Senior Scientific/Regulatory Writer

Job ID
REQ-10021041

9月 17, 2024

Ireland

摘要

-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.

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部门
Operations

Business Unit
CTS

地点
Ireland

站点
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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