Senior Regulatory Writer

Job ID
REQ-10045011

3月 27, 2025

Japan

摘要

規制要件に従って、管理されたドキュメントシステム、記録保持、および電子記録保持プロセスを含む情報サービスを保証します。規制機関からの要件へのコンプライアンスを確保します。技術および非技術文書変更システムを維持します。レコードを分類および管理するための手順が確実に実施されます。すべてのドキュメントの書式設定、標準、ポリシー、および操作手順の要件を解釈し、適用します。提出コンポーネントを識別し、文書化基準を伝達し、規制ドシエの組み立てを調整することができます。データの分析と評価、関連情報の抽出、情報の要約、検索された資料のエグゼクティブサマリーの作成を行います。製品情報に関する広範な知識を維持し、地域、地域、および部門の顧客との継続的な連絡を維持することができます。

About the Role

Major Accountabilities
1. To author, review and manage high quality clinical documents and safety documents: complex Clinical Study Reports (CSR), submission documents [clinical portions of the Common Technical

Document (CTD)], other documents for health authorities [e.g., Briefing Books (BB), answers to questions, PMS and re-examination related documents].
2. Extended member of Japan Project Team (JPT) and Integrated Clinical Trial Team (iCTT). Core member of Japan Submission Team (JST).
3. Major contributor to planning of data analyses and presentation used in CSRs and submission documents.
4. Documentation specialist in iCTTs and JSTs to ensure compliance of documentation to internal company standards and external regulatory guidelines. Provide content expertise and guidance for clinical portions of the CTD.
5. Lead Writer for submissions, contributing to key messaging and pooling strategy, providing content guidance, and ensuring compliance of documentation to internal company standards and external regulatory guidelines.
6. Contribute to process improvement in RWS and/or cross-functional initiatives or activities.
7. Coach and/or mentor less experienced writers.
8. Leader in cross-functional communication to optimize feedback and input towards high quality documents.
9. Maintain audit, SOP and training compliance.
10. Ensure adequate reporting of adverse events / technical complaint / compliance issue in accordance with company procedures.
11. 100% timely delivery of all training requirements including compliance.

Education:(minimum/desirable)

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

Languages:

Fluent Japanese/English (oral and written).

Experience / Professional Requirement:

- ≥ 4 years medical writing experience or other relevant pharma industry experience combined with scientific and regulatory knowledge, plus in-depth knowledge of medical writing processes.
- Advanced knowledge of global regulatory environment and process (key regulatory bodies, key documents, approval processes).
- Advanced knowledge and experience, and demonstrated record of accomplishment in Japan local registering of drugs.
- Excellent communication skills (written, verbal, presentations)
- Advanced knowledge of biostatistics principles.
- Strong ability to prioritize and manage multiple demands and projects.
- Ability to define and solve complex problems (“Problem-solver”)
- Broad knowledge and future oriented perspective.
- Ability to drive and manage organizational and team performance across cultures.
- Proven track record in matrix environment.
- Some experience in managing global, cross-functional teams or simple global projects.
- Ability to motivate and coach people.

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Benefits and Rewards: Read our handbook to learn about all the ways we 'll help you thrive personally and professionally: https://www.novartis.com/sites/novartiscom/files/novartis-life-handbook.pdf

Accessibility and Accommodation:

Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.china@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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Benefits and Rewards: Read our handbook to learn about all the ways we 'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

部门
Development

Business Unit
Universal Hierarchy Node

地点
Japan

站点
Toranomon (NPKK Head Office)

Company / Legal Entity
JP05 (FCRS = JP005) Novartis Pharma K.K.

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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利便性と合理的配慮

ノバルティス は 障害 を 持 つ 個人 と 協力 し、合理的配慮 を 提供 することをお 約束 します。健康状態 や 障害 を 理由 に 採用 プロセス のいかなる 部分 においても、あるいは 職務 の 必須事項 を 果 たすた めに 合理的配慮 が 必要 な 場合 は midcareer-r.japan@novartis.com 宛 てに 電子 メール をお 送 りください。その 際 ご 依頼内容、ご 連絡先、求人票 の 番号 を 明 してください。

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