RA CMC Senior Manager

Job ID
REQ-10034907

1月 02, 2025

India

摘要

Independently provide strategic and operational global CMC regulatory direction and documentation for projects/products covering development, registration and approval/post approval activities. Make informed regulatory decisions, balancing patient and business risks and benefits leading to timely Health Authority approvals.

About the Role

Major Accountabilities:

- Formulate, lead and drive 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.
- Proactively communicate CMC regulatory strategies, risks and key issues throughout the life cycle in a timely manner to project teams and other stake holders. Represent department in cross-functional project teams as appropriate.
- Lead, prepare and communicate CMC Risk Management Assessments, contingency plans, and lessons learned on major submissions and escalate 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. Establish and maintain a single point of contact with FDA.
- Represent department on due diligence teams for in-licensing and divestment opportunities.

Key Performance Indicators (KPIs):

- Produces high quality strategic project documentation and presentations (e.g., project plans, documentation, Risk Management Assessments, lessons learned, etc.); no late changes in strategy due to inadequate prior evaluation.
- Timeliness of deliverables: 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; changes in project status communicated as required.
- 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.
- Builds and maintains collaborative partnerships with stakeholders.

Education / Language / Experience:

Minimum: Science Degree (e.g. Chemistry, Pharmacy, Biochemistry, Biotechnology, Biology) or equivalent

Desirable: Advanced Science Degree

Languages:

Fluent English required (oral and written). Excellent written/spoken communication skills

Experience:

- Minimum 5 years in regulatory preferred, and/or experience in the pharmaceutical industry.
- Working knowledge/experience in regulatory submission and approval processes.
- Working knowledge of chemistry/biotechnology, analytics or pharmaceutical technology. Ability to critically evaluate data from a broad range of scientific disciplines. Knowledge of product development and life cycle desirable.
- Demonstrated track record to successfully work in interdisciplinary global teams; leading, planning and prioritizing activities simultaneously on multiple projects.
- Ability to work independently and successfully with global project teams and prioritize activities considering timelines and workload.
- Effective planning, organizational and interpersonal skills.
- Computer/IT systems literacy

Commitment to Diversity and Inclusion:
Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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*

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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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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