【1100～1600万円】【R D】 Clinical Regulatory Writer （CReW） 研究開発本部 薬事…

アストラゼネカ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る…

Job Information

Recruiter
JAC Recruitment Co., Ltd.

Hiring Company
アストラゼネカ株式会社

Job ID
1573302

Industry
Pharmaceutical

Company Type
International Company

Job Type
Permanent Full-time

Location
Tokyo - 23 Wards

Salary
11 million yen ~ 16 million yen

Work Hours
09:00 ～ 17:15

Holidays
【有給休暇】有給休暇は入社時から付与されます 【有給休暇】 初年度 4～16 日 （ 1 か月目～ ） 入社月により付与日数が…

Refreshed
January 22nd, 2026 15:07

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 NJB2303392】
■職務内容 / Job Description
Clinical Regulatory Writer （CReW） is responsible for the authoring of clinical regulatory documents and submission packages that communicate the evidence base of product knowledge in a credible consistent and compliant way.
CReW leads the authoring of the clinical parts of documents such as CSP / MICF / CSR / IB / CTD / Regulatory defences in line with the project communication strategy and ensure quality and efficiency in delivery. For CSP/MICF/IB CReW centralize

and coordinate those developments using external vendors across clinical studies.
CReW also leads or contributes the authoring of the clinical parts of the briefing documents for PMDA consultations to improve communication quality of documents. CReW reviews other clinical documents with the purpose of facilitating the translation of Target Product Claims into a fully supported proposed product label and to improve communication quality of documents.

Required Skills

【経験 / Experience】
＜必須 / Mandatory＞
A comprehensive knowledge of the drug development processes including key regulations/guidelines（e.g. GCP ICH GLs）and knowledge on a “need to know basis” in relevant therapeutic area
Experience in medical communications gained through working in the pharmaceuticals industry or a medical communications agency
Delivery of regulatory submissions including CTN JNDA/sJNDA and response to PMDA/MHLW queries during review

＜歓迎 / Nice to have＞
Experience in leading a preparation of clinical regulatory documentation.
Experience in supporting documentation preparation across programme and strategy level
Experience in supervising internal communication and outsourced writing.
Experience of any digital tool/ technologies in medical writing.

【資格 / License】
＜必須 / Mandatory＞
Bachelor’s Degree in Science or related discipline

【能力 / Skill set】
＜必須 / Mandatory＞
Medical writing skill
Logical thinking/Presentation skill to express intention in an efficient way in Japanese English
Interpersonal and communication skills with team member or stakeholders
Facilitation skill to lead an innovative solution in conflicting discussion

【語学 / Languages】
＜必須 / Mandatory＞
日本語 Japanese：Native Level
英語 English：Business English （Achieve common understanding at the context level with customers）

Company Description

医療用医薬品の開発、製造及び販売