# Associate Regulatory Writer

Job ID
REQ-10061500

9月 10, 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

- To write and/or edit with guidance of senior writer high quality clinical and safety documents: simple Clinical Study Reports (CSR), submission documents [clinical portions of the Common Technical Document (CTD)], and other documents for health authorities [e.g., Briefing Books

(BB), answers to questions, PMS and re-examination related documents].
- Extended member of Japan Project Team (JPT) and extended member of Integrated Clinical Trial Team (iCTT). Core member of Japan Submission Team (JST).
- Participate in planning of data analyses and presentation used in CSRs, summary documents and other relevant documents.
- Act as documentation consultant in CTTs to ensure compliance of documentation to internal company standards and external regulatory guidelines.
- Act as liaison between CTTs and publishing teams to ensure timely delivery of final documents for publishing.
- Support the development of RWS through participating in RWS initiatives and other related activities.
- Contribute to development of processes within RWS and cross-functional initiatives.
- Maintain audit, SOP and training compliance.
- Ensure adequate reporting of adverse events/ technical complaint/ compliance issue in accordance with company procedures.
- 100% timely delivery of all training requirements including compliance.

Education:

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:

- Some medical writing experience or other relevant pharma industry experience combined with scientific and regulatory knowledge.
- Knowledge of regulatory environment and process (key regulatory bodies, key documents, approval processes).
- Knowledge and experience, and demonstrated record of accomplishment in Japan local registering of drugs.
- Excellent communication skills (written, verbal, presentations)
- Knowledge of biostatistics principles.
- Ability to prioritize and manage multiple demands andprojects.
- Ability to define and solve problems ("Problem-solver")
- Knowledge and future oriented perspective
- Understanding of matrix environment
- Global, cross-cultural perspective and customer orientation.

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817million. That ' s how many lives our products touch. And while we ' re proud of that fact, in this world

of digital and technological transformation, we must also ask ourselves this: how can we continue to improve and extend even more people ' s lives?

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の未来を描いています。詳細はホームページをご覧ください。 https://www.novartis.co.jp

Japan

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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、求人票の番号を明記してください。

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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
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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