

Senior Medical Safety Writer (m/f/d)

Job ID
REQ-10045090
Μαί 13, 2025
Spain

Περίληψη

Location: Barcelona, Spain. #LI-Hybrid

Join us as a Risk Management Champion! Lead the creation of high-quality global Risk Management Plans and reports, drive process improvements, and ensure Health Authority comments are addressed. Collaborate with cross-functional teams and harmonize best practices across Therapeutic Areas. Make a difference with Novartis!

About the Role

Major accountabilities:

- Lead the authoring, review, and independent management of Safety Concerns and other critical content in Risk Management Plans (RMPs) and other aggregates reports as required; as well as the preparation of initial Risk Management Plans (RMPs) and other aggregates reports as required for newly launched, acquired products, or new indications RMP update.
- Review and ensure HA comments are addressed in all relevant department's deliverables for a product/class across the TAs in collaboration with medical function, QPPV office and other global stakeholders.
- Contribute to the planning of data analyses and presentation, including statistical analysis plan reviews and meetings, for RMP submissions. And create a strategy for that purpose.
- Contribute to complex cross functional global projects focusing on quality improvement, including IT projects/systems (AI, automation, etc.).
- Provide expert opinion in the development of safety document templates and Standard Operating Procedures pertaining the department's deliverables to comply with emerging worldwide regulations.
- Ensure team awareness and assess impact of updates to global PV regulatory requirements for department's deliverables. Also identify knowledge gap, develop training materials and conduct workshops. Mentor junior writers to enhance their skills and contributions, and sustain a pool of SMEs.
- Act as consultant for teams across functions within Novartis and external service providers involved in aggregate report and risk management document preparation.
- Deputize for Team Lead / Group Head Global AR&RM and assist with the recruitment of new staff.

Essential Requirements:

- Graduate/Postgraduate/Doctorate degree in Life Sciences/Pharmacy/Medical Sciences or equivalent degree.
- At least 7 years' experience in drug safety/development or closely related areas of responsibility, with a minimum of 5 years' experience in in safety writing

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

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>

Τομέας

Development

Business Unit

Innovative Medicines

Τοποθεσία

Spain

Τοποθεσία

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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