Senior Safety Case Expert

Job ID
REQ-10037915
Febr. 05, 2025
Indien

Zusammenfassung

Responsible to ensure case processing and ancillary activities in compliance with PS&PV business rules, standard operating procedures and regulatory requirements. Responsible for preparation and maintenance of manuals and other relevant/assigned documents Subject matter expert for cross-sub functional projects within PS&PV
Lead implementation of new process and process amendments/changes

About the Role

Major Accountabilities

- Monitor all case processing related activities to facilitate oversight on External Service Providers (ESP's) quality and compliance of deliverables
- Evaluation and QC of Serious Adverse Event / Post Marketing Adverse Event to ensure accurate and consistent data entry and processing from source documents, with emphasis on accuracy, timeliness and quality. Perform Argus data entry as needed.
- Perform daily quality review (QR) for Individual Case Safety Reports (ICSR) by comparing source documents and the case information entered the safety database to ensure accurate and consistent data entry/quality. Coach/Train/Mentor other team members including ESPs, as required
- Lead/support the process changes according to internal and externals drivers, including development and monitoring of process related metrics
- Lead the preparation and maintenance of manuals and other relevant/assigned documents
- Participate in the creation and maintenance of training material and communications for Novartis and ESPs.
- Act as Subject Matter Expert / consultant to PS&PV associates, Country Organizations and
- other Global Line Functions on regulatory requirements and assigned business process.
- Develop, contribute and maintain guidance documents including providing inputs to Vigilance Agreement (VA) and other such safety management plans
- Support in audits/inspection as Subject Matter Expert, and develop and implement Corrective and preventative Actions (CAPA) to address safety findings
- Assess and analyze case processing related queries from Health Authorities and prepare and share the

responses within the timelines.

- Support in-collaboration with other functions within PS&PV to facilitate process improvements
- Collaborate with Data Management team to enable reconciliation for locking of Clinical database
- Alert the Medical Safety Physicians of potential safety issues and assist the Medical Safety Physicians in monitoring the safety profile of products.
- Work with Novartis country safety departments, License partners and medical function to ensure that reports are accurately collected, evaluated and data based. Lead the testing activities for case processing related safety systems/IT applications.
- Lead PS&PV Operational Projects and support high complex/critical projects or database validation activities as required .

Minimum Requirements:

- Graduate/Postgraduate/Doctorate degree in Life Sciences/Pharmacy/Medical Sciences or equivalent degree.• 8+yrs of Industrial experience with 3 to 5 years of experience in drug safety / Development or closely related areas of responsibility
  • Good professional verbal and nonverbal communication skills
  • Experience in Document writing desirable
  • Self-motivation and proactive stance to work
  • Sense of urgency and commitment for timely completion of activities
  • Previous Pharmacovigilance data entry experience is desirable.
  • Strong negotiation and ability to operate effectively in a global environment and across line functions.

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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IN10 (FCRS = IN010) Novartis Healthcare Private Limited
Functional Area
Research & Development

Job Type
Full time
Employment Type
Regular
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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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