Vigilance Process Manager

Job ID
REQ-10059927

8月 17, 2025

India

摘要

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

About the Role

Major accountabilities:

- Drive continuous process improvement through by alignment of relevant stakeholders globally and locally, assessing opportunities for streamlining and automation. Lead assigned complex cross functional and PS&PV projects and support/deputize for transformational projects led by Senior Vigilance Process Managers / Vigilance Process Leads, including IT projects/systems, leading enhancements in alignment with the company and department strategy.
- Collaborate closely with the product owner and product team, to ensure that the product

meets the required standards and is fit for its intended purpose. This involves providing expertise in process management, identifying, and mitigating risks, ensuring compliance with relevant regulations, and facilitating continuous improvement Act as process owner for assigned vigilance processes

- Lead active surveillance and impact assessments on emerging regulations and drive process changes to ensure ongoing compliance to global regulatory requirements.
- Analyse the impact of other Novartis processes and organizational changes on assigned processes. Author and maintain the assigned processes and the associated procedural documents.
- Mentor and train new starters in PS&PV and associates from other Global Line Functions and develop and maintain training material and communications for Novartis and third-party associates.
- Collaborate with other functions to monitor regulatory compliance as well as compliance to internal requirements, measure effectiveness and implement mitigation strategies when required.
- Act as Subject Matter Expert / consultant to PS&PV associates, Country Organizations and other Global Line Functions on regulatory requirements and assigned business process. Own and maintain relevant PSMF sections and annexes.
- Maintain of the content of Business Continuity Plans for all respective processes, including IT applications for Key Business Processes. Lead projects to optimize methodologies and processes used to monitor safety cases and aggregate reports quality: Vigilance Process Manager, PS&PV
- Develop and maintain tools in collaboration with Innovation, Tech & Systems and other Global Line Functions to assist in the monitoring of quality, introducing automation where possible. 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 corrective and preventative actions in alignment with the company strategy. Lead collaboration with other Global Line Functions across Novartis Divisions and Third Parties to establish and meet joint accountabilities. Lead and/or support as business representative during mergers, spin-offs and acquisitions. Represent Novartis externally as a subject matter expert; possibly participate and/or join external conferences and networks for respective area of expertise.

Key performance indicators:

- Assigned processes compliant with international regulations and Novartis standards.
- Successful and timely implementation of assigned process improvements /completion of projects and successful delivery of the associated efficiencies and business benefit.
- Number, timeliness, and quality of deliverables according to established Health Authority directives and internal processes.
- No critical findings from audits/inspections.
- Escalation of risks to Functional Head and risk mitigation measures adequately managed

Minimum Requirements:

- PhD, PharmD, M Pharm, BDS/MDS, BSc, MSc, or equivalent in Life Sciences
- Languages-Fluency in English. Knowledge of other languages desirable.
  Experience/Professional requirement:
- 5-8 years in pharmaceutical industry, especially in pharmacovigilance
- Experience of leading process improvement initiatives.

- Experience in project management and demonstrated ability to lead work groups in a matrix environment.
- ARGUS, Veeva, PV regulations implementation, Inspection, Building business case and Process re-engineering.
- Strong analytical skills Strong organizational skills and ability to work autonomously.
- Case processing, regulatory compliance, Process owner; Stakeholder management, High adaptability, business analysis, executive decision-making
- Strong negotiation, presentation and communication skills, and ability to operate effectively in an international environment and across functions. Ability to mentor and coach. Quality focus

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
India

站点
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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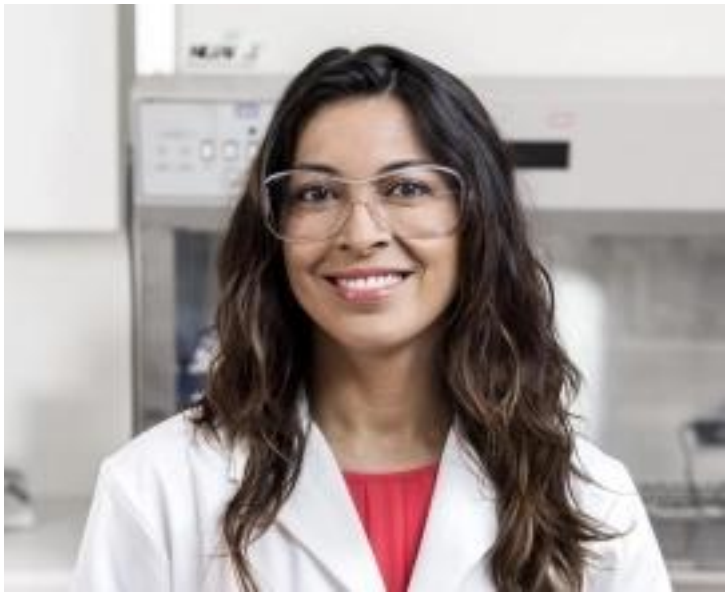
Accessibility and accommodation

Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.india@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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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