NOVARTIS

Senior Regulatory Affairs Manager

Job ID
REQ-10072808
Mar 19, 2026
LOC_CN

About the Role

Major accountabilities:

- Is responsible for implementing regulatory strategy and managing operational activities for assigned medium regions.
- Provides input into global regulatory strategy and contributes to Regulatory Functional Plan (RFP) and Seed Document, or their equivalents, including identification of gaps or risks in global strategic plan for assigned regions.
- Partners with regions to align on regulatory strategy in order to fulfil business objectives -Implements RFP across assigned regions.
- Determines requirements and sets objectives for Health Authority (HA) interactions with DRA GPT representative and/or GTAL.
- Facilitates preparation and finalization of briefing books and contributes to preparation of summary documents.
- Develops and implements plans for timely response to HA requests and coordinates responses.
- May serve as local HA liaison depending on location (e.g., FDA or EMA).
- Drives coordination, planning, and submission of dossiers in assigned regions worldwide.
- Review of global dossier summary documents.
- Develops and implements plans to avoid/minimize clock stops during submission review.
- Reviews, approves and submits Clinical Trial Applications (CTAs) and Investigational New Drugs (INDs).
- Reviews and submits Risk Management Plans.
- May lead negotiations for regional approvals independently or with DRA GPT representative and/or GTAL.
- Responsible for facilitating timely submission and approval of dossier with HAs under the guidance of the DRA GPT representative and/or GTAL.
- Erroneous decisions result in critical delays and modifications to projects or operations; cause substantial expenditure of additional time, human resources, and funds; and jeopardize future business activity -Contributes to and often leads the development of departmental 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:

- Successful implementation of global regulatory strategy for timely submissions and approvals with the best possible labels based on available data.
- Identification of main HA issues -Participation in relevant regulatory Boards leading to valuable input from these Boards.
- Successful Participation in HA interactions to achieve business objectives.
- Adherence to Novartis policy and guidelines -Project & stakeholder feedback

Minimum Requirements:
Work Experience:

- Functional Breadth.
- Cross Cultural Experience.
- Operations Management and Execution.
- Project Management.

Skills:

- Clinical Trials.
- Detail Oriented.
- Drug Development.
- Lifesciences.
- Negotiation Skills.
- Regulatory Compliance.

Languages :

- English.

Role Requirements

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

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.
Read our handbook (PDF 30 MB)

Division
DIV_GD
Business Unit
Development
Location
LOC_CN
Site
Beijing (Beijing)
Company / Legal Entity
CN06 (FCRS = CN006) Beijing Novartis Pharma Co., Ltd
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Full time
Employment Type
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Shift Work
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