Senior Medical Safety Writer (m/f/d)

Job ID
REQ-10045090

4月 04, 2025

Spain

摘要

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.inclusionch@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

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.

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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