Regulatory Writer " >

Job ID
321003BR
Jun 10, 2021
China

Job Description

500+ Ongoing clinical trials;160+ Projects in clinical development;80+ Major submissions planned 2020-2022. Novartis GDD (Global Drug Development) oversees the development of new medicines discovered by our researchers and partners. It drives breakthrough innovations to improve and extend the lives of millions.

Your key responsibilities:
Your responsibilities include, but are not limited to:

· To author and review high quality clinical and safety documents: non registration Clinical Study Reports (CSR), Development Safety Update Reports (DSUR), Risk Management Plans (RMP),.
· Lead for outsourced Narrative projects. Coordinate other outsourced activities in DE.
· Core member of Clinical Trial Team (CTT) / participate in Safety Management Team (SMT). Actively participate in planning of data analyses and presentation used in CSRs.
· Act as documentation consultant in CTTs and SMTs to ensure compliance of documentation to internal company standards and external regulatory guidelines.
· May act as Program Writer ensuring adequate medical writing resources are available for assigned program and consistency between documents.
· Act as liaison between CTTs and publishing teams to ensure timely delivery of final documents for publishing.
· Support the development of DE through participating in DE initiatives and other related activities. Contribute to development of processes within DE. May contribute to cross-functional initiatives.
· Fostering cross-functional communication to optimize feedback and input towards high quality documents. Maintain audit, SOP and training compliance.

Minimum Requirements

What you'll bring to the role:
· Minimum university life science degree or equivalent is required. Advanced degree or equivalent education/degree in life sciences/healthcare is desirable.
· ≥ 2 years medical writing experience or other relevant pharma industry experience combined with scientific and regulatory knowledge, plus strong knowledge of the medical writing processes.
· Good knowledge of and some experience in global regulatory environment and process (key regulatory bodies, key documents, approval processes, safety reporting requirements).
· Knowledge of process for and some experience in global registering of drugs (simple submissions).
· Excellent communication skills (written, verbal, presentations). Very good understanding of biostatistics principles.
· Ability to prioritize and manage multiple demands and projects. Ability to define and solve complex problems ("Problem-solver")

· Broad knowledge and future oriented perspective. Proven track record in matrix environment
· Experience in contributing to global, cross-functional projects. Global, cross-cultural perspective and customer orientation.

Why Novartis?
769 million lives were touched by Novartis medicines in 2020, and while we're proud of this, we know there is so much more we could do to help improve and extend people's lives.

We believe new insights, perspectives and ground-breaking solutions can be found at the intersection of medical science and digital innovation. That a diverse, equitable and inclusive environment inspires new ways of working.

We believe our potential can thrive and grow in an unbossed culture underpinned by integrity, curiosity and flexibility. And we can reinvent what's possible, when we collaborate with courage to aggressively and ambitiously tackle the world's toughest medical challenges. Because the greatest risk in life, is the risk of never trying!

Imagine what you could do here at Novartis!

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.

Join our Novartis network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, follow us via Novartis Group WeChat Recruitment Account.
Division
Global Drug Development
Business Unit
GDO GDD
Location
China
Site
Shanghai
Company / Legal Entity
CNIBR Co. Ltd.
Functional Area
Research & Development
Job Type
Full Time
Employment Type
Regular
Shift Work
No
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