# Global Program Safety Lead / Senior Global Program Safety Lead - CRM

Job ID REQ-10048846

4月 30, 2025

Spain

# 摘要

Join our dynamic Cardio Renal Metabolic (CRM) team at Novartis, where we are committed to enhancing patient safety and improving healthcare outcomes.

We are looking for a passionate and experienced Global Program Safety Lead to lead our drug surveillance program and ensure compliance with governmental regulations.

About the Role

Primary Location: Barcelona, Spain

Alternate Location(s): London, United Kingdom

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 the location is accessible for you.

## Major accountabilities:

- Design and develop safety surveillance strategies for our products.
- Oversee the company's drug surveillance program, including follow-up, risk assessment, and relatedness to product on adverse reaction reports.
- Provide safety support to clinical development teams and participate in the resolution of any legal liability.
- Manage safety issue resolution from the formation of the Global Program Team (GPT) through Life Cycle Management.
- · Develop and maintain key internal safety documents and ensure they are regularly updated.
- Lead the preparation of safety strategies for health authority responses and collaborate with project team members.
- Contribute to the development of departmental and functional/business unit goals and objectives.
- Report technical complaints, adverse events, and special case scenarios related to Novartis products within 24 hours of receipt.

#### Role Requirements:

- Medical Degree or equivalent (preferred), PhD, PharmD or equivalent graduate level health care professional degree required
- 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
- Significant experience with (safety or others) issue management
- Proven expertise in drug development, clinical trial methodology, regulatory requirements, scientific methodology, statistics and writing of publications
- Solid experience in leading cross-functional, multi- cultural teams

### Languages:

- Fluent English both spoken and written is essential
- Understanding in another major language (e.g. French, German, Spanish) is desirable

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? <a href="https://www.novartis.com/about/strategy/people-and-culture">https://www.novartis.com/about/strategy/people-and-culture</a>

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Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: <a href="https://www.novartis.com/careers/benefits-rewards">https://www.novartis.com/careers/benefits-rewards</a>

部门

Development

Business Unit Innovative Medicines

地点 Spain

站点 Barcelona Gran V í a

Company / Legal Entity ES06 (FCRS = ES006) Novartis Farmac é utica, S.A.

Alternative Location 1 London (The Westworks), United Kingdom

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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