Medical Safety Expert

Job ID
REQ-10063803

11月 03, 2025

India

摘要

-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:

- Provides support according to the needs for delivery activities, i.e. co-authoring safety documents and assisting in providing safety input to regulatory and clinical documents, as well as ad hoc Health Authority queries.

- Assist in monitoring the safety profile of products including with activities such as literature review, medical review/evaluation of individual cases or signal detection.
- Perform literature review -Provide support for the preparation of ad hoc Health Authority queries for TAs, also in particular for short term notice requests.
- Perform follow up activities on Health Authority Assessment Reports.
- Assist in providing safety input to Regulatory Affairs and clinical documents.
- Support maintenance and management of local deviations -Assist in evaluating and writing other safety deliverables as assigned -Provide support as needed for new indication submission (regulatory document safety input).
- Prepare responses to internal safety requests and contribution to responses to external safety queries.
- Act as Subject Matter Expert (SME) for Medical Operations/ Medical Function -Lead the training and mentoring of junior team members/colleagues -Distribution of marketing samples (where applicable)

Key performance indicators:

- Timeliness and quality of safety analyses, interpretations, and presentations -Compliance with internal and external regulations and procedures -Compliance, consistency and quality of safety deliverables

Minimum Requirements:
Work Experience:

- People Challenges.
- Managing Crises.
- Functional Breadth.
- Collaborating across boundaries.
- Operations Management and Execution.
- Project Management.

Skills:

- Clinical Research.
- Clinical Trials.
- Functional Teams.
- Literature Review.
- Medical Records.
- Process Safety.
- Regulatory Compliance.
- Safety Science.

Languages :

- English.

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部门
Development

Business Unit
Development

地点
India

站点
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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