Medical Writer Japan

CSLベーリング株式会社での募集です。 臨床開発メディカルライターのご経験のあ...

募集職種

人材紹介会社
株式会社ジェイ エイ シー リクルートメント

採用企業名
CSLベーリング株式会社

求人ID
1598327

業種
医薬品

会社の種類
外資系企業

雇用形態
正社員

勤務地
東京都 23区

給与
700万円 ~ 1300万円

勤務時間
08:45 ~ 17:30

休日・休暇
【有給休暇】初年度 16日 1か月目から（入社月によって異なります）【休日】完全週休二日制 土 日 祝日 夏季休暇 年末年始...

更新日
2026年08月06日 04:00

応募必要条件

キャリアレベル
中途経験者レベル

英語レベル
ビジネス会話レベル

日本語レベル
ネイティブ

最終学歴
大学卒： 学士号

現在のビザ
日本での就労許可が必要です

募集要項

【求人No NJB2390126】
The Senior Medical Writer is responsible for planning preparing and managing medical writing projects as well as creating and reviewing documents in some instances.

Reporting to the Head of Clinical Development Japan the Senior Medical Writer is responsible for the creation and maintenance of document/presentation templates and the assembly and quality control review of medical writing projects

related to clinical development as well as regulatory submissions.

■Key Roles Responsibilities
Responsible for planning and preparing high quality medical writing deliverables that support the clinical development and regulatory requirements for Japan:

・Develops medical writing project timelines in collaboration with relevant functions and global counterparts
・Responsible for ensuring the appropriate plan process and tools are in place for content editing formatting quality checking and publishing
・Creates and reviews documents according to the plan
・Coordinates the review QC and assembly of medical writing deliverables including appropriate measures for PMDA inspections
・Provides input into medical writing vendor selection defines the scope of work to be outsourced and is responsible for medical writing vendor oversight on the outsourced deliverables

In close collaboration with the global counterpart make sure the Japan ・deliverables fully meet Japanese regulatory requirements and conventions
・Participates in the development implementation and communication of Best
・Practices SOPs templates work instructions style guides content guides and relevant systems/tools to ensure efficient preparation of high quality medical writing deliverables
・Proactively determines the needed changes to existing or creation of new guideline standards templates and relevant systems/tools
・Cultivates an understanding of modern medical writing processes and solutions through survey of relevant literature attendance at meetings and use of external networks
・Provides expert medical writing support to other functions as appropriate

Manage vendors with respect to deliverable timelines costs and quality while keeping desirable relationships
・Responsible for building and maintaining collaborative relationships with medical writing partner（s）（CRO vendor alliance partner etc）to ensure an effective efficient productive and professional working relationship
・Negotiate with partners to determine roles responsibilities processes and mutual expectations
・Negotiate with partners to determine the timeline that will be used for document delivery

スキル・資格

■Qualifications Skills Experience
・An undergraduate degree in pharmacy biological sciences or related disciplines is essential post graduate qualifications desired
・Prior experience of working in the role of medical writer within the CRO/Pharma/Biotech industry
・A minimum of 5 years Clinical experience in the role of medical writer
・At least one experience as a lead writer for J CTD
・Experience in developing clinical study reports in English is preferable
・A solid understanding of the Clinical Development Process including the documents that are required at each stage of development
・Excellent writing and oral communication skills（clear and logical）in both English and Japanese
・Strong interpersonal skills and time management skills
・Expert MS Office skills with a special focus on word processing tables and graphics spreadsheet presentations and templates
・An excellent understanding of all aspects of ICH and J GCP
・An ability to analyze interpret and communicate data accurately and concisely Ability to work independently and as a team member
・Ability to work to deadlines while maintaining focus on details and quality
・Demonstrated ability to work collaboratively; demonstrated negotiating skills and resourcefulness

会社説明

血漿分画製剤、バイオ医薬品の輸入・製造・販売