U NOVARTIS

Manager, Reg&Dev Policy Japan

Job ID REQ-10021929

9月 12, 2024

Japan

摘要

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.

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? <u>https://www.novartis.com/about/strategy/people-and-culture</u>

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: <u>https://www.novartis.com/careers/benefits-rewards</u>

部门 Development

Business Unit Innovative Medicines

地点 Japan

站点 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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Accessibility and accommodation

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send an e-mail to <u>midcareer-r.japan@novartis.com</u> and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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



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