【800 ~ 1200万円】Medical Writer

大手外資製薬メーカーでの募集です。 臨床開発メディカルライターのご経験のある方...

Job Information

Recruiter
JAC Recruitment Co., Ltd.

Hiring Company
大手外資製薬メーカー

Job ID
1587435

Industry
Pharmaceutical

Company Type
International Company

Job Type
Permanent Full-time

Location
Tokyo - 23 Wards

Salary
8 million yen ~ 12 million yen

Work Hours
09:00 ~ 17:15

Holidays
詳細は求人ご紹介時にご案内いたします。

Refreshed
June 27th, 2026 09:00

General Requirements

Career Level
Mid Career

Minimum English Level
Business Level

Minimum Japanese Level
Native

Minimum Education Level
Post Grad Degree (PHD/MBA etc)

Visa Status
Permission to work in Japan required

Job Description

【求人No NJB2343381】
日本国内における臨床および規制関連文書の作成を統括し、プロジェクトの品質とスケジュール目標の達成を支援します。
対象文書は、第2相・第3相臨床試験報告書、規制申請資料、規制当局向け説明資料、対応文書、希少疾病用医薬品申請書など多岐にわたります。
最適化されたプロセスとシステムを活用し、関連部門と連携して効率的な文書作成体制を構築。
国内外の規制要件に対応しつつ、臨床開発と規制申請の円滑な進行をリードする役割を担います。

Required Skills

Qualifications

B.S. in medical / pharmaceutical / veterinarian / life science area or three years or more experience in either pharmaceutical R D industry is mandatory.

PharmD/PhD/MD in a relevant scientific discipline or MS/BS with a minimum of 3 years（MS）to 5 years（BS）in preparing regulatory submission documents or have equivalent credentials and experience.
Good understanding of global pharmaceutical drug development and requirements for submission of regulatory dossiers to global health authorities.
Good understanding of the tendency of each review department of PMDA regarding the contents of review reports and inquiries.
Demonstrated ability required for strong writing skills both in Japanese and in English preferably in authoring and leading the production of clinical/regulatory documents for submission to PMDA. Samples of required and experienced abilities are the followings:
Capable of updating appropriately the first draft of M2.5.1 and M2.5.6 authored by J CDL/J CS and providing appropriate advice when authoring the first draft or can prepare the first draft in collaboration with J CDL/J CS
Capable of independently finalizing other clinical modules getting cooperation from R D Development team.
Also capable of independently authoring the draft inquiry to regulatory regarding clinical matters.
Experience in authoring the clinical part of the pre JNDA/Eop2 consultation documents.
Capable of communicating with the Global team about the contents/strategies of the authoring documents such as CTD module and the response to inquiries.
Ability to analyze and interpret complex data from a broad range of scientific disciplines.
Excellent organizational communication facilitation and interpersonal skills in a cross functional team.
Demonstrated ability to manage timelines and keeping quality of work.
Working knowledge of a document management system.
Skills to appropriately manage CROs or translation vendors.
Skills to read scientific documents in English and communicate with the global members both in English.

Company Description

ご紹介時にご案内いたします