CSR Appendices Oversight Manager

Job ID
REQ-10051532

May 13, 2025

USA

Summary

This position will be located at East Hanover, NJ site and will not have the ability to be located remotely.
“Please note that this role would not provide relocation and only local candidates will be considered.”

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.

#LI-Hybrid

Key Responsibilities:

- 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.

About the Role

Requirements:

- Bachelor's degree in life‐sciences/healthcare/pharmacy/information management and relevant industry experience. Preferred
- Thorough knowledge of clinical document management processes
- Advanced knowledge of clinical documentation practice guidelines & principles (Good Documentation Practice, Data integrity, ICH eCTD andFDA Portable Document formatting specifications (PDF) guidance)
- Experience of authoring, compilation and formatting of CSR appendices according to ICH E3
- Minimum of 5 years in clinical development/clinical operations or similar business

Area Preferred

- Prior 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

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between $114,100 and $195,600/year; ***however, while salary ranges are effective from 1/1/25 through 12/31/25, fluctuations in the job market may necessitate adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills, and abilities.*** The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range

of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an "at-will position" and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

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

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status.

Accessibility & Reasonable Accommodations

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.

部門
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Innovative Medicines

国
USA

State
New Jersey

勤務地
East Hanover

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

Functional Area
Research & Development

職種
Full time

雇用形態
Regular

Shift Work
No

Apply to Job.

Job ID
REQ-10051532

CSR Appendices Oversight Manager

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