Medical Safety Expert

Job ID REQ-10063803

11月 03, 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

Language

英语

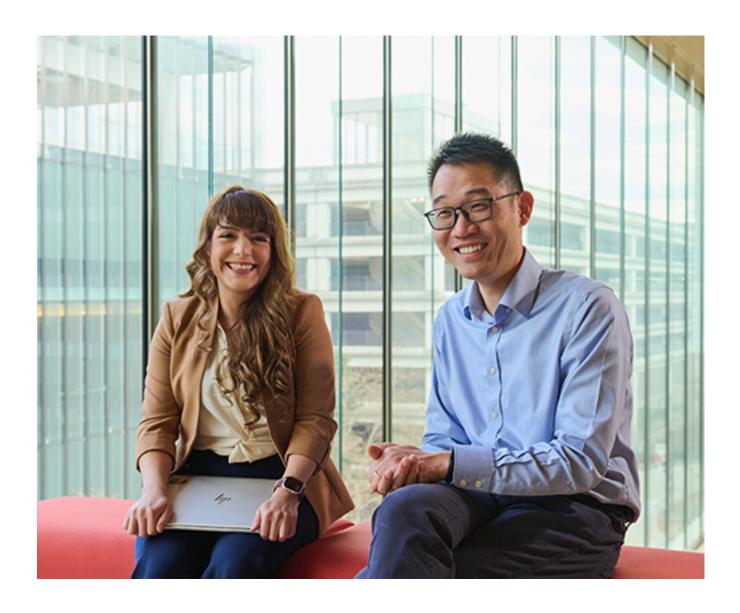
Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? https://www.novartis.com/about/strategy/people-and-culture

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| 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 |

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