Sr. Global Program Safety Team Lead (Immunology)

Job ID
REQ-10041765

6月 18, 2025

USA

摘要

The Sr Global Program Safety Team Lead (Immunology) serves as strategic leader of the Medical Safety organization to improve patients ’ lives and impact on overall Novartis results through robust safety risk management. This role requires an experienced and knowledgeable safety clinician responsible to predict safety risks and assess scientific information to guide the assigned teams on strategic considerations, effective risk management and overall positive impact in development programs.
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.
This is a management position requiring excellent collaboration skills and matrix leadership, who will work closely with the Head Patient Safety managing complex safety issues across several indications.

About the Role

Major accountabilities:

- Manages an efficient and successful disease area within the Therapeutic Area (TA)/Development Unit (DU) Medical Safety organization, which provides robust medical and science-driven contribution to BenefitRisk evaluation throughout product lifecycle to enable Novartis to provide impactful medicines to patients worldwide
- Enhances scientific and clinical experience of Medical Safety physicians / scientists through continuous training and coaching. Prepares safety objectives and evaluates and manages performance of the Medical Safety associates within the TA/DU. Identifies talents and high potential associates and is able to defend and discuss in front of leadership team. Together with associates identifies carrier development opportunities and support associates in the carrier path
- Provides 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) -Is responsible for safety issue management from formation of Global Program Team (GPT) through Life Cycle Management
- Is 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.
- Responsible for documentation/tracking/record keeping of the assigned compounds medical safety activities
- Is 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 -Contributes to and often leads the development of departmental and functional/business unit goals and objectives
- Distribution of marketing samples (where applicable)

Key performance indicators:

- Timeliness and quality of safety analyses, interpretations, and presentations and communication in all the assigned programs
- Strategic input and guidance in the assigned programs
- Compliance with internal SOPs/WPs and external regulations & procedures

Essential Requirements:

- 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)
- 5 years clinical experience postdoctoral
- At least 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
- Expertise in preparing or contributing to preparation of clinical safety assessments and regulatory reports/submissions involving safety information - to include NDA submission documents

- Strong experience in leading cross-functional, multicultural teams
- Strong experience with (safety or others) issue management
- Strong experience in drug development, clinical trial methodology, regulatory requirements, scientific methodology, statistics and writing of publication
- Strong leadership skills including coaching, motivating, and directing, and fostering teamwork. Ability to develop and maintain effective working relationships with subordinates, superiors and peers

Desirable Experience

- Strong negotiation and conflict management skills
- Strong experience with medical writing and delivering high quality documents such as RMPs, PSURs

The pay range for this position at commencement of employment is expected to be between $204.400 and $379,600 /year; however, while salary ranges are effective from 1/1/25 through 12/31/2025, fluctuations in the job market may necessitate adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills and abilities. The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an "at-will position" and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

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

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

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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

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The Novartis Group of Companies are committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the application process, or to perform the essential functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

部门
Development

Business Unit
Universal Hierarchy Node

地点
USA

状态
New Jersey

站点
East Hanover

Company / Legal Entity
U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Alternative Location 1
Basel (City), Switzerland

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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