Senior Vigilance Process Manager

Job ID
REQ-10059480

8月 07, 2025

Spain

摘要

Monitors and audits the company ' s drug, biologics or medical devices surveillance program including the intake, evaluation, processing and follow-up on adverse reports. Participates in the resolution of any legal liability and in complying with government regulations. Ensures accurate receipt, maintenance and assessment against product labeling. Reports events or reactions as required by regulatory agencies including adverse events data from clinical trials, spontaneous or solicited sources, periodic and experience reports. May provide trending and safety signal detection and assessment. Supports all clinical trial activity and post marketing.

About the Role

#LI-Hybrid

Location: Barcelona Gran Via

The Senior Vigilance Process Manager will support the end-to-end management of the assigned pharmaco - and devices vigilance 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. You will drive continuous process optimization and simplification by alignment of relevant stakeholders globally and locally and assessing opportunities for streamlining and automation.

Key requirements

- Ensure the establishment and management of global business processes lifecycle (of PV area of expertise,) by leveraging SMEs knowledge, processes and technology, fostering process performance mindset and developing processes maturity assessment in alignment with the PS&PV strategic business roadmap.
- Drive (when needed) strategy & design authority decision for process changes, including coordination and oversight of change management in collaboration with appropriate SMEs.
- Ensure through SMEs in respective areas the policy & risk controls are effectively in place and process compliance.
- Act as POC of End-to End process that drives process health and continuous improvement for sustained process maturity.
- Act as SPOC for audits and inspections as relevant and based on scope of audit/inspection (e.g. if the scope is on an entire process).
- 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.
- 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.

Essential requirements

- 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.

Desirable Requirements

- Expertise in the pharmaceutical industry, particularly pharmacovigilance. Experience in

medical device vigilance is 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

Commitment to Diversity and Inclusion / EEO paragraph

Novartis is committed to building an outstanding, inclusive work environment and diverse teams ' representative of the patients and communities we serve.

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
Spain

站点

Barcelona Gran V í a

Company / Legal Entity
ES06 (FCRS = ES006) Novartis Farmac é utica, S.A.

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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