

Manager, Global Program Regulatory Manager (GPRM) Japan

Job ID
REQ-10027926

10月 31, 2024

Japan

摘要

Contribute to the overall activities in drug development* toward obtaining the marketing authorization and maintenance activities of post marketing products in assigned TA area.

* Drug development including development of drug, medical device, companion diagnostics and tissue-engineered medical products

About the Role

Major accountabilities:

- Assist developing innovative and high quality regulatory strategies to facilitate regulatory processes in development and ensure registration with optimized labels that contribute to health and welfare of the Japanese nation.
- Contribute to the regulatory activities in day-to-day operations for assigned TA area.
- Lead cross functional communication for preparing and finalizing Japanese labeling for new

drugs.

- Lead regulatory related actions to maintain post marketing products in Japan.
- Establish strong relationship with the Japanese HA and obtaining high credibility in responsible projects.
- Ensure adherence to regulations, guidelines and global/internal procedures as required.
- Represent RA within specific internal discussions across line functions and external industry meetings.
- Mentor RA associates on drug development.
- Ensure adequate reporting of adverse events / technical complaint / compliance issue in accordance with company procedures.
- 100% timely delivery of all training requirements including compliance.

Key performance indicators:

- Achieve planned submission and approval in time in responsible projects.
- Obtain preferable outcomes of PMDA consultation in development phase projects for which the GPRM-J is responsible.
- No critical problem for maintaining post marketing product in responsible projects.
- Fulfil regulatory responsibilities in Japan to the GPT/GBT and RA subteam, and achieve registration with the best possible labeling.

Minimum Requirements:

Work Experience:

- Train and mentor RA members concerning drug development.
- Understand varied knowledge of Japan regulation.
- Possess extensive knowledge of MHLW/PMDA management, structures and organizations, and maintain trustful working relationship with MHLW/PMDA.
- Contribute to discussions on licensing conditions and integrate legal considerations into regulatory strategy.
- Possess extensive scientific knowledge of assigned TA/disease area, and facilitate scientific interactions between experts relevant for drug development/maintenance.
- Address scientific issues across line functions and implement action plans.
- Define internal procedures for complying with effective regulatory requirements and enhancing quality and efficiency of the processes.
- 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.
- Excellent in effectively making presentation to clarify discussion items and raise key points to focus on in English.
- Contribute drug development planning by integrating expertise in the regulatory, legal and business environments.
- Possess extensive knowledge of global regulatory environment, and take appropriate actions to resolve issues identified in the projects that may negatively affect development strategy and progress.

Education :

- Degree in pharmacy, medicines, science, agriculture and/or pharmaceutical engineering discipline required. Advanced degree (Master Degree, PhD, etc.) preferred.

- Pharmacist license preferred.

Languages :

- 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: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: <https://www.novartis.com/sites/novartiscom/files/novartis-life-handbook.pdf>

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.china@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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>. You can follow us via Novartis Recruitment WeChat Official Account and Novartis Recruitment WeChat Video Account.

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
Innovative Medicines

地点
Japan

站点
Head Office (Japan) (Pharmaceuticals)

Company / Legal Entity
JP05 (FCRS = JP005) Novartis Pharma K.K.

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

[Apply to Job](#)

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 midcareer-r.japan@novartis.com and let us know the nature of your request and

your contact information. Please include the job requisition number in your message.

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.



Job ID
REQ-10027926

Manager, Global Program Regulatory Manager (GPRM) Japan

[Apply to Job](#)

Source URL:

<https://www.novartis.com.cn/careers/career-search/job/details/req-10027926-manager-global-program-regulatory-manager-gprm-japan>

List of links present in page

1. <https://www.novartis.com/about/strategy/people-and-culture>
2. <https://www.novartis.com/sites/novartiscom/files/novartis-life-handbook.pdf>
3. <mailto:diversityandincl.china@novartis.com>
4. <https://talentnetwork.novartis.com/network>
5. <https://www.novartis.com/about/strategy/people-and-culture>
6. <https://talentnetwork.novartis.com/network>
7. <https://www.novartis.com/careers/benefits-rewards>
8. <https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Head-Office-Japan-Pharmaceuticals/Manager--Global-Program-Regulatory-Manager--GPRM--JapanREQ-10027926-2>
9. <mailto:midcareer-r.japan@novartis.com>
10. <https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Head-Office-Japan-Pharmaceuticals/Manager--Global-Program-Regulatory-Manager--GPRM--JapanREQ-10027926-2>