

Submission Readiness Document Manager

Job ID
REQ-10020610
Oct 02, 2024
Switzerland

Summary

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.

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

About the Role

Major Accountabilities (Describe the 5-7 main results of the role to be achieved)

- 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.

Minimum Requirements:

- Bachelor's degree in life-sciences/healthcare/pharmacy/information management and relevant industry experience.

Languages:

- English fluency (written, oral) required.

Relevant Experiences:

- Thorough knowledge of clinical document management processes
- Advanced knowledge of clinical documentation practice guidelines & principles (Good Documentation Practice, Data integrity, ICH eCTD and FDA Portable Document formatting specifications (PDF) guidance)
- Experience of 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

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

Switzerland

Site

Basel (City)

Company / Legal Entity

C028 (FCRS = CH028) Novartis Pharma AG

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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