

Global Regulatory Manager

Job ID
REQ-10063787

10月 06, 2025

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。解释并执行所有文档格式、标准、策略和操作规程要求。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

- 管理多个大型和复杂的全球监管提交项目。
- 制定和提供提交材料,为开发、注册和维护全球产品所需的技术相关监管战略、情报和知识做出贡献

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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。
-经验丰富的专业人才,对专业领域有充分的了解:以创造性的方式解决广泛的问题。这份工作是一个完全合格、面向职业、具有旅行水平的职位。
-解决不同范围的问题,分析数据需要评估可识别因素。
-在选择获取解决方案的方法和技术时表现出良好的判断力。
-在自己的专业领域拥有高级内部和外部人员的网络。
-贡献许多成本中心的目标和目标:可能有助于服务线目标
-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。解释并执行所有文档格式、标准、策略和操作规程要求。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
管理危机

Skills

生命科学
法规遵从性
文档管理
项目管理
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

Development

Business Unit

Universal Hierarchy Node

地点

India

站点

Mumbai (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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