

【800 ~ 1200万円】Manager Expert Scientific Writer

ブリストル・マイヤーズ スクイブ株式会社での募集です。 臨床開発メディカルライ...

Job Information

Recruiter
JAC Recruitment Co., Ltd.

Hiring Company
ブリストル・マイヤーズ スクイブ株式会社

Job ID
1619939

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
【有給休暇】有給： 初年度は使用期間終了後1日 ~ 10日（入社時期によって初年度の付与日数は異なります。）2年目（13日）私...

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October 29th, 2026 18:20

General Requirements

Career Level
Mid Career

Minimum English Level
Business Level

Minimum Japanese Level
Native Level

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

Visa Status
Permission to work in Japan required

Job Description

【求人No NJB2343381】
Position Summary

Lead the authoring of clinical/regulatory documents in Japan.

The scope of clinical/regulatory documents includes clinical study reports（CSR）for local Ph 2 or 3 study regulatory

submission documents（CTD）briefing document for PMDA consultation regulatory response documents orphan drug designation.

Lead the authoring of clinical/regulatory documents and support the performance goals（including quality and timeline）for the clinical development and regulatory submission in Japan as planned by the R D Development Teams.
Establish cross divisional cooperative partnership with other functions according to the optimized and standardized processes and systems.
Fulfill the role of Japan Documentation Lead.
Duties/Responsibilities

Play the following roles and take responsibilities at each phase in the life cycle of the BMSKK asset;

Build the storyboard to author regulatory dossier policies and align with global team based on the information provided by DT.
As DOC lead understand the global authoring regulatory dossier strategy and lead the finalizing of domestic regulatory dossiers of clinical part.
Set an appropriate and the shortest timeline to complete authoring regulatory dossiers and comply with the timeline.
Propose to the team the optimal strategy for preparing regulatory submission documents based on the tendencies of each review division concerning the contents of PMDA review reports and inquiries.
Complete the clinical modules with J CDL/J CS based on the storyboard.
Manages and provides global submission materials to stakeholders as needed.
Authoring and conducting a coordinating activity as CSR author.
Take charge of the CSR authoring part in the inspection.
Manage the operational execution by strategically using outsource vendors and ensure quality of deliverables.
Comply with internal and external processes and guidelines.
Review and edit other clinical/regulatory documents as required.
Drive continuous process improvements by identifying and simplifying processes. Lead implementation of business process improvements based on information from collected metrics.
Give advice to other scientific writers to help them improve their capabilities in creation of clinical/regulatory documents for Japan.
Provide additional value by creating better collaborative work environment internally and externally to ensure that Japan team has a good communication with HQ counterparts as well as key stakeholders such as clinical research and regulatory.

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

医薬品の輸入、製造、販売