

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

EMajor 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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Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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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