Expert Regulatory Writer

Job ID
REQ-10063377

10月 13, 2025

United Kingdom

摘要

#LI-Hybrid (12 days per month on-site)
Location: London (The Westworks), United Kingdom

Are you passionate about crafting clear, impactful clinical and safety documentation that drives regulatory success? We ' re looking for a skilled and experienced Medical Writer to lead the development of high-quality submissions that support global marketing applications. In this pivotal role, you ' ll provide expert guidance across cross-functional teams, mentor emerging talent, and ensure excellence in every document delivered.

About the Role

Major accountabilities:

- **Author**, **review**, and/or **independently manage** high-quality clinical and safety documents,

including: Complex Clinical Study Reports (CSRs), Protocols, Concept Sheets, and Informed Consent Forms (ICFs), Complex CTD submission documents (e.g., Clinical Overviews, Summaries of Clinical Efficacy and Safety, Clinical Pharmacology and Biopharmaceutics), Other regulatory documents (e.g., Briefing Books, responses to Health Authority questions).
- **Lead** writing teams for complex submissions, **contribute** to key messaging and pooling strategy, and **provide** expert guidance on clinical content within the CTD.
- **Ensure** documentation complies with internal standards and external regulatory guidelines.
- **Input** into planning and presentation of data analyses, including **reviewing** statistical analysis plans and **participating** in relevant meetings.
- **Act** as documentation expert within Global Clinical Teams (GCTs) and Clinical Submission Teams (CSTs).
- **Provide** strategic and content expertise for clinical sections of the CTD.
- **Report** technical complaints, adverse events, or special case scenarios related to Novartis products within 24 hours of receipt.
- **Distribute** marketing samples, where applicable.

Essential Requirements:

- University life science degree or equivalent.
- Fluent in English (oral and written).
- Proficient in medical writing or other relevant pharmaceutical industry roles, with strong scientific and regulatory knowledge and deep understanding of medical writing processes.
- Expert knowledge of global regulatory environments and processes, including key regulatory bodies, core submission documents, approval pathways, and safety reporting requirements.
- Proven expertise and successful track record in global drug registration.
- Exceptional communication skills - written, verbal, and presentation.
- Strong understanding of biostatistics principles and their application in regulatory documentation.
- Demonstrated ability to manage multiple priorities and projects effectively in a fast-paced environment.

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: 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

部门
Development

Business Unit
Universal Hierarchy Node

地点
United Kingdom

站点
London (The Westworks)

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

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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