Senior Vigilance Process Manager

Job ID
REQ-10053917
Jun 16, 2025
Spain

Summary

LOCATION: Barcelona, Spain
ROLE TYPE: Hybrid Working, #LI-Hybrid

As a Senior Vigilance Process Manager, you will be responsible for end-to-end management of assigned pharmacovigilance processes across Novartis and leadership of cross functional and transformative Patient Safety & Pharmacovigilance (PS&PV) projects to ensure compliance to global regulatory requirements with maximum efficiency.

About the Role

KEY RESPONSIBILITIES

- 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 subject matter expert (SME) assigned complex cross functional and PS&PV projects, including IT projects/systems, which are of a high priority / criticality to the business.
- 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 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 SME / consultant to PS&PV associates, Country Organizations and other Global Line Functions on regulatory requirements and assigned business processes.
  - Own and maintain relevant Pharmacovigilance System Master File (PSMF) sections and annexes.
  - Maintain the content of Business Continuity Plans for all respective processes, including IT applications for Key Business Processes.
- Assume the role of end-to-end process owner when assigned.
- 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 and acquisitions.

ESSENTIAL REQUIREMENTS

- PhD, PharmD, MSc degree or Life sciences degree or equivalent
- Fluency in English. Knowledge of other languages desirable.
- Minimum 6-8 years of experience in the pharmaceutical industry, particularly pharmacovigilance.
- 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
- Quality focus

Why Novartis?
Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

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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.

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? https://www.novartis.com/about/strategy/people-and-culture

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Development
Business Unit
Innovative Medicines
Location
Spain
Site
Barcelona Gran Vía
Company / Legal Entity
ES06 (FCRS = ES006) Novartis Farmacéutica, S.A.
Alternative Location 1
Madrid Provincial, Spain
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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