# Manager, GPRM Japan

Job ID REQ-10057720

7月 13, 2025

Japan

### 摘要

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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.
- Take regulatory related actions to maintain post marketing products in Japan.
- Establish goodrelationship with the Japanese HA in responsible projects
- Contribute to the adherence to regulations, guidelines and global/internal procedures.
- Ensure adequate reporting of adverse events / technical complaint / compliance issue in accordance with company procedures
- 100% timely delivery of all training requirements including compliance

#### **Education:**

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

# Experience/Professional requirement:

- Demonstrate good presentation skills in delivering clear messages to audience and modifying language and style to meet the needs from audience.
- Understand the drug development/maintenance processes,

milestones in the assigned disease area and Novartis procedures for decision board review and approval.

- Understand basic knowledge of Japan regulation
- Possess basic knowledge of global regulatory environment, and contribute to elaborating the project specific development/regulatory strategy and plan.
- Report and summarize discussions in which RA plays an important role. Good in writing and reading English (e.g. exchange of scientific and technical information by e-mail and generation of scientific and technical documentation).
- Proactively communicate issues and potential solutions.
- Provide updates on current situation, and ensure that the same information is disseminated throughout the organization as needed.
  Network with others and share information.
- Demonstrate cultural awareness and work in cross cultural environment.

# English Skill:

Fluent English as business language.

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#### 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 diversity and incl. 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.

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Be aware of fake job advertisements and job offers

Novartis is aware of employment scams which make false use of our company name or leader's names to defraud job seekers. Novartis does not make job offers without interview and never asks candidates for money.

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部门 Development

Business Unit Universal Hierarchy Node

地点 Japan

站点

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

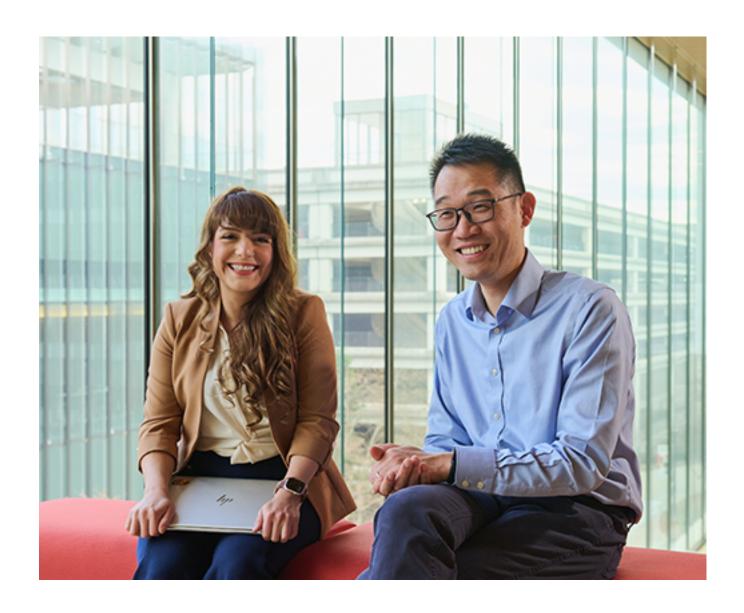
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電子 メール をお 送 りください。その 際 ご 依頼内容、ご 連絡先、求人票 の 番号 を 明してください。



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