NOVARTIS

Medical Safety Assessments and ESP Engagement Manager

Job ID
REQ-10085040
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Индия
Available in: English

Сводка

-Responsible for the drug surveillance program including the necessary follow-up, risk assessment, and relatedness to product on adverse reaction reports, oversight of safety in clinical trials and post marketing programs. Participates in the resolution of any legal liability and complying with governmental regulations. Provides and contributes trending and safety signal detection and risk management assessment for the products' life cycle. Provides safety support to the clinical development teams.

About the Role

Major Accountabilities:

- Lead and oversee day-to-day MSA & EE operations, ensuring timely and high-quality delivery of all assigned safety and operational activities.
- Drive compliance, inspection readiness, and adherence to global pharmacovigilance regulations, quality standards, and internal procedures.
- Act as deputy for Group Leads when required, including governance participation, MRQC arbitration, decision-making, and operational oversight.
- Provide leadership and accountability for strategic initiatives, ensuring deliverables, timelines, quality outcomes, risk mitigation, and business continuity planning.
- Lead and support safety deliverables for PVA 3 and PVA 4 compounds, ensuring effective execution and stakeholder alignment.
- Identify, drive, and implement continuous process improvements to enhance efficiency, quality, compliance, and operational excellence across safety activities.
- Proactively monitor performance metrics, identify risks and issues, conduct effectiveness checks, and implement corrective actions to ensure sustained operational effectiveness.
- Support pharmacovigilance audits and inspections by contributing to inspection readiness activities, serving as a Subject Matter Expert (SME), and addressing audit findings.
- Collaborate with external service providers (ESPs) and cross-functional stakeholders through governance forums, training, communication, and performance management activities.
- Partner with PS&PV Quality and Clinical Quality teams to implement Quality Plans and ensure timely closure and tracking of all CAPAs arising from audits, inspections, and quality reviews.

Minimum Requirements

- Advanced degree in Healthcare/Life Sciences preferred (MD, MBBS, MSc, PharmD, PhD) with fluency in written and spoken English.
- Minimum 10 years of experience in Drug Safety, Pharmacovigilance (PV) Operations, and/or Project Management.
- Strong expertise in drug safety processes, including procedural documentation, workflow design, and operational excellence.
- Proven ability to lead and collaborate with large cross-functional teams in complex, global initiatives.
- Results-oriented professional with a proactive, accountable, and quality-focused approach, capable of working effectively under pressure.
- Excellent communication, stakeholder management, planning, organizational, and computer skills, with the ability to manage multiple priorities in a dynamic environment.
- Demonstrated leadership capabilities, including mentoring, negotiation, conflict resolution, decision-making, problem-solving, and presentation skills.

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
Alternative Location 1
Telangana, Индия
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.

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