Submission Readiness Document Manager

Job ID
REQ-10021014

9月 10, 2024

USA

摘要

Onsite
Location: East Hanover, New Jersey
Hybrid
#LI-Hybrid

About the role:

Novartis has a job opportunity for a Submissions Readiness Document Manager. In this role, you will be responsible for delivery and oversight of submission readiness of clinical documents, to support authoring formatting, and publishing of clinical documents required for regulatory submissions, and achieve rapid, accurate and timely submissions to health authorities. You will drive implementation of CDGM initiatives, projects and process improvement activities to enhance clinical document management systems, processes and standards at Novartis.

About the Role

Your Key Responsibilities:

- 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.
- Coordinate and oversee the authoring and finalization of the CSR appendices for assigned studies.
- Support implementation of the submission document readiness management strategy for clinical documents and clinical documents templates.
- Executes vendor oversight plan, monitors service metrics and identifies opportunities for improvement to the operating model. Acts as point of escalation for issues.
- 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 stakeholders (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.
- Identify 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 stakeholders.
- Provides audit/inspection support, contributes to root cause analysis identification and creation/delivery of CAPAs.

Video Link

- https://www.youtube.com/watch?v=ggbnzRY9z8w

Role Requirements:

Essential Requirements:

- Bachelor ' s degree in life-sciences/healthcare/pharmacy/information management and relevant industry experience and a minimum of 3+ years in clinical development/clinical operations or similar business area
- Advanced knowledge of clinical documentation practice guidelines & principles (Good Documentation Practice, Data integrity, ICH eCTD and FDA Portable Document formatting specifications (PDF) guidance)
- Experience authoring, compilation and formatting of CSR appendices according to ICH E3
- 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
- Good understanding of technical processes and PC environment including Microsoft suite of products

- Advanced ability to work independently
- Experience with project work or project management in a global, cross- functional multicultural and international matrix organization

- Excellent communication, organization and tracking skills

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The Novartis Group of Companies are 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 application process, or to perform the essential functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

部门
Development

Business Unit
Innovative Medicines

地点
USA

站点
East Hanover

Company / Legal Entity
U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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