Global Clinical Publishing Associate

Job ID
REQ-10006976
Sep 03, 2024
India

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.

Role Requirements

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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Division
Development
Business Unit
Innovative Medicines
Location
India
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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