NOVARTIS

RA CMC Senior Submission Coordinator

Job ID
REQ-10032508
Dez. 04, 2024
Indien

Zusammenfassung

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

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Abteilung
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Innovative Medicines
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Website
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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