

Senior Risk Management Manager

Job ID
REQ-10013031
Jul 16, 2024
Spain

Summary

Lead activities and initiatives designed to identify and categorize risks that potentially impact the Vigilance system and the broader CMO&PS organization as well as the prepare action plans for CMO&PS leadership endorsement. Ensure oversight of management of Patient Safety deviations and quality incidents in AQWA/1QEM

About the Role

The Senior 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 prepare action plans for PS&PV leadership endorsement. Ensure oversight of management of Patient Safety deviations and quality incidents in 1QEM.

Your key responsibilities, but not limited to;

- Through oversight and trending of the below areas:
 - Receipt of deviations and incidents
 - Entry into 1QEM
 - Timely completion of investigations
 - Implementation of appropriate CAPAs and availability of appropriate evidence
 - Completion of effectiveness checks
 - Timely closure in 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 deviation and quality incident process.
 - Monitor compliance of the Patient Safety organization to deviation and quality incident 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 PS&PV 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
- Support the execution and monitoring of global self assessments within PS&PV
- 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 Governance & Risk management team and escalate key findings to the Head Governance & Risk 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.
- Support as business representative during mergers and acquisitions.

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.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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connected and learn about suitable career opportunities as soon as they come up:

<https://talentnetwork.novartis.com/network>

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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