Expert Regulatory Writer (m/f/d), Clinical Documentation

Job ID
REQ-10058957

9月 04, 2025

Switzerland

摘要

Internal job title: Expert Regulatory Writer

As an Expert Regulatory Writer, you will be responsible for authoring, reviewing, and managing the production of high-quality clinical documentation for submission to regulatory authorities in support of clinical trial and marketing applications. You will serve as a subject matter expert, providing authoritative consultancy on documentation-related matters to other departments, and mentoring less experienced writers.

This position is part of the Regulatory Writing and Submissions (RWS) team and reports directly to the Unit Head.

#LI-Hybrid

About the Role

Key Responsibilities:

- **Independently author, review, and manage high-quality clinical documents,** including Clinical Trial Protocols (CTPs) and amendments, complex Clinical Study Reports (CSRs), and CTD submission documents (e.g., clinical overviews, summaries of clinical efficacy and safety, clinical pharmacology and biopharmaceutics summaries), as well as other regulatory documents (e.g., briefing books, responses to Health Authority questions).

- **Lead writing teams for complex submissions**, contributing to key messaging and pooling strategies, offering expert guidance on clinical content, and ensuring compliance with internal standards and external regulatory requirements.

- **Act as a member** of Clinical Trial Teams (CTTs), leading the Protocol and CSR sub-teams, core member of Clinical Submission Teams (CSTs), and extended member of Global Clinical Teams (GCTs).

- **Provide input** into the planning and presentation of data analyses (e.g., review of statistical analysis plans and participation in related meetings) for use in CSRs, submission documents, and responses to regulatory queries.

- **Ensure documentation** compliance with internal standards and external guidelines while providing strategic and content expertise for the CTP and clinical sections of the CTD.

- **Serve as Program Writer for large and/or complex programs**, liaising with clinical teams and internal management to ensure adequate medical writing resources and consistency across documents.

- **Lead and contribute to RWS practices and process** improvements within RWS and cross-functionally.

- **Coach and mentor junior writers.**

- **Facilitate cross-functional communication** to ensure effective feedback and input for high-quality documentation.

- **Maintain compliance with audit requirements, SOPs, and training standards.**

Essential Requirements:

- Academic degree in life sciences, healthcare, or a related field; an advanced degree is preferred.
- Full professional proficiency in English (native or near-native level).
- Several years of experience in medical writing or relevant pharmaceutical industry roles, with strong scientific and regulatory knowledge and expertise in medical writing processes.
- In-depth understanding of the global regulatory environment, including key Health Authorities, clinical trial design principles, documentation requirements, approval processes, and safety reporting.
- Proven experience and success in global drug registration.
- Strong knowledge of biostatistics principles.
- Excellent communication skills and experience working in a matrixed organizational environment.
- Demonstrated ability to prioritize and manage multiple projects and demands, and to solve complex problems effectively.
- Track record of successfully managing global, cross-functional teams or complex international projects.
- Proven ability to motivate and influence team members.

Why Novartis?

Our purpose is to reimagine medicine to improve and extend people ' s lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here:

https://www.novartis.com/about/strategy/people-and-culture

Disclaimer*: Some restrictions on flexible working options may apply and will be discussed during interview if applicable

You ' ll receive:

You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook: https://www.novartis.com/careers/benefits-rewards

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

Hiring decisions are only based on the qualification for the position, regardless of gender, ethnicity,

religion, sexual orientation, age and disability.

The law provides for severely disabled / equal applicants the opportunity to involve the local representative body for disabled employees (SBV) in the application process. If you

would like to request this, please let us know in advance as a note on your CV.

Adjustments for Applicants with Disabilities:

The law provides for severely disabled / equal applicants the opportunity to involve the local representative body for disabled employees (SBV) in the application process. If you would like to request this, please let us know in advance as a note on your CV.

Join our Novartis Network:

If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here:

https://talentnetwork.novartis.com/network

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
Universal Hierarchy Node

地点
Switzerland

站点
Basel (City)

Company / Legal Entity
C028 (FCRS = CH028) Novartis Pharma AG

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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