CSR Appendices Oversight Manager

Job ID
REQ-10027368

Jan 23, 2025

United Kingdom

Summary

Responsible for delivery and oversight of CSR appendices authoring, formatting, compilation and publishing 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.

This is a hybrid position based in either London or Dublin offices.

About the Role

Major accountabilities:

- Responsible for efficient and appropriate management, coordination and oversight of CSR appendices for assigned studies 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.
- 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 CSR appendices and works with key stakeholders to define and implement appropriate remediations.
- Serves as Subject Matter Expert on CSR appendices training materials, formal and informal processes, and tracking tools for CSR appendices 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.
- English fluency (written, oral) required.
- 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

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部門
Development

部門
Universal Hierarchy Node

国
United Kingdom

勤務地
London (The Westworks)

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

Alternative Location 1
Dublin (NOCC), Ireland

Functional Area
Research & Development

職種
Full time

雇用形態
Regular

Shift Work
No

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