NOVARTIS

Senior Safety Signal Expert

Job ID
REQ-10015917
Jul 18, 2024
India

Resumen

-Performs safety signal detection and triage activities for assigned post-marketing products using internal and external spontaneous reporting databases. Assist in providing input to safety documents, as well as ad hoc Health Authority queries as it relates to automated signal detection. Provide support to the Safety Leads by creating quality deliverables within agreed timeframes and adhering to a high standard of accuracy in compliance with Patient Safety business rules, standard operating procedures and global and local regulatory requirements.

About the Role

.Major Activities

- Perform safety signal detection and triage activities for the assigned product portfolio.
- Work closely with the safety leads for the respective products and support them in monitoring the safety profile of products by performing postmarketing signal detection activities using internal and external spontaneous reporting databases.
- Provide medical evaluation of technical hits in Empirica for assigned products adhering to current processes and timelines. Perform a cumulative assessment at first time occurrence of a hit. Focus on new cases/ Cases with significant follow up information at re-occurrence of a hit.
- Perform signal triage and provide Empirica review results to safety leads within assigned timeframe.
- Present and discuss results of postmarketing signal detection activities at Product Safety Team, SMT/SMB, Joint Safety Committees as appropriate.
- Provide input to MSRB presentations to safety team/ Global Head of Safety Signal Detection.
- Act as a core member of the SMT and support the safety leads on safety management related topics particularly Health Authority database (FAERS/Vigibase/Eudravigilance) related queries .
- Perform database searches in external Health Authority databases (FAERS/ Vigibase), analyzing and reporting the results.
- Perform QC checks of Health Authority database searches done by colleagues.
- Assist in providing safety input to safety documents, as well as ad hoc Health Authority queries as it relates to postmarketing signal detection activities (e.g. input from Eudravigilance data to PSURs).
- Act as Subject Matter Expert (SME) for postmarketing Safety Signal Detection (participation in initiatives). Monitor the Eudravigilance database for assigned products, if required.
- Mentors newly recruited junior colleagues by supporting their integration into the Safety Signal Expert role.

Minimum Requirement

- Medical Degree (MBBS or MD) required. Medical degree with specialization preferred.

- 3+ years of PV, Medical practice or Clinical Drug Development experience post MBBS.
- Experience in safety document or medical writing including experience coding with MedDRA and WHO dictionaries.
- Excellent understanding of ICH GCP , GVP guidelines and medical terminology
- Attention to detail and quality focused
- Strong organizational and project management skills
- Strong negotiation and communication skills, and the ability to operate effectively in an international environment
- Excellent understanding of Human physiology, pharmacology, clinical study objectives, and the drug development process
- Strong technical understanding of Biomedical/Biostatics concepts and problem solving skills
- Good presentation skills
- Strong computer skills including, but not limited to, creation of spreadsheets, templates, presentations and working with safety databases/applications.
- Ability to work independently, under pressure, demonstrating initiative and flexibility through effective innovative leadership ability.
- Ability to mentor, and coach within Patient Safety and cross functionally

Why Novartis?

Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

You'll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. https://www.novartis.com/careers/benefits-rewards Commitment to Diversity and Inclusion: 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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Development
Business Unit
Innovative Medicines
Ubicación
India
Sitio
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
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Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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