China Regulatory Policy Head

Job ID
REQ-10064698

10月 16, 2025

China

摘要

-Provides strategic direction to teams to achieve registration and drives preparation and submission of regulatory documentation. Interacts and negotiates with regulatory agencies in order to expedite competitive approval of pending registration applications and serves as a regulatory liaison on the project team(s) throughout the product lifecycle. Ensures timely approval on of new drugs, biologics/biotechnology and/or medical devices and continued approved status of marketed drugs or medical devices. Coordinates and reviews preparation of regulatory submissions, including preparation of specific regulatory components.

About the Role

Major accountabilities:

- Is Leader of global regulatory team for the assigned program.
- Is responsible for Heavyweight project in development or a brand with major ongoing

development activities, requiring complex regulatory strategies.
- Functions as a core member of the GPT (Global Program Team) to define the global regulatory strategy for the development, submission, approval and life cycle management of the project(s) and/or brand(s) in the major and emerging markets.
- Provide global regulatory direction and evaluate regulatory risks/gaps and trade -offs for the overall development plan; develop contingency plans for identified risks -Ensure that execution of regional regulatory strategies are aligned with global strategy -Responsible for obtaining timely consultation with Novartis regulatory advisory boards on regulatory strategy -Lead interactions with regulatory consultants for strategic input and challenge -Accountable for developing and driving the regulatory advocacy strategy -Develop global regulatory strategy and plans for Health Authority (HA) interactions -Responsible for implementation of CDS into labels in major regions (US, EU, Japan and Emerging Growth Markets) -Review of global promotional materials and press releases for NP4 Managerial -Leads DRA subteam consisting of RPRM ' s across regions.
- Provides mentoring and coaching for members of DRA subteam.
- Contributes to and often leads the development of departmental and functional/business unit goals and objectives.
- Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable)

Key performance indicators:

- Timely preparation of high quality regulatory documents -Health Authority issues and major issues with cross functional impact are appropriately highlighted -Project and stakeholder feedback -Adherence to Novartis policy and guidelines

Minimum Requirements:
Work Experience:

- Functional Breadth.
- Strategy Development.
- Critical Negotiations.
- Cross Cultural Experience.
- Representing the organization.
- Operations Management and Execution.
- Project Management.

Skills:

- Clinical Trials.
- Cross-Functional Teams.
- Drug Development.
- Lifesciences.
- Negotiation Skills.
- People Management.
- Problem Solving Skills.
- Regulatory Compliance.
- Risk Management.
- Strategy Execution.

Languages :

- English.

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? https://www.novartis.com/about/strategy/people-and-culture

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: https://www.novartis.com/careers/benefits-rewards

部门
Development

Business Unit
Universal Hierarchy Node

地点
China

站点
Beijing (Beijing)

Company / Legal Entity
CN14 (FCRS = CN014) China Novartis Institutes for BioMedical Research Co., Ltd.

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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Accessibility and accommodation

Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.china@novartis.com 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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