

Regulatory Affairs CMC Manager

Job ID
REQ-10075420
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Китай

Сводка

-Responsible for regulatory activities specifically related to chemistry, manufacturing, and control (CMC). Activities such as the preparation & 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 and lead global CMC regulatory strategy with a focus on innovation, maximizing the business benefit balanced with regulatory compliance -Lead and implement all global CMC submission activities (planning, authoring, reviewing, coordination, submission) for assigned projects/products.
- Identify the required documentation and any content, quality and/or timelines 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 HA submission, applying agreed CMC global regulatory strategies, current regulatory trends and guidelines.
- Ensure technical congruency and regulatory compliance, meeting agreed upon timelines and e-publishing requirements.
- Prepare and communicate CMC Risk Management Assessments, contingency plans, and lessons learned on major submissions and escalate with management as appropriate.
- Initiate and lead Health Authority interactions and negotiations as appropriate; setting objectives, preparing briefing books, coordinating and planning rehearsals and risk mitigation plans.
- 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; no late changes in strategy due to inadequate prior evaluation.
- 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 -RA CMC regulatory documentation follows Novartis guidelines and meets regulatory guidelines.
- 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:

- Cross Cultural Experience.
- Operations Management and Execution.
- Collaborating across boundaries.
- Project Management.

Skills:

- Change Control.
- Cross-Functional Teams.
- Documentation Management.
- Negotiation Skills.
- Project Management.
- Regulatory Compliance.
- Risk Assessment.
- 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>

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.

[Read our handbook \(PDF 30 MB\)](#)

Дивизион
Development
Business Unit
Development
Место

Китай
Сайт
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

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.

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