Senior Regulatory Writer

Job ID
REQ-10043323

5月 16, 2025

United Kingdom

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 authoritative documentation-related consultancy to other line functions. To coach/mentor and/or train less experienced writers.

About the Role

Major accountabilities:

- To author, review and/or independently manage high quality clinical and safety documents: Clinical Study Protocols (CSP) and protocol amendments, complex Clinical Study Reports (CSR), Risk Management Plans (RMP),
  complex CTD submission documents (clinical overviews, summaries of clinical efficacy and safety, summaries of clinical pharmacology and biopharmaceutics), other documents for

health authorities (e.g., Briefing Books, answers to questions).
- Lead writing team for complex submissions, actively contributing to key messaging and pooling strategy, providing expert content guidance for clinical portions of the CTD, and ensuring compliance of documentation to internal company standards and external regulatory guidelines
- ad hoc member of Clinical Trial Team (CTT) / extended member of Safety Management Team (SMT). Core member of multiple Clinical Submission Teams (CST).
- Input into planning of data analyses and presentation (statistical analysis plan review and meetings) used in CSRs, submission documents and/or answers to questions.
- Documentation expert in GCTs and CSTs to ensure compliance to internal company standards and external regulatory guidelines.
- Provide content and strategic expertise for clinical portions of the CTD.
- Program Writer for large and/or complex programs ensuring adequate medical writing resources are available for assigned program and consistency between documents.
- Lead process improvement in RWS and cross-functional initiatives and/or activities.
- Identify training needs to foster high level of performance within RWS. Coach and/or mentor less experienced writers.
- Leader in cross-functional communication to optimize feedback and input towards high quality documents.

Role Requirements

- Minimum university life science degree or equivalent is required. Advanced degree or equivalent education/degree in life sciences/healthcare is desirable.
- Fluent English (oral and written).
- Extensive medical writing experience or other relevant pharma industry experience combined with scientific and regulatory knowledge, plus expert knowledge of medical writing processes.
- Expert knowledge, extensive experience, and demonstrated record of accomplishment in global registering of drugs.
- Expert knowledge of biostatistics principles.
- Proven ability to drive and manage organizational and team performance across cultures.
- Proven track record in matrix environment
- Repeat experience in managing global, cross-functional teams or complex global projects.
- Demonstrated ability to motivate and coach people.

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部门
Development

Business Unit
Universal Hierarchy Node

地点
United Kingdom

站点
London (The Westworks)

Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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