NOVARTIS

RA CMC Senior Submission Coordinator

Job ID
REQ-10032508
déc 04, 2024
Inde

Résumé

Provide advanced regulatory CMC operational, submission and compliance support to department in accordance with defined requirements to guarantee timely preparation of high-quality CMC regulatory submissions and associated compliance information throughout the life cycle.

About the Role

Major accountabilities:

- Independently, perform RA CMC compliance and operational support including QC check, DA checks, IND AR writing & coordination. CMC contact for some countries, compliance/regulatory database entry and reports and ensure appropriate eCTD operator attributes, module chapters
- Create CMC submission documentation such as folders structure, metadata forms, RA request forms, populating RA CMC tracking sheets, letters, and various Health Authority forms. Act as super-user, business data owner and data steward in the applicable Regulatory Information Management System
- Proactively ensure CMC documentation is eCTD compliant and submission ready. Support eCTD compliance maintenance for the external documentation linked to the CMC submission modules, including third party documentation
- Independently support CMC project teams for document finalization, ancillary documents coordination and source documents management. Coordinate, prepare, compile and track CMC submissions for delivery to RA Operations
- Support RA CMC project teams to handle Country Organization (CO) request in the RA CMC ticketing system, organizing submission coordination activities like source documents and ancillary documents collection
- Perform super-user role of documentation system / support super-user for e.g. account requests / modifications as assigned
- Actively participate as a member of the global RA CMC project teams by contributing to the project operational and compliance strategy, identifying the potential compliance issues and sharing lessons learned
- Acquire and maintain GMP Certificates and Manufacturing Authorizations required for RA CMC submission in the Document Management System
- Coordinate preparation of declarations required for submission in RoW countries
- Support other GSOC team members in leading various operations, compliance, Data & Digital initiatives

Key performance indicators:

- High quality regulatory submissions and operational documentation
- Timeliness of deliverables: No delays in approvals of clinical studies, global registration dossiers or

variations due to late or inadequate CMC documentation and compliance support on matters within RA CMC control
- Proactive and accurate information / communication about operational and compliance issues within own department and to key stakeholders
- Independently ensure that the operational activities and CMC regulatory documentation follow Novartis and eCTD guidelines. Regulatory compliance met in all compliance systems
- Build and maintain collaborative partnerships with stakeholders
- Partner with other GSOC team members to ensure business continuity

Minimum Requirements:
Work Experience:

- Preferably 3 years in regulatory submission management.
- Working experience in pharma industry data systems, data and submission management
- Ability to work successfully with global project teams and prioritize activities considering timelines and workload
- Effective planning, organizational and interpersonal skills
- Prior submission management/publishing experience desired
- Computer literacy/IT systems literacy: Excellent data processing skills with current operating systems

Skills:

- Documentation Management.
- Project Excellence
- Digital & Data savvy
- Interpersonal Skills
- 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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

Division
Development
Business Unit
Innovative Medicines
Emplacement
Inde

Site
Hyderabad (Office)
Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited
Functional Area
Recherche & Développement
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

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.

Job ID
REQ-10032508

RA CMC Senior Submission Coordinator

Apply to Job

Source URL: *https://www.adacap.com/careers/career-search/job/details/req-10032508-ra-cmc-senior-submission-coordinator*

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://talentnetwork.novartis.com/network
3. https://www.novartis.com/careers/benefits-rewards
4. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Hyderabad-Office/RA-CMC-Senior-Submission-Coordinator_REQ-10032508
5. mailto:diversityandincl.india@novartis.com

6. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Hyderabad-Office/RA-CMC-Senior-Submission-Coordinator_REQ-10032508