



【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...

#### 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

アストラゼネカ株式会社

#### 求人ID

1573302

#### 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

1100万円～1600万円

#### 勤務時間

09:00～17:15

#### 休日・休暇

【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...

#### 更新日

2026年02月05日 23:00

#### 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 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.

## スキル・資格

### 【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)

## 会社説明

医療用医薬品の開発、製造及び販売