Senior Scientific/Regulatory Writer

Job ID
REQ-10021041
Sep 17, 2024
Ireland

Summary

-To write, review and/or manage the production of high quality clinical and safety documentation for submission to regulatory authorities in support of marketing applications. To provide documentation related consultancy to other line functions.

About the Role

Major accountabilities:

- Core member of clinical Trial Team/participate in safety Management Team -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.
- Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable)

Key performance indicators:

- Delivery of high quality clinical and safety documents in time and in compliance with internal and external standards -Customer / partner/ project feedback and satisfaction -Adherence to Novartis policy and guidelines

Minimum Requirements:
Work Experience:

- Functional Breadth.
- Cross Cultural Experience.
- Collaborating across boundaries.
- Operations Management and Execution.

Skills:

- Clinical Research.
- Clinical Trials.
- Detail Oriented.
- Medical Writing.
- Regulatory Compliance.

- Safety.

Languages :

- English.

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
Operations
Business Unit
CTS
Location
Ireland
Site
Dublin (Novartis Corporate Center (NOCC))
Company / Legal Entity
IE02 (FCRS = IE002) Novartis Ireland Ltd
Alternative Location 1
Home Worker, United Kingdom
Alternative Location 2
Hyderabad (Office), India
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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