External Vigilance Engagement Manager

Job ID
REQ-10011548
Jun 21, 2024
Spain

Summary

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

The **External Vigilance Alliance Manager** provides expertise and advice on pharmacovigilance and / or device vigilance for all ***assigned*** Novartis Enterprise contractual arrangements including Global and Local Vigilance Agreements and Clinical Trial Supply Agreements. You will negotiate and maintain global vigilance agreements with external business partners, managing these global alliances, including oversight of compliance, and acting as key contact person for Development, Patient Safety (PS) & Pharmacovigilance (PV) and external customers.

Your key responsibilities, but not limited to;

- Maintain knowledge of current and developing regulations / guidelines for pharmacovigilance and/or device vigilance and provide expertise and advice to all concerned Novartis line-units and external partners for Novartis Enterprise contractual arrangements, for co-development agreements and full marketing agreements, and including support for Clinical Trial Supply Agreements for individual trials and for local vigilance agreements for Novartis Group Companies, as required.
- Take part in VAPRA activities for new deals as required to assess potential partner PV systems for the impact on Novartis Enterprise.
- Manage assigned global vigilance agreements with external business partners by leading negotiations/negotiating team to define conditions of the agreement with external business partners, guided by the Group Lead or senior EVAM**.**
- Ensure regular contact with key customers to facilitate agreement compliance and good relations, and acting as key contact person for external and internal stakeholders to identify needs and address resolution of issues.
- With the Head External Vigilance Engagements / Group Lead communicate requirements to PS&PV functions and external line-units to ensure compliance with global vigilance agreements; with Head External Vigilance Engagements / Group Lead and Compliance Team, ensure external business partners and PS & PV management are alerted to compliance and reconciliation issues and have oversight of

corrective actions and their effectiveness to improve and maintain a high level of compliance.
- Supervise and control of local vigilance agreements, as required, to adhere to Development PS & PV standards.
- Support and advise PS & PV and concerned Novartis line-units on how to meet vigilance requirements for Clinical Trial Supply Agreements, including compliance monitoring as required.
- Initiate appropriate updates to vigilance agreement in a timely manner; support Head External Vigilance Engagements / Group Lead to ensure that vigilance agreements are implemented as required to maintain regulatory compliance and Development PS&PV standards. En- sure accuracy and up-to-date information of agreements in the vigilance agreement repositories.
- Communicate data configuration requirements to Systems Operations to ensure accurate and complete automatic distribution of case reports to Vigilance Agreement Partners (VAPs) and regularly review and verify expediting requirements in collabo- ration with the Compliance & Quality team.
- Assist in the development, maintenance and training Novartis PS & PV and other concerned departments on worldwide Novartis pharmacovigilance standards & procedures for pharmacovigilance agreements, using internal guidelines, tools and templates.
- Represent External Vigilance Alliance in internal and external meetings as needed, ***guided by senior Group Lead / senior EVAM as required***.
- Support internal Novartis and VAP audits, Novartis audits of VAPs, VAP regulatory inspections, Novartis regulatory inspections.

Desirable requirements:

- Minimum 2 years' experience in clinical safety / (pharmaco)vigilance or in a regulatory / compliance related area including a thorough knowledge of the functional requirements of clinical safety reporting and a clinical safety database.
- Good current knowledge of industry regulations and guidelines in the field of Pharmacovigilance and/or device vigilance.
- Experience in Clinical Trial Safety preferable.
- Strong negotiation/problem solving skills
- Experience and ability to work in matrix cross-functional environments.
- Organizational skills, planning, prioritizing and flexibility to adjust to changing deadlines and priorities; ability to work independently and under pressure.
- Leadership skills for leading meetings, negotiation teams and implementation training.

Educational Background:

Degree in Biomedical Science or related scientific discipline. Higher degree desirable.

Languages:

Fluency in spoken and written English, knowledge of other languages desirable but not required.

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! Imagine what you could achieve here at Novartis!

Commitment to Diversity & Inclusion:

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

Accessibility and accommodation

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

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

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