Submission Readiness Document Manager

Job ID
REQ-10011500
Jul 28, 2024
India

Summary

Internal Role Title: Submission Readiness Document Manager

Location: Hyderabad, India #LI-Hybrid

About the Role:

Clinical Document Governance Management (CDGM) is accountable for strategy and delivery of clinical document management (CDM) systems, processes, standards and operations of CDM services (including Trial Master File management (TMF), clinical submission readiness, record retention and archiving, Good Documentation Practice capability build) across Novartis globally. In addition, CDGM is driving the transformation of TMF at Novartis, through the introduction and adoption of new technologies, processes, and ways of working.

The Submission Readiness Document Manager. Will be responsible for delivery and oversight of submission readiness of clinical documents, to support authoring and publishing of clinical documents required for regulatory submissions and achieve rapid, accurate and timely submissions to health authorities

Drives implementation of CDGM initiatives, projects and process improvement activities to improve clinical document management systems, processes and standards at Novartis.

About the Role

- **Responsible for efficient and appropriate management of submission-relevant documentation ((e.g., Protocol, CSR, ICF, PDR, etc.) for global clinical,) to meet electronic publishing requirements, Health Authority guidelines, Good Clinical Practices and Novartis SOPs.**
- **Support implementation of the submission document readiness management strategy for clinical documents and clinical documents templates.**

- **Develop and maintain submission readiness processes, contribute to or drive initiatives to improve and innovate business and technical aspects of submission readiness activities, in collaboration with other CDGM groups, business and IT Functions.**
- **Collaborate with cross-functional partners (e.g., Regulatory Writing & Submissions, Regulatory Affairs, Trial Management, etc.) on the planning, preparation, and delivery of high-quality documents within timelines, including expedited support for urgent requests to meet regulatory deadlines.**
- **Identifies and communicate processing risks/trends/patterns related to regulatory submission documents and works with key stakeholders to define and implement appropriate remediations.**
- **Serves as Subject Matter Expert on Regulatory Document Manager training materials, formal and informal processes and tracking tools for submission readiness oversight activities in collaboration with CDM Process team and other key partners**
- **Provides Audit/Inspection support, contributes to root cause analysis identification and creation/delivery of CAPAs.**

Essential Requirements

- **Proficient English (both spoken and written)**
- **Bachelor’s degree or equivalent experience in life sciences/healthcare/pharmacy/information management and relevant proven experience.**
- **Detailed knowledge of clinical document management processes**
- **Sophisticated knowledge of clinical documentation standard methodology guidelines & principles (good documentation**

practice, data integrity)

- **3-5 years in clinical development/clinical operations or similar business area**
- **2-3 years working experience with document management systems and excellent understanding of system structures and generic document management functionality**
- **Experience with project work or project management in a global, cross- functional multicultural and international matrix organisation**
- **Good understanding of technical processes and PC environment including Microsoft suite of products. Sophisticated ability to work independently**

Why Novartis?

Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

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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
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
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.

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