NOVARTIS

Medical Safety Expert

Job ID
REQ-10020964
Sep 06, 2024
India

Summary

Provide support for medical safety management within the Patient Safety & Pharmacovigilance department, including medical review and assessments of Individual Case Safety Reports (ICSR), aggregate reports, co-authoring safety
documents, assisting in providing safety input to regulatory and clinical documents, as well as ad-hoc Health Authority queries. Provide support to the safety lead 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.
Provide support to defines, develop and implement metrics, standard and tool to oversee efficiently the performance of the Pharmacovigilance and Medical Devices Vigilance system in regard to medical review of safety cases and management of safety signals.

About the Role

Major accountabilities:

• Perform medical review of ICSRs including (SUSARs, cases from special countries), assessment of Literature cases and authoring of enhanced MAC.
• Support safety lead for authoring medical assessment letters based on the bi-annual/six monthly line listing.
• Perform literature review of assigned articles (CQC, pre-screening and SICO) and assist safety lead in review of articles for inclusion in PBRER, DSUR, IB etc.
• Provide rotating support to the TAs as per the business needs, (i.e. co-authoring safety documents, assisting in providing safety input to regulatory and clinical documents).
• Assist the TA Safety Leads in monitoring the safety profile of products including but not limited to the activities such as literature review, medical review of individual cases, including collecting additional follow-up information as necessary, medical evaluation of quality defects.
• Together with the Safety Leads, co-author of the PBRER. Provides medical inputs to the sections 9, 15, 16, 17, 18, including analytical input to PBRER for risks defined in the RMP. Perform follow up activities on HA assessment reports.
• Co-authors and contributes to the medical sections of Development Safety Update Report (DSUR), Investigator Brochures (IB), labelling documents (e.g. CDS, (SMPC, USPI, Japanese PI), Product Guidance Documents (PGD)
and Expert Statements.
• Supports the preparation and review of Investigator Notifications (INs).
• Provide support signal detection and signal evaluation activities for assigned products.
• Provide support for the preparation of Health Authority queries.

• Assists Safety Leads in evaluating and writing other safety related documents including but not limited to Clinical Overview, Development Safety Profiling Plan (d-SPP) and RMP.
• Provides safety input to Addendum to Clinical Overview (ACO) for license renewal.
• Provides support as needed for new indication submission (regulatory document safety input).
• Supports the safety lead for preparation and participation on internal review meetings like, SMT, MSRB and GLC.
• Act as Subject Matter Expert (SME) for Medical Function process and provide support during audit and inspections.
• Collaborate with other Global Line Functions across Novartis and Third Parties to meet joint accountabilities.
• Contribute to PV&PV initiatives as well as cross-functional projects to optimize medical review processes and quality.
• Contribute to development and optimization of training materials. Deliver training to the Novartis staff and external.

Minimum Requirement :

• Bachelor of Science in Pharmacy /Bachelor of Science in Nursing / PharmD/PhD in relevant field or Medical Degree (MBBS or MD) required. Minimum 3yrs of experience in the pharmaceutical industry or related. Experience in safety document or medical writing including experience coding with MedDRA and WHO dictionaries.
• Excellent understanding of clinical trial methodology, ICH GCP, GVP guidelines
and medical terminology
• Attention to detail and quality focused
• Strong organizational and project management skills
• Strong 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.

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

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

Division
Development
Business Unit

Innovative Medicines
Location
India
Site
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
Apply to Job

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.

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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