

# 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 (Novartis Corporate Center (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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