Group PV Head

Job ID
REQ-10043810
März 10, 2025
China

Summary

-Monitors and audits the company’s drug, biologics or medical devices surveillance program including the intake, evaluation, processing and follow-up on adverse reports. Participates in the resolution of any legal liability and in complying with government regulations. Ensures accurate receipt, maintenance and assessment against product labeling. Reports events or reactions as required by regulatory agencies including adverse events data from clinical trials, spontaneous or solicited sources, periodic and experience reports. May provide trending and safety signal detection and assessment. Supports all clinical trial activity and post marketing.

About the Role

Major accountabilities:

- End to end management of assigned pharmacovigilance processes across Novartis Divisions -Responsible for ensuring compliance to global regulatory requirements with maximum efficiency -Lead assigned cross functional patient safety projects -Author and maintain procedural documents for assigned processes and drive continuous improvement by alignment of relevant stakeholders globally and locally -Develop and maintain training material and communications for Novartis group and third party associates -Support impact assessments on emerging regulations and ensure ongoing compliance to global regulatory requirements -Lead assigned process improvement initiatives including IT projects/systems (leading enhancements and managing releases) -Analyze the impact of other process and organizational changes -Work in collaboration with other functions to produce compliance reports and complete quality checks to monitor regulatory compliance as well as compliance to internal requirements.
- In the case of any delays, investigate the root cause and develop and implement corrective and preventative actions.
- Measure effectiveness of actions taken -Act as a subject matter expert during audits and inspections (e.g. FDA and EMA), lead the preparation of responses to findings and the development and implementation of corrective and preventative actions.
- Resolve queries from other functions and Country Organizations (COs) related to assigned processes and act as a consultant on regulatory requirements.
- Mentor and train new starters -Distribution of marketing samples (where applicable)

Essential Requirements:
•Health Care Sciences Professional (Medical background, e.g. Medical Doctor is preferred) degree or equivalent training and experience
•At least 5 years experience in pharmacovigilance
or at least 2 years safety/PV physician, clinical physician, or medical affairs experience

Desirable Requirements:
•Project management skills
•Excellent communications and negotiation (networking) skills
•Safety Science, Medical Science
•AI technic
•Fluent in both written and spoken English
•Fluent in both written and spoken local language

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

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/sites/novartis_com/files/novartis-life-handbook.pdf

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Division
Development
Business Unit
Innovative Medicines
Standort
China
Site
Shanghai (Shanghai)
Company / Legal Entity
CN14 (FCRS = CN014) China Novartis Institutes for BioMedical Research Co., Ltd.
Functional Area

Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

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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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