

Vigilance Compliance Excellence Manager

Job ID
REQ-10008948
Juni 27, 2024
Indien

Zusammenfassung

Responsible for developing and implementing new monitoring activities and metrics for new safety case management, aggregate reporting and risk management plan processes and assessing and adapting already established metrics in response to changes in the regulatory and Novartis environment. Manages the completion of monitoring activities and production of metrics.

About the Role

Major accountabilities:

- Develop and implement compliance and quality metrics for new safety case management, aggregate reporting and risk management plan processes, working with the process/metrics owners, Quality Assurance (QA) and other global line functions as appropriate.
 1. Develop and maintain tools in collaboration with Innovation, Tech & Systems, and other Global Line Functions to assist in the monitoring of compliance and quality, introducing automation where possible.
 2. Develop and implement training material and communications
- Supporting the review of emerging worldwide regulations, performing impact assessments, and driving process changes required to ensure ongoing compliance to global regulatory requirements.
- Ensure changes required by new regulations/health authority's guidance are implemented timely and by the effective date.
- Leading and supporting the development and maintenance of respective procedural documents including ownership of relevant PSMF sections and annexes.
- Review feedback from Health Authorities or other external parties and prepare responses and integrate the feedback into Novartis group standards as appropriate.
- Act as a subject matter expert during audits and inspections (e.g., FDA and EMA), lead the preparation of responses to findings and the development and implementation of CAPAs.
- Manage assigned monitoring activities / metrics production: Lead investigations into any deficiencies identified, develop and implement corrective and preventative actions (CAPAs) and measuring the effectiveness of these.
- Collaborate with other Global Line Functions across Novartis Divisions and Third Parties to establish and meet joint accountabilities.
- Ensure that any risks identified through metrics data analysis and reports and are escalated to the Operational Metrics and Risk Committee appropriately.
- Escalation to PS&PV leadership and other global line functions as appropriate and/or External Service Providers (ESPs) of compliance and quality issues.

- Representing Novartis externally as a subject matter expert.
- Support the sharing of best practice with regards to metrics methodologies and mentor associates to develop a stronger understanding of compliance and quality metrics.
- Support as business representative during mergers and acquisitions.
- Train and mentor new PS&PV associates and associates from other global line functions.

Minimum Requirements:

Work Experience:

- Minimum 4 to 7 years of experience in the pharmaceutical industry, particularly pharmacovigilance
- Experience in project management and demonstrated ability to lead working groups in a matrix environment
- Ability to deal and interact with a wide variety of people at all levels.
- Strong organizational skills
- Strong negotiation, presentation and communication skills, and ability to operate effectively in an international environment and across functions
- Strong analytical skills
- Quality focus

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 do here at Novartis!

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here:

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

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?

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Abteilung

Development

Business Unit

Innovative Medicines

Ort

Indien

Website

Hyderabad (Office)
Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited
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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