

# Regulatory Affairs CMC Manager

Job ID

REQ-10075420

Июн. 22, 2026

Китай

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## 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>

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[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](mailto: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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