

Senior Global Risk Management Plan Manager

Job ID
REQ-10006898

9月 16, 2024

Spain

摘要

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?

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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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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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