Senior Medical Information Manager 2

Job ID
390368BR
Apr 23, 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:

- 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) -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:

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

Skills:

- NA.

Languages :

- English.

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Division
Operations
Business Unit
CTS
Location
Ireland
Site
Dublin (NOCC)
Company / Legal Entity
IE02 (FCRS = IE002) Novartis Ireland Ltd
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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