Medical Writer Japan

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Job Information

Recruiter
JAC Recruitment Co., Ltd.

Hiring Company
CSLベーリング株式会社

Job ID
1598327

Industry
Pharmaceutical

Company Type
International Company

Job Type
Permanent Full-time

Location
Tokyo - 23 Wards

Salary
7 million yen ~ 13 million yen

Work Hours
08:45 ~ 17:30

Holidays
【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...

Refreshed
June 25th, 2026 16:58

General Requirements

Career Level
Mid Career

Minimum English Level
Business Level

Minimum Japanese Level
Native

Minimum Education Level
Bachelor's Degree

Visa Status
Permission to work in Japan required

Job Description

【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

Required Skills

■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

Company Description

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