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 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.

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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

Shift Work
No

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利便性と合理的配慮

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