Regulatory Writer

Job ID
REQ-10056903

7月 28, 2025

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

#LI-Hybrid (3 days per week on-site)
Location: Dublin, Ireland

Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

The Regulatory Medical Writer will be responsible for writing and reviewing high quality clinical and

safety documentation for submission to regulatory authorities.

Major responsibilities

- 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 RWS.
- Be a 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.

Desirable requirements

- 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
- Proven track record in matrix environment
- Experience in contributing to global, cross-functional projects.

Essential requirements

- Minimum university life science degree or equivalent is required. Advanced degree or equivalent education/degree in life sciences/healthcare is desirable.
- 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).

Commitment to Diversity and Inclusion / EEO paragraph

Novartis is committed to building an outstanding, inclusive work environment and diverse teams representative of the patients and communities we serve.

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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部门
Development

Business Unit
Innovative Medicines

地点
Ireland

站点
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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