Risk Management Manager (Pharma Industry)

Job ID
REQ-10013017

6月 13, 2025

Spain

摘要

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 Risk Management Manager leads activities and initiatives designed to identify and categorize risks that potentially impact the Vigilance system and the broader PS&PV organization as well as the preparation of action plans for PS&PV leadership endorsement. Ensure oversight of management of Patient Safety Quality Issues and Quality Events in AQWA/1QEM.

Your key responsibilities, but not limited to;

- Through oversight and trending of the below areas;
- Receipt of Quality Issues and Quality Events
- Entry in to AQWA/1 QEM
- Timely completion of investigations
- Implementation of appropriate CAPAs and availability of appropriate evidence
- Completion of effectiveness checks
- Timely closure in AQWA,/1QEM
- Drive the development of actionable insights and mitigation plans to ensure that any opportunities for improvement are identified and acted upon as early as possible.
- Lead and support strategic projects related to Risk Management of the Novartis Vigilance System.
- Prepare/maintain guidance documents and training material to educate Patient Safety associates on the Quality Issue & Quality Event process.
- Monitor compliance of the Patient Safety organization to Quality Issue & Quality Event handling processes and standards and where deficiencies are identified, develop and implement strategies to address these.
- Collaborate with the Compliance, Process Excellence, QPPV Office and other functions to produce metrics and complete trend analyses designed to identify areas of risk with impact on the Vigilance System and/or CMO&PS organization.
- Collaborate with other Global Line Functions across Novartis Divisions and Third Parties to establish and meet joint accountabilities
- Lead the development and maintenance of respective procedural documents including ownership of relevant PSMF sections and annexes.
- Support the review of emerging worldwide regulations, performing impact assessments, and driving process changes required to ensure ongoing compliance to global regulatory requirements
- Act as a subject matter expert during audits and inspections, lead the preparation of responses to findings and the development and implementation of corrective and preventative actions.
- Prepare reports and/or presentations to document the outcome of risk assessments for the Process Governance and Risk Mitigation management team and escalate key findings to the Head Compliance and Risk Management and/or relevant governance or LT board.
- Support with management of the Operational Metrics & Risk Committee as the Secretary; scheduling the meetings, preparing the agenda and track and follow up on actions.

Desirable Skills:

- Minimum 4 years of experience in the pharmaceutical industry, particularly pharmacovigilance
- Experience in project management and demonstrated ability to lead work groups
- Ability to deal and interact with a wide variety of people at all levels.
- Strong negotiation, presentation and communication skills, and ability to operate effectively in an international environment and across functions
- Excellent analytical skills.
- Ability to mentor and coach

Educational Background:

PharmD, MSc Degree in Life Sciences or equivalent.

Languages:

Excellent English language skills.

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.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

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部门
Development

Business Unit
Innovative Medicines

地点
Spain

站点
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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