NOVARTIS

# Regulatory Affairs Associate

Job ID
REQ-10083967
июл 22, 2026
Индия
可用于: 中文 | Deutsch | English | Español | Français | Italiano | 日本語 | Nederlands | Русский | Slovenščina | Türk

### Сводка

为Novartis以及区域/全球组织提供有效的运营和监管支持，以进行指定的监管提交和维护活动，包括编制和提交监管文件、维护监管数据库和档案及艺术品相关活动。

### About the Role

Major Accountabilities

~ 协调并为指定产品编制高质量的监管文件以供提交
~ 在指定日期完成CTA/NDA提交；
~ 在指定日期获得CTA、NDA和其他相关补充申请的批准；
~ 确保按时提交和批准许可证续签；
~ 确保CMC/BPI/PSUR/RMP符合NMPA法规和Novartis内部政策；
~ 确保注册主文件更新
~ 协助协调与CFDA / CDE进行面对面会议，以讨论新项目
~ 及时顺利传达卫生局提出的问题；
~ 及时更新注册状态并将其传达给部门经理
~ 及时预订并跟踪注册样本、档案、证书…；
~ 开始与主要利益相关方建立良好的沟通和关系。
~ 熟悉公司和部门标准操作程序（SOP）和工作程序
~ 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

~按时、按质完成指定任务。
~遵守法规和内部程序
~ Relevant databases and archives up~to~date.

Work Experience

~运营管理和执行
~项目管理
~职能广度
~跨文化经历

Skills

~数据库
~项目规划
~临床试验
~协作
~生命科学
~注重细节
~法规遵从性

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

**Benefits and Rewards:** Learn about all the ways we'll help you thrive personally and professionally.
Read our handbook (PDF 30 MB)

Дивизион
Development
Business Unit
Development
Место
Индия
Сайт

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

### 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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### Regulatory Affairs Associate

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