Medical Safety Lead

Job ID
REQ-10052016

6月 06, 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:

- Monitors the clinical safety of projects /products including activities such as literature review, evaluation of individual cases or signal detection, and responds to safety related questions appropriately .

- Performs medical assessment and related activities for cases whenever required, including collecting additional follow-up information as necessary, medical evaluation of product quality defects with adverse events, review of line listings of single cases, and preparation of investigator notifications and periodic medical assessments for ethics committees.
- Identifies safety signals based on the review of solicited or unsolicited single cases.
- Performs signal detection, monitoring and evaluation of all safety signals.
- Provides inputs into responses to inquiries from regulatory authorities or health care professionals on safety issues.
- Prepares safety data for Health Authority review boards.
- Provides inputs to responses for legal queries and Country Organization requests involving safety issues.
- Provides expert evaluation on the clinical context of adverse event reports, assessment of the medical conditions, and the implications on Novartis products.
- Collaborates productively on clinical safety tasks with colleagues from Clinical Development, Regulatory Affairs, Medical Affairs, Medical Information, Statistics, Safety Data Management, Epidemiology and other related departments.
- Contributes to the development of departmental goals and objectives.
- 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.
- Critical Negotiations.
- People Leadership.
- Collaborating across boundaries.
- Operations Management and Execution.

Skills:

- Clinical Trials.
- Functional Teams.
- Literature Review.
- Management Skills.
- Medical Information.
- Medical Records.
- Medical Strategy.
- Pharmacovigilance.
- Regulatory Compliance.
- Risk Management.
- Safety Science.

Languages :

- English.

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部门
Development

Business Unit
Innovative Medicines

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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