Submission Readiness Document Manager

Job ID
REQ-10011497

9月 24, 2024

United Kingdom

摘要

This role can be based in London, England or Dublin, Ireland.

Both locations are Hybrid working patterns (12 days per month in the office)

#LI Hybrid

Novartis is not able to offer relocation or visa support for this role: please only apply if the location is accessible for you and you have the right to work in the the country you are applying to.

Closing date for applications: 08 October 2024

About the Role

Reporting to the CDM Submission Readiness Team Lead, the 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.

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.
- 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 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.
- Identifies and communicate processing risks/trends/patterns related to regulatory submission documents and works with key stakeholders to define and implement appropriate remediation.
- 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.

Role Requirements:

- Fluent English (both spoken and written)
- Bachelor ' s degree in life sciences / healthcare / pharmacy / information management.
- 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 organization
- Thorough knowledge of clinical document management processes
- Advanced knowledge of clinical documentation best practice guidelines & principles (good

documentation practice, data integrity)
- Good understanding of technical processes and PC environment including Microsoft suite of products

Skills:

- Advanced ability to work independently
- Agility
- Collaboration

Commitment to Diversity & Inclusion:

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

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

Join our Novartis Network:

If this role is not suitable to your experience or career goals but you wish to stay connected to learn more about Novartis and our career opportunities, join the Novartis Network here: https://talentnetwork.novartis.com/network

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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Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

部门
Development

Business Unit
Innovative Medicines

地点
United Kingdom

站点
London (The Westworks)

Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.

Alternative Location 1
Dublin (Novartis Corporate Center (NOCC)), Ireland

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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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.

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