

# Senior Vigilance Process Manager

Job ID

REQ-10012505

Jul 18, 2024

India

## Summary

End to end management of assigned pharmaco- and devices vigilance processes across Novartis and leadership of cross functional and transformative PS&PV projects to ensure compliance to global regulatory requirements with maximum efficiency.

## About the Role

### Major accountabilities:

- Drive continuous process optimization and simplification by alignment of relevant stakeholders globally and locally and assessing opportunities for streamlining and automation. Lead /support as Senior SME assigned complex cross functional and PS&PV projects, including IT projects/systems, which are of a high priority / criticality to the business. Act as process owner for one or more assigned high complexity/ high impact vigilance process within their functional area:
- Lead active surveillance and analysis of emerging regulations, perform impact assessments and drive process changes required to ensure ongoing compliance to global regulatory requirements. Analyze the impact of other Novartis processes and organizational changes on assigned processes.
- Lead the development, communication strategies and maintenance of respective procedural documents and training materials. Collaborate with other functions to establish requirements for metrics trend analyses, generate knowledge and mitigate any identified risks.
- Act as Subject Matter Expert / consultant to PS&PV associates, Country Organizations and other Global Line Functions on regulatory requirements and assigned business processes. Own and maintain relevant PSMF sections and annexes. Maintain the content of Business Continuity Plans for all respective processes, including IT applications for Key Business Processes.
- Lead development and ensure implementation of new safety database enhancements, new safety case processing conventions and standards for data migrations in response to changes in the regulatory and business environment in collaboration with other stakeholders, as workstream or project lead, as required.
- Act as a subject matter expert during audits and inspections of the vigilance system (e.g., EMA, FDA) and lead preparation of responses to findings and the development and implementation of corrective and preventative actions in alignment with the company strategy.
- Lead collaboration with other Global Line Functions across Novartis and Third Parties to establish and meet joint accountabilities.
- Lead and/or act as business representative during mergers, spin-offs and acquisitions. Represent team in Governance boards and cross-functional forums and deputize for Functional Manager ad-hoc.
- Represent Novartis externally as a subject matter expert; possibly participate and/or join external conferences and networks for respective area of expertise.

**Minimum Requirements:**

- Minimum 6-8 years of experience in the pharmaceutical industry, particularly pharmacovigilance. Experience in medical device vigilance desirable.
- Leadership and (matrix) management experience.
- Ability to lead global and cross-functional work groups and deliver cross-functional initiatives in a matrix environment, deal and interact with a wide variety of people at all levels.
- Strong organizational, analytical and project management skills.
- Strong negotiation and communication skills and ability to operate effectively in an international, matrix environment

**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!

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**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:

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**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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Division

Development

Business Unit

Innovative Medicines

Location

India

Site

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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