Global Risk Management Plan Manager

Job ID
REQ-10011544
Sep 13, 2024
Spain

Summary

Monitors and audits the company's drug, biologics or medical devices surveillance program including the intake, evaluation, processing and follow-up on adverse reports. Participates in the resolution of any legal liability and in complying with government regulations. Ensures accurate receipt, maintenance and assessment against product labeling. Reports events or reactions as required by regulatory agencies including adverse events data from clinical trials, spontaneous or solicited sources, periodic and experience reports. May provide trending and safety signal detection and assessment. Supports all clinical trial activity and post marketing.

About the Role

The **Global Risk Management Plan Manager** Provide support to the medical safety physicians in the management, coordination, development, reviewing, and tracking of Safety Risk Management Plans to ensure that documents are of high quality, regulatory compliant, and that logistics and distribution are handled in an appropriate and timely manner. Initiates the tracking of commitments and liaises with relevant functions that maintain and monitor the commitments.

- Support the Global Product Safety Leader (GPSL) and the designated medical writer for the timely preparation, development and finalization of high quality and regulatory compliant safety Risk Management Plans (RMP).
- Support the GPSL/GPT to resolve issues as they arise regarding the RMP strategy, RMP preparation, RMP implementation and RMP overall process.
- Guide the GPSL and key authors to ensure that commitments are appropriately worded and reviewed by all relevant line functions and comments incorporated into final document.
- Coordinate activities from the different line units to ensure all documents required to support the RMP main document are included in the RMP annexes and available in the Document Management System according to Novartis processes.
- Manage all logistical aspects related to the timely development of the safety RMP annexes and works with authors of the different line functions to ensure RMP annexes content meets Novartis and Health Authorities (HA) requirements.
- Support the Safety Lead in updating the RMP according to HA requirements and ensures they are aligned with Periodic Safety Update Report (PSUR)/ Periodic Benefit Risk Evaluation Report (PBRER).
- Review the RMP to ensure consistency and regulatory compliance of RMP sections and annexes.
- Track HA feedback and assessment on RMP and ensures HA requirements are implemented as required (e.g. in individual RMP, in global RMP template).
- Timely submission and delivery of high quality RMPs to Health Authorities.
- RMP document and annexes are fully compliant with Novartis and Health Authorities technical and format

requirement.
- All documents required to support the RMP main document are included in the RMP annexes and available in the Document Management System according to Novartis processes.
- Distribution of RMP CoSTA commitments to affiliates and HQ GPT is performed within 15 working days of Health Authority approval.
- Database of Health Authorities feedback on RMP is kept up to date.

Experience/Professional requirement:

At least 5 years in a pharmaceutical company, preferably in drug safety, clinical research, or regulatory affairs.

- Proven ability to work with large cross-functional teams in complex projects. Has demonstrated teamwork and effective communication skills. Works effectively and is able to establish relation- ships with other line functions.
- Knowledge in 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.
- 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

(minimum/desirable): Scientific Degree required. Advanced degree (Masters, PharmD or PhD) desirable.

Why Novartis?

766 million lives were touched by Novartis medicines in 2021, and while we’re proud of this, we know there is so much more we could do to help improve and extend people’s lives.

We believe new insights, perspectives and ground-breaking solutions can be found at the intersection of medical science and digital innovation. That a diverse, equitable and inclusive environment inspires new ways of working.

We believe our potential can thrive and grow in an unbossed culture underpinned by integrity, curiosity, and flexibility. And we can reinvent what's possible, when we collaborate with courage to aggressively and ambitiously tackle the world’s toughest medical challenges. Because the greatest risk in life, is the risk of never trying! Imagine what you could achieve here at Novartis!

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.

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

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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.

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
Apply to Job

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