NOVARTIS

# Medical Safety Writer (m/f/d)

Job ID
REQ-10045134
Mar 26, 2025
Spain

## Summary

Location: Barcelona, Spain. #LI-Hybrid

We are seeking a skilled Medical Safety Writer (m/f/d) to join our dynamic team. The successful candidate will be responsible for writing risk management plans (RMP) and other aggregate reports, ensuring that Health Authority (HA) comments are addressed adequately. Additionally, the role involves conducting independent quality control (QC) of deliverables to meet Novartis quality standards and HA expectations.

## About the Role

**Major accountabilities:**

- Lead the preparation of initial Risk Management Plans (RMPs) and other aggregates reports as required for newly launched, acquired products, or new indications RMP update. Drive key messaging and pooling strategy, offering expert content guidance for RMP documents.
- Lead coordination to ensure information received, analyzed and incorporated into RMP updates as per the regulatory requirements.
- Independent QC of deliverables to ensure the information presented is complete, consistent and compliant to regulatory and Novartis standards.
- Provide support to the planning of data analyses and presentation, including statistical analysis plan reviews and meetings, for RMP submissions.
- Support in creating strategy for data analyses and presentation in global periodic safety reports and other department' deliverables as required; as well as in addressing the Health Authority (HA) comments adequately in deliverables, or SOPs.
- Support in the development of safety document templates and Standard Operating Procedures pertaining to the department's deliverables.
- Contribute to global projects focusing on process, system & quality improvement initiatives (including AI projects).
- Contribute as subject matter expert during Health Authorities inspections/audits and contribute to development, implementation of appropriate Corrective and Preventative Actions (CAPA). Act also as mentor/trainer.

**Essential Requirements:**

- Graduate/Postgraduate/Doctorate degree in Life Sciences/Pharmacy/Medical Sciences or equivalent degree.
- 4 to 8 years of experience in drug safety/ development or closely related areas of responsibility, with a minimum of 3 years' experience in safety /medical /scientific / regulatory writing.

- Sound expertise in data analysis and presentation, strong project management and communication skills, paired with ability to lead global and cross-functional work groups.
- Excellent understanding of drug development process, GCP and medical terminology.
- Fluent English (oral and written).

**Desiderable Requirements:**

- Preferably, at least 2 years of experience in safety writing.

**You will receive:**

You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. https://www.novartis.com/careers/benefits-rewards

Other Spanish standard benefits are Company Pension Plan; Life and Accidental Insurance; Meals, Allowance or Canteen in the office; Flexible working hours.

**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.

**Accessibility and accommodation:**

Novartis is committed to working with and providing reasonable accommodation to all individuals. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to receive more detailed information about the essential functions of a position, please send an e-mail to diversity.inclusion_ch@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

**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
Spain
Site
Barcelona Gran Vía
Company / Legal Entity
ES06 (FCRS = ES006) Novartis Farmacéutica, S.A.

Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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