RA CMC Associate Manager-II

Job ID
REQ-10020392
Σεπ 03, 2024
India

Περίληψη

-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:

- 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.

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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Τομέας
Development
Business Unit
Universal Hierarchy Node
Τοποθεσία
India
Τοποθεσία
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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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.india@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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