Expert Regulatory Writer

Job ID
REQ-10045012

3月 27, 2025

Japan

摘要

規制要件に従った、管理された文書化システム、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。規制当局からの要件への準拠を保証します。技術文書および非技術文書の変更システムを維持します。記録を分類および維持するための手順が確実に実施されていることを確認します。すべての文書のフォーマット、標準、ポリシー、および操作手順の要件を解釈し、実施します。提出物の構成要素を特定し、文書の基準を伝達し、規制関係書類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うことができます。製品情報に関する幅広い知識と、地域、地域、および部門の顧客との継続的な連絡を維持できます。
グローバル製品の開発、登録、維持に必要な申請および技術関連の規制戦略、インテリジェンス、および知識を開発および提供します。グローバルな開発プロジェクトや販売製品をサポートするためのグローバルなシステム、ツール、プロセスの実装を推進するための戦略的および技術的なインプット/サポートを開発します。

About the Role

Major Accountabilities

1. To author, review and/or independently manage multiple concurrent high quality clinical and safety documents complex Clinical Study Reports (CSR), complex submission documents [clinical portions of the Common Technical Document (CTD)]), other documents for health authorities (e.g., Briefing Books, answers to questions, PMS and re-examination related documents).
2. Extended member of Japan Project Team (JPT) and extended member of Integrated Clinical Trial Team (iCTT). Core member of Japan Submission Team (JST).
3. Strategic input into planning of data analyses and presentation (statistical analysis plan review and meetings) used in CSRs, submission documents and/or answers to questions.
4. Documentation expert in JPTs and JSTs to ensure compliance of documentation to internal company standards and external regulatory guidelines. Provide authoritative content and strategic expertise for clinical portions of the CTD.
5. Lead Writer for large and/or complex programs ensuring no submission-critical issues including consistency between documents for assigned programs.
6. Lead Writer 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.
7. Lead process improvement in RWS and cross-functional initiatives and/or activities.
8. Identify training needs to foster high level of performance within RWS. Coach/mentor and/or train less experienced writers.
9. Leader in cross-functional communication to optimize feedback and input towards high quality documents.
10. Maintain audit, SOP and training compliance.
11. Ensure adequate reporting of adverse events / technical complaint / compliance issue in accordance with company procedures.
12. 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 and English (oral and written).

Experience / Professional Requirement:

- ≥ 8 years medical writing experience or other relevant pharma industry experience combined with scientific and regulatory knowledge, plus expert knowledge of medical writing processes.
- Expert knowledge of and repeat experience in local regulatory environment and process (key regulatory bodies, key documents, approval processes).
- Expert knowledge and extensive experience, and demonstrated record of accomplishment in Japan local registering of drugs.
- Advanced knowledge and some experiences of accomplishment in global registering of drugs.
- Excellent communication skills (written, verbal, presentations).

- Expert knowledge of biostatistics principles.
- Proven ability to prioritize and manage multiple demands and projects.
- Demonstrated ability to define and solve complex problems (“Problem-solver”).
- Broad knowledge and future oriented perspective.
- Proven ability to drive and manage organizational and team performance across cultures.
- Proven track record in matrix environment.
- Experience in contributing to global, cross-functional teams or complex global projects.
- Demonstrated ability to motivate and coach people.

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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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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