Global Program Safety Lead

Job ID REQ-10058896			
8月 14, 2025			
Spain			

摘要

Are you ready to make a significant impact in medical safety?

Novartis is seeking passionate individuals to join our innovative team. You will work with cutting-edge technology, collaborate with experts, and drive excellence in patient safety.

If you're eager to advance your career and be part of a forward-thinking company, we want you on our team!

About the Role

#LI HYBRID

Location: Barcelona, Spain

Secondary Location: Madrid, Spain

Working model: Hybrid

Note: We are currently recruiting for various Therapeutic Areas, and your application will be considered for all relevant positions.

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). Lead the Safety Management Team (SMT). Responsible for managing safety issues from the formation of the GPT through Life Cycle Management.
- Safety Strategy Preparation: Own the projects/products safety strategy and lead the production of medical safety deliverables.
- Core Global Labelling: Responsible for initial development and ongoing maintenance of safety information in Core Data Sheet, addressing safety issues in all project/product indications.
- Signal Detection and Safety Management: Oversee overall signal detection, monitoring, evaluation, interpretation, and appropriate management of safety information, based on data from all relevant sources.
- Regulatory and Professional Inquiries: Lead the preparation of the safety strategy for health authority responses and collaborate with other project team members. Respond to inquiries from regulatory authorities or healthcare professionals regarding safety issues.
- Departmental and Functional Goals: Contribute to and often lead the development of departmental and functional/business unit goals and objectives. Proactively engages in the development of competencies across the Medical Safety Function

Role Requirements:

- Medical Degree or equivalent is preferred; PhD, PharmD or equivalent graduate level health care professional degree required
- 3 years clinical experience postdoctoral
- Minimum 5 years 'experience in drug development in a major pharmaceutical company (of which 2 years in a global position), including 2 years in safety at an operational or medical position.
- Experience in 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
- Experience with (safety or others) issue management
- Experience in leading cross-functional, multicultural teams

Languages: Fluent English (both spoken and written) is mandatory. 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? 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** Universal Hierarchy Node 地点 Spain 站点 Barcelona Gran Vía Company / Legal Entity ES06 (FCRS = ES006) Novartis Farmac é utica, S.A.

Alternative Location 1

Madrid Delegaci ó n, Spain
Functional Area Research & Development
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.



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