

Manager, Reg&Dev Policy Japan

Job ID
REQ-10021929

Sep 12, 2024

Japan

Summary

Job Purpose: 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.)

Minimum Requirements:

Work 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).

Languages :

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

Education:

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

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Division
Development

Business Unit
Innovative Medicines

Location
Japan

Site
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

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