Development Regulatory Affaires

Job ID
REQ-10057720

11月 06, 2025

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.
* 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.
- 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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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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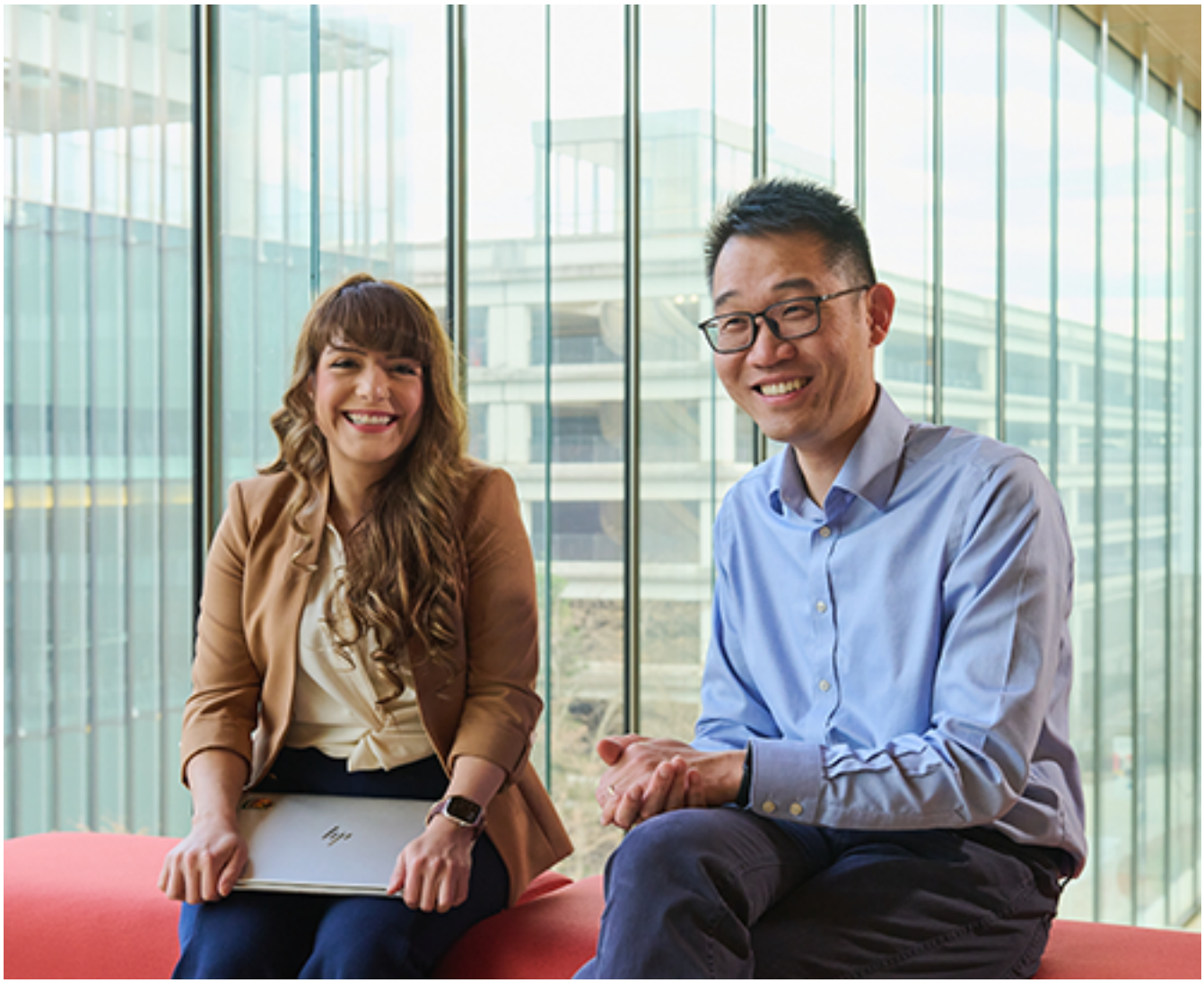

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