NOVARTIS

External Vigilance Engagements Lead

Job ID
REQ-10088191
Сен. 25, 2026
Индия

Сводка

Provide expertise and cross functional leadership on pharmacovigilance and/or device vigilance for all assigned Novartis Enterprise contractual arrangements including Global and Local Vigilance Agreements, and Clinical Trial Supply Agreements; and the management of transition of vigilance systems and processes (including for medical devices, and diagnostic portfolios) as part of Mer-gers & Acquisitions, divestments, in and out-licensing and other global strategic projects. Negoti-ate and maintain vigilance agreements with external business partners, managing these alliances, including oversight of compliance, and acting as key contact person for Development, PS&PV and external customers.

About the Role

Major Accountabilities

- Expertise - 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 and Development Integration teams (Transitions), if applicable.
- Strategy/VAP Risk Assessment (VAPRA) – take part in VAPRA activities for new deals as required to assess potential partner's PV systems for the impact on the Novartis Enterprise.
- Negotiation and Alliance Management– Manage assigned vigilance agreements with external business partners by leading negotiations to define conditions of the agreement, *guided by the EVE Director/EVE Associate Director.*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. Initiate appropriate updates to vigilance agreements in a timely manner; support Head EVE / EVE Director to ensure that vigilance agreements are implemented as required to maintain regulatory compliance and Development PS&PV standards. Ensure accuracy and up-to-date information of agreements in the vigilance agreement repository.
- Lead assigned transition projects in PS&PV, which are of high priority/criticality to the business, by implementing the strategy defined in alignment with the Development Integration strategy and assembling the appropriate teams and supervising/directing their work. Escalate to the line function managers as appropriate any potential disruption of the project plan in a timely manner to avoid delays/failures in transition project deliverables. Maintain the project team's awareness of strategic changes in project goals, status, and milestones at all times, as communicated by the Head EVE/ EVE Director.
- Regulatory and Partner Compliance – communicate requirements to PS&PV functions and external line-units to ensure compliance with vigilance agreements and with transition project plan as required; with Head EVE / EVE Director 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.
- Training and communication – 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 Engagements in internal and external meetings as needed,*guided by EVE Director/EVE Associate Director as required*
- Audits and Inspections: support internal Novartis and VAP audits, Novartis audits of VAPs, VAP regulatory inspections, Novartis regulatory inspections, including those covering transition projects

.

Essential Requirement

- Degree in Biomedical Science or related scientific discipline. Higher degree desirable.
- Minimum 2 – 5 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. Candidates should have knowledge of clinical safety-reporting requirements, safety databases and relevant industry regulations. Clinical trial safety experience is preferred, while experience with vigilance agreements, partner management or transition projects would be advantageous.

- Strong interpersonal communication skills and negotiation/problem solving skills
- Experience and ability to work in matrix cross-functional environments

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

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.
Read our handbook (PDF 30 MB)

Дивизион
Development
Business Unit
Development
Место
Индия
Сайт
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

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.

Job ID
REQ-10088191

External Vigilance Engagements Lead

Apply to Job
Job ID
REQ-10088191

External Vigilance Engagements Lead

Apply to Job

Source URL: *https://www.novartis.ru/careers/career-search/job/details/req-10088191-external-vigilance-engagements-lead*

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://www.novartis.com/sites/novartis_com/files/novartis-life-handbook.pdf
3. mailto:diversityandincl.india@novartis.com
4. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Hyderabad-Office/External-Vigilance-Engagements-Lead_REQ-10088191
5. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Hyderabad-Office/External-Vigilance-Engagements-Lead_REQ-10088191