Vigilance Process Manager

Job ID
REQ-10041111
Feb 25, 2025
Spanien

Summary

Location: Barcelona, Spain
Type: Hybrid working, #LI-Remote.
As a Vigilance Process Manager, you will be responsible for the end-to-end management of assigned pharmaco- and devices vigilance processes across Novartis and leadership of cross functional and Patient Safety (PS) & Pharmacovigilance (PV) projects to ensure compliance to global regulatory requirements with maximum efficiency.

About the Role

KEY RESPONSIBILITIES

- 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
- 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.
- 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.
- Act as a subject matter expert during audits and inspections (e.g. (Food and Drug Administration FDA and European Medicines Agency (EMA)), lead the preparation of responses to findings and the development and implementation of corrective and preventative actions in alignment with the company strategy.

ESSENTIAL REQUIREMENTS:

Education: PhD, PharmD, MSc degree or Life sciences degree or equivalent

Languages: Fluency in English. Knowledge of other languages desirable.

Experience/Professional requirement:

- Minimum 4-6 years of experience in the pharmaceutical industry, particularly pharmacovigilance. Experience in medical device vigilance desirable. (Experience in Clinical Development with an interest in PV will be considered)
- Experience of leading process improvement initiatives.
- Experience in project management and demonstrated ability to lead work groups in a matrix environment.
- Strong analytical skills
- Strong organizational skills and ability to work autonomously
- 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

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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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Functional Area
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Job Type
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Employment Type
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