

Associate Submission Manager

Job ID
REQ-10015168

8月 12, 2024

India

摘要

确保受控的文档系统,记录保留和信息服务,包括符合法规要求的电子记录保留流程。确保符合监管机构的要求。维护技术和非技术文档更改系统。确保程序到位,以分类和维护记录。解释和执行所有文档格式,标准,政策和操作程序要求。可以识别提交组件,传达文档标准并协调监管档案的汇编。可以分析和评估数据,提取相关信息,准备信息摘要和所搜索材料的执行摘要。可以保持对产品信息的广泛了解,并与当地,区域和部门客户保持持续联系。

About the Role

Major Accountabilities

- 管理中小型全球监管提交项目。
- 为开发、注册和维护全球产品所需的技术相关监管战略、情报和知识提供提交和贡献。
- ~
- 促进战略和技术投入/支持,推动全球系统、工具和流程的实施,以支持全球发展项目和/或营销产品。

- 频繁的内部公司和外部联系人。代表特定项目的组织
- 在分析情况或数据需要审查各种因素的情况下,对中等范围的问题进行工作。
- 在收到诺华产品后24小时内报告与诺华产品相关的技术投诉/不良事件/特殊情况
- 营销样本的分发(如适用)

Key Performance Indicators

确保受控的文档系统,记录保留和信息服务,包括符合法规要求的电子记录保留流程。确保符合监管机构的要求。维护技术和非技术文档更改系统。确保程序到位,以分类和维护记录。解释和执行所有文档格式,标准,政策和操作程序要求。可以识别提交组件,传达文档标准并协调监管档案的汇编。可以分析和评估数据,提取相关信息,准备信息摘要和所搜索材料的执行摘要。可以保持对产品信息的广泛了解,并与当地,区域和部门客户保持持续联系。

Work Experience

运营管理和执行

项目管理

跨界协作

职能广度

跨文化经历

Skills

生命科学

临床研究报告

法规遵从性

文档管理

卓越运营

数据分析

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
Biomedical Research

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

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Accessibility and accommodation

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