

Global Program Regulatory Manager Japan

Job ID

REQ-10076025

Apr 16, 2026

LOC_JP

About the Role

Major Accountabilities

- ~ 根据注册计划，通过具有商业吸引力的标签实现最佳产品注册
- ~ 根据当地法规/法律/准则、公司战略和全球合规性，维护并保护 CMC/CDS/安全更新方面的产品许可证
- ~ 确保遵守 NP4、KRPIA 行为准则、相关 CPO 活动的相关法规和法律（龙更新、RMP、包装材料、促销材料/活动、PMS/药物安全报告等）
- ~ 促进和保持与内部和外部利益相关者之间的良好关系
- ~ 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

贡献和支持提交产品注册，进度报告，补充，修订和/或定期经验报告的发展。支持该部门的所有注册活动，以确保符合当地药品监管环境的要求。

Work Experience

- ~运营管理和执行
- ~项目管理
- ~职能广度
- ~跨文化经历

Skills

- ~分析能力
- ~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

Role Requirements

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 \(PDF 30 MB\)](#)

Division

DIV_GD

Business Unit

Development

Location

LOC_JP

Site

Toranomon (NPKK Head Office)

Company / Legal Entity

JP05 (FCRS = JP005) Novartis Pharma K.K.

Functional Area

FCT_RD

Job Type

Full time

Employment Type

正式

Shift Work

No

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