

External Vigilance Engagements Lead

Job ID

REQ-10088191

Sep 25, 2026

LOC_IN

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

Role Requirements

Division

DIV_GD

Business Unit

Development

Location

LOC_IN

Site

Hyderabad (Office)

Company / Legal Entity

IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area

FCT_RD

Job Type

Full time

Employment Type

Regular

Shift Work

No

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