NOVARTIS

RA Reg CMC Assoc Director

Job ID
REQ-10041002
Feb 17, 2025
China

Summary

-Responsible for regulatory activities specifically related to chemistry, manufacturing, and control (CMC). Activities such as the preparation and publication of REG CMC documentation for submissions to Health Authorities. In addition interact with HA's on REG CMC questions to support new product or post marketed launches.

About the Role

Major accountabilities:

- Formulate, lead and drive global CMC regulatory strategy drawing on substantial regulatory expertise with a focus on innovation, maximizing the business benefit balanced with regulatory risks and compliance.
- Lead and drive all global CMC submission activities (planning, authoring, reviewing, coordination, submission) for assigned projects/products, while applying the global strategy into submissions.
- Identify the required documentation and any content, quality and/or timeliness issues for global submissions and negotiate the delivery of approved technical source documents in accordance with project timelines.
- Author and/or review high-quality CMC documentation for Health Authority submissions, establishing and applying CMC global regulatory strategies, current regulatory trends and guidelines.
- Proactively communicate CMC regulatory strategies, risks and key issues throughout the life cycle in a timely manner to project teams and other stakeholders.
- Lead, prepare and communicate CMC Risk Management Assessments, contingency plans and lessons learned on major submissions and escalate as appropriate.
- Initiate and lead Health Authority interactions and negotiations; setting objectives, preparing briefing books, coordinating and planning rehearsals and risk mitigation plans.
- Provide strategic advice and direction within the department and cross-functionally through specialized assignments.
- Share regulatory knowledge with less experienced members of RA CMC department.
- 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:

- Produces high quality strategic project documentation and presentations; adapts strategies to anticipate evolving project needs.
- No delays in approvals of clinical studies, global registration dossiers or variations due to late or inadequate submission documentation on matters within RA CMC control.

- Delivers reliable, timely and accurate information / communication about project specific issues within own department and to key stakeholders and builds commitment.
- RA CMC regulatory documentation follows Novartis guidelines and meets regulatory guidelines.
- Plans ahead considering emerging trends.
- Provides high quality regulatory evaluation and strategic advice on time (change control, etc.); regulatory compliance met in all compliance systems.
- Maintains collaborative partnerships with stakeholders.

Minimum Requirements:
Work Experience:

- Managing Crises.
- Cross Cultural Experience.
- Critical Negotiations.
- Functional Breadth.
- Project Management.
- Operations Management and Execution.
- Collaborating across boundaries.

Skills:

- Change Control.
- Drug Development.
- Lifesciences.
- Negotiation Skills.
- Pharmaceutical Products.
- Product Lifecycle Management (Plm).
- Project Management.
- Regulatory Compliance.
- Risk Management.

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

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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

Division
Development
Business Unit
Innovative Medicines

Location
China
Site
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
Apply to Job

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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