U NOVARTIS

Senior Global Program Safety Team Lead - Immunology

Job ID REQ-10055040

6月 25, 2025

Switzerland

摘要

Are you ready to lead with excellence and make a significant impact on our company's safety surveillance strategy? We are looking for a dynamic and strong people manager to design and develop our safety surveillance strategy for product approval.

Join us and be the driving force behind our commitment to safety and excellence!

About the Role

Major accountabilities:

 Manage 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.

- Enhance scientific and clinical experience of Medical Safety physicians / scientists through continuous training and coaching. Prepare safety objectives and evaluates and manages performance of the Medical Safety associates within the TA/DU. Identify talents and high potential associates and able to defend and discuss in front of leadership team. Together with associates identifies career development opportunities and support associates in the career path.
- Provide 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.
- 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
- Responsible for responses to inquiries from regulatory authorities or health care professionals on safety issues.
- Lead the preparation of the safety strategy for health authority responses and strategy, in collaboration with other project team members. Contribute to and often lead the development of departmental and functional/business unit goals and objectives.

Minimum 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.

Languages :

- English.
- Additional languages are an advantage.

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? <u>https://www.novartis.com/about/strategy/people-and-culture</u>

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: <u>https://www.novartis.com/careers/benefits-rewards</u>

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

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