Global Clinical Publishing Associate

Job ID
REQ-10006976
Mai 26, 2024
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Summary

Ensure compliance with internal and external guidelines, to compile and add electronic navigation to clinical and regulatory documents. Support the timely submission of documents to the Health Authorities (HAs) and provide publishing consultancy to the clinical teams and other line functions.

About the Role

Major accountabilities:

- In collaboration with the clinical teams, compile, integrate and publish clinical documents with word processing, electronic publishing, and document management systems in the Novartis Development environment.
  • Perform technical quality control (electronic functionality, adherence to internal and external document standards) of published documents.
  • Maintain basic knowledge of current electronic publishing standards, regulatory guidelines, and legal requirements.
  • Under direct supervision of the immediate manager, acts as the Program Publisher for various programs in clinical development.

Key performance indicators:

- Publish clinical documents (taking into account complexity and size) in accordance with department standards and organization KPIs.
  • Ensure published clinical documents meet current internal and external quality standards for electronic and/or paper HA submissions, including minimizing publishing-related technical QC findings and no rework once finalized.
  • Timeliness of deliverables meet both individual document and overall project timelines.

Minimum Requirements:

Experience with regulatory submission format, including familiarity with submission publishing activities and CTD format criteria.
• Effective interpersonal skills, strong written and oral communication and presentation skills.
• Project management and time management skills to manage multiple ongoing projects simultaneously.
• Familiar with regulatory requirements and HA guidance, including FDA regulations, ICH and EMA guidelines/directives.
• Working knowledge of regulatory affairs.
• Works independently and with minimal supervision.

• Proficiency with computer programs/systems (MS office, etc.) with demonstrated ability to learn new systems quickly.
• Analytical skills and problem solving skills.
• Ability to coordinate and work effectively with cross-functional teams.

Work Experience:

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

Skills:

- Clinical Study Reports.
- Data Analysis.
- Documentation Management.
- Lifesciences.
- Operational Excellence.
- Regulatory Compliance.

Languages :

- English.

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

Division
Development
Business Unit
Innovative Medicines
Standort
Indien
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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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.

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