

## RA CMC Manager

Job ID  
REQ-10012091

9月 03, 2024

India

### 摘要

-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.

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部门

Development

Business Unit

Innovative Medicines

地点

India

站点

Hyderabad (Office)

Company / Legal Entity

IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area

Research & Development

Job Type

Full time

Employment Type  
Regular

Shift Work  
No

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