NOVARTIS

Senior Global Program Regulatory Manager Japan

Job ID
REQ-10076554
апр 27, 2026
Япония

Сводка

シニアGPRM-Jとして、医薬品の開発段階から市販後に至るまでの薬事戦略を主導・支援し、日本における最適な承認取得および製品維持を実現する。日本およびグローバルの規制環境に精通した専門性を活かし、PMDA等の規制当局との信頼関係を構築するとともに、クロスファンクショナルおよびグローバルチームと連携し、ノバルティスの事業価値最大化に貢献する。また、業界活動や後進の育成を通じて、ノバルティス・ジャパンのリーディングカンパニーとしての地位確立を支える。

About the Role

Major Accountabilities

For the following activities, lead own products and support/aid manager GPRM-J/GPRM-J for other products to solve complicated issues/problems.

- Developing innovative and high quality regulatory strategies to facilitate regulatory processes in development

- Ensure registration with optimized labels that contribute to health and welfare of the Japanese nation.

- Take regulatory actions to maintain products marketed in Japan.

- Ensure adherence to regulations, guidelines and global/internal procedures as required.

Establish mutual-trust relationship with the Japanese HAs and obtain high credibility.

Leadership and direct/indirect involvement in the industry activities to lead the regulatory discussion in complying with Novartis's wishes.

Key Performance Indicators

Achieve planned submission and approval score

Obtain preferable outcomes of PMDA consultation in development phase projects

No critical problem for maintaining post marketing products

Fulfill regulatory responsibilities in Japan to the GPT and RA sub-team, and support manager GPRM-J/GPRM-J to achieve registration with the best possible labeling

Issue the Japanese regulations/requirements which Novartis's wishes are reflected

Work Experience

1. 10 years or more experience in pharmaceutical industry, and demonstrate extensive knowledge in drug development/maintenance and global regulatory environment.

2. Possess extensive knowledge of Japanese regulation and enough skills beyond own TA to apply the knowledge into actual product development and maintenance of post marketing product.

3. Integrate scientific issues from a regulatory standpoint across line functions to generate development options.

4. Provide advices to senior management and advocate a course of actions assessing the potential impact of emerging pharmaceutical affairs law, regulations and guidelines affecting Novartis pipeline and portfolio.

5. Possess extensive knowledge of the Japanese HAs management, structures and organizations, and maintain trustful working relationship with the Japanese HAs.

6. Possess extensive scientific knowledge of RA Unit.

7. Coach manager GPRM-J/GPRM-J on drug development.

8. Contribute to discussions on licensing conditions and integrate legal considerations into regulatory strategy.

9. Define internal procedures for complying with effective regulatory requirements and enhancing quality and efficiency of the processes.

10. Effectively negotiate with cross functional teams and lead an agreement in the optimal solution, and manage internal/external negotiation on development strategies and business critical issues.

11. Discuss local regulatory strategies at global level in English.

12. Contribute drug development planning by integrating expertise in the regulatory, legal and business environments.

13. Have the ability to participate in industry group activities as a representative of the Novartis Japan, and ex-press opinions positively and lead the industry's other members.

Language

Fluent English as business language

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
Япония
Сайт
Toranomon (NPKK Head Office)
Company / Legal Entity
JP05 (FCRS = JP005) Novartis Pharma K.K.
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No

利便性と合理的配慮

ノバルティス は 障害 を 持 つ 個人 と 協力 し、 合理的配慮 を 提供 することをお 約束 します。健康状態 や 障害 を 理由 に 採用 プロセス のいかなる 部分 においても、あるいは 職務 の 必須事項 を 果 たすた めに 合理的配慮 が 必要 な 場合 は midcareer-r.japan@novartis.com 宛 てに 電子 メール をお 送 りください。その 際 ご 依頼内容、 ご 連絡先、求人票 の 番号 を 明 してください。

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