Medical Safety Expert

Job ID
REQ-10063803

10月 08, 2025

India

摘要

负责药物监控计划，包括不良反应报告的必要随访、风险评估和产品相关性、临床试验安全监督以及上市后计划。参与解决任何法律责任并遵守政府法规。为产品的生命周期提供并贡献趋势和安全信号检测和风险管理评估。为临床开发团队提供安全支持。

About the Role

Major Accountabilities

-根据交付活动的需求提供支持，即共同撰写安全文件，协助为监管和临床文件以及临时卫生局查询提供安全输入。
-协助监控产品的安全状况，包括文献综述、个别病例的医疗审查/评估或信号检测等活动。
-执行文献评论
-支持为卫生局准备特别查询，特别是短期通知请求。
-就卫生当局评估报告开展后续活动。

-协助为监管事务和临床文件提供安全输入。支持本地偏差的维护和管理
-协助评估和编写分配的其他安全交付成果
-根据需要为新指示提交监管文档安全输入提供支持。
-准备对内部安全请求的响应和对外部安全查询响应的贡献。
-担任医疗运营/医疗职能的学科专家SME）
-领导初级团队成员/同事的培训和指导
-营销样本的分发如适用）

Key Performance Indicators

- 安全分析、解释和演示的及时性和质量
- 遵守内部和外部法规和程序
- 安全交付成果的合规性、一致性和质量

Work Experience

运营管理和执行
项目管理
跨界协作
职能广度
人员挑战
管理危机

Skills

临床研究
过程安全
法规遵从性
职能团队
安全科学
文献综述
病案
临床试验

Language

英语

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

Benefits and Rewards: Read our handbook to learn about all the ways we ’ ll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

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
正式

Shift Work
No

Apply to Job

Accessibility and accommodation

Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.india@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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