NOVARTIS

Senior Global Risk Management Plan Manager

Job ID
REQ-10006898
Sep 16, 2024
Spain

Summary

Guides the Safety Lead and the Safety Management Team (SMT)/Global Program Team (GPT) on Good Pharmacovigilance Practices and other regulatory and internal requirements for Safety Risk Management, including strategic support to new submissions and innovative products. Provides support to the Safety Lead in the management, coordination, development, reviewing, and tracking of Safety Risk Management Plans (RMP) to ensure that documents are of high quality, regulatory compliant, and that logistics and distribution are handled in an appropriate and timely manner.

About the Role

The Senior Manager Aggregate Reporting and Risk Management - RMP, liaises within the team and with the Global Product Safety Lead (GPSL) to ensure alignment & synergies between Periodic Safety Update Report (PSUR), Development Safety Update Report (DSUR) and Risk Management Plans (RMP). Initiates the tracking of commitments and liaises with relevant functions that maintain and monitor the commitments.

Your key responsibilities, but not limited to:

- Drive the development of a robust and feasible RMP strategy aligned with the benefit-risk profile of the product, together with the Safety Lead and the SMT/GPT, including for new submissions and innovative medicines, aligned with business priorities.
- Guide strategic decisions and designing a robust worldwide implementation plan of the RMP strategy, including for new submissions and innovative medicines, by navigating complex stakeholder matrixes.
- Lead initiatives related with Good Pharmacovigilance Practices and other regulatory and internal requirements for Safety Risk management, as well as company and industry practices.
- Represent the RM function in the Safety management team, works in close collaboration with the Safety Lead, Regulatory and other team members of the SMT/GPT (Clinical, Medical Affairs, Epidemiology, Biostatistics, Clinical Pharmacology, and Marketing, etc.) for the risk minimization activities planning and defining of effectiveness, including for new submissions and innovative medicines.
- Partner with the commercial team to integrate RMP requirements in marketing launch activities, as well as in communications to COs.
- Mentor new hires in the AR &RM team as RMP expert.
- Deputizes for the Team Lead or Group Head AR&RM in defined meetings and initiatives.

Experience/Professional requirement:

- At least 7 years in a pharmaceutical company, preferably in drug safety, clinical research, or regulatory affairs, with 3 or more years expert knowledge in safety risk management.

- Proven ability to work with large cross-functional teams in complex projects, including new submissions and innovative medicines. Has demonstrated teamwork and effective communication skills. Partners with other line functions and establishes effective relationships with stakeholders at all levels.
- Knowledge of worldwide regulatory requirements for drug registration (scientific and technical aspects) and clinical drug development.
- Proven ability to interpret, discuss efficacy and safety data relating to multiple therapeutic area to the level required for delivering successfully RMPs and aggregate safety reports.
- Solid Medical/Scientific writing and verbal skills

Languages:

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

Education:

Scientific Degree required. Advanced degree (Masters, PharmD or PhD) 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?
https://www.novartis.com/about/strategy/people-and-culture

Commitment to Diversity & 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.

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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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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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