

RA CMC Associate Manager II

Job ID
REQ-10030417
Nov 20, 2024
India

About the Role

Major accountabilities:

- Author high quality global CMC documentation for Health Authority submission throughout the product lifecycle, 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.
- 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.
- As needed, coordinate /collect /store source documentation needed for direct submission to Health Authorities.
- Actively participate as a member of the global RA CMC team by contributing to the regulatory strategy, identifying the critical issues and lessons learned.
- Perform activities in support of the overall department such as data entry into the Regulatory Information Management System, other CMC database entry, or maintenance and operational activities as needed.
- 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 regulatory documentation -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 & accurate information / communication about project documentation specific issues within own department and to key stakeholders.
- RA CMC regulatory documentation follows Novartis guidelines & meets regulatory guidelines.
- Builds & maintains collaborative partnerships with stakeholders.

Minimum Requirements:

Work Experience:

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

Skills:

- Documentation Management.
- Lifesciences.
- Operational Excellence.
- 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>

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Division

Development

Business Unit

Innovative Medicines

Location

India

Site

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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