Medical Safety Lead

Job ID
REQ-10033097

12月 18, 2024

Switzerland

摘要

In close collaboration with the Global Program Safety Lead (GPSL) provides robust safety evaluation expertise and medical innovation in order to improve patients ’ lives and impact on overall Novartis results. As a member of the Medical Safety organization, prioritizes the safety of patients, ensures optimal patient safety for assigned compounds and shares responsibility for the integration, analysis, and evaluation of internal and external safety information through product lifecycle management.

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 based on single cases and aggregate data using proper signal detection tools.
- 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.
- May support the GPSL and the Senior Medical Safety Lead in submission activities as required by providing pharmacovigilance inputs to initial development and updates of core data sheet (CDS) and its related documents. In this context, the Medical Safety Lead may deputize for the Senior Medical Safety Lead for the preparation of safety documents (e.g. summary of clinical safety, clinical overview) for review by GPSL.
- Prepares medical input to aggregate clinical safety regulatory reports.
- Provides inputs and collaborates on preparation of Safety Profiling Plan (SPP) and Risk Management Plan (RMP) updates.
- Provides guidance as appropriate to Clinical and Pharmacovigilance Operations for the coding and causality/expectedness assessment of adverse event reports.
- 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.
- Provides safety inputs for clinical and regulatory deliverables including clinical study protocols, clinical study reports, and investigator brochure.
- Provides relevant inputs for Global Program/Brand Team (GPT/GBT), Global Clinical Team (GCT), and Clinical Trial Team (CTT) meetings as needed.
- Provides support as needed for licensing activities, regulatory authority inspections and for project/product recall activities.
- Contributes to the development of departmental goals and objectives.

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
- Ability to work effectively within a matrix organization

Minimum Requirements:
Work Experience:

- At least 4 years in drug development in a major pharmaceutical company, including 2 years in patient safety at an operational or medical position (or equivalent experience) .
- Experience in drug development, clinical trial methodology, regulatory requirements, scientific methodology, statistics and writing of publications is desirable.
- Proven ability to analyze, interpret, discuss, and present safety information

- Experience in preparing or contributing to preparation of clinical safety. assessments and regulatory reports involving safety information

Education:

Bachelor of Science in Pharmacy / Bachelor of Science in Nursing / PharmD / PhD in relevant field or Medical Degree (MBBS or MD) required. Medical degree with specialization preferred. Medical degree is essential for associates performing medical review of single case reports whenever business needs require this activity.

Languages :

- Fluent in spoken and written English.

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部门
Development

Business Unit
Innovative Medicines

地点
Switzerland

站点
Basel (City)

Company / Legal Entity
C028 (FCRS = CH028) Novartis Pharma AG

Alternative Location 1
Barcelona Gran V í a, Spain

Alternative Location 2
Hyderabad (Office), India

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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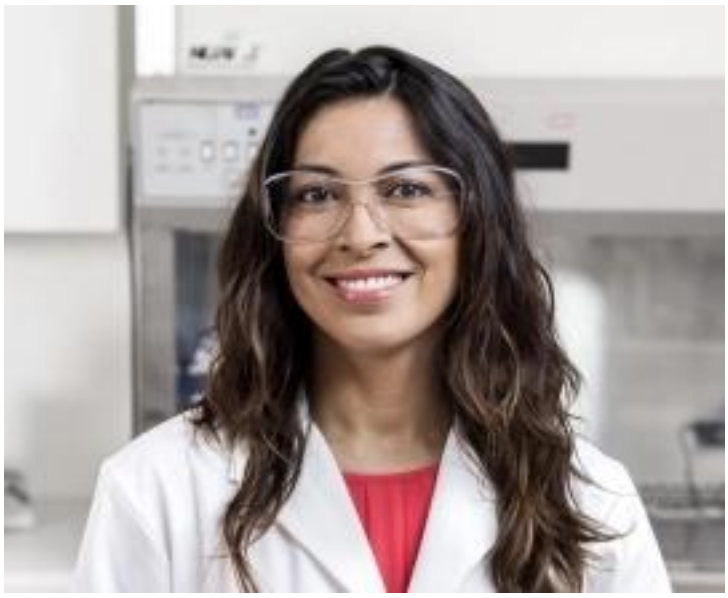

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