safety organization and is part of our (RLT) Radioligand Therapy team.

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.

About the Role

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

Role Requirements:

- Medical Degree or equivalent is preferred
- PhD, PharmD or equivalent graduate level health care professional degree required
- 3-5 years of experience in Oncology
- Minimum 7 years progressive experience in drug development in a major pharmaceutical company (of which 5 years in a global position), including 5 years in safety at a medical position
- Strong experience in drug development, clinical trial methodology, regulatory requirements, scientific methodology, statistics and writing of publications
- Expertise in preparing or contributing to preparation of clinical safety assessments and regulatory reports/submissions involving safety information – to include NDA submission documents
- Experience with contributing to Safety Science
- Strong experience in leading cross-functional, multi- cultural teams
- Strong experience with (safety or others) issue management

Desirable Skills:

- Experience in Radioligand and/or Nuclear Medicine
- Specialty Board Certification

Languages:

- Fluent English (both spoken and written) is essential
- 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>

Division

Development

Business Unit

Innovative Medicines

Location

Switzerland

Site

Basel (City)

Company / Legal Entity

C028 (FCRS = CH028) Novartis Pharma AG

Alternative Location 1

Barcelona Gran Vía, Spain

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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