Regulatory and Development Policy Manager

Job ID
REQ-10051539

5月 11, 2025

Japan

摘要

Monitor and communicate regulatory intelligence and policy information to facilitate decision making for compliant and quality global development aligned with business objectives.

About the Role

Major Accountabilities

Monitor and search relevant laws, guidelines and other regulatory information published on Health Authority webpages and databases, public conferences, workshops and press.

Collect and communicate intelligence, learning from Scientific Advice and/or other health authority advisory boards (e.g., FDA Advisory Committees) for our products to RA DUs, Regions and Functions as appropriate.

Contribute to internal knowledge management systems and produce analyses reports.

Prepare and coordinate internal Novartis feedback from cross-functional teams on draft regulations and guidelines

Communicate new and emerging regulatory requirements to RA colleagues and relevant line functions via written communication, such as newsletters, information e-mails.

Support internal activities for the development of policy strategies and advocacy plans.

Make presentations, as appropriate, as a means to communicate new or evolving regulatory requirements.

Key Performance Indicators

Proactive communication of new and evolving regulatory requirements.

Timely coordination and follow-up of Novartis feedback to draft legislation/guidelines.

Active participation at internal working groups and team meetings

Active contribution to internal presentations (e.g. GREF, GPN, etc.)

Education / Language / Experience /

Education: Science based BS or MS with requisite experience and demonstrated capability.
Advanced degree (MD, Ph D, PharmD) desirable.

Languages: Fluency in English as a business language. Additional language(s) beneficial.

Experience:
2-4 years involvement in regulatory and/or drug/biologic development.
Experience in a global/matrix environment or cross-functional teams in the pharmaceutical industry or health authority.
Strong interpersonal, communication, negotiation and problem solving skills.
Basic organizational awareness (e.g., interrelationship of departments, business priorities).

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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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