CareerCross by JAC Recruitment

【800～1250万円】Senior Regulatory Writer

臨床開発メディカルライターのご経験のある方は歓迎です。

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
非公開

求人ID
1530568

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
800万円 ~ 1200万円

勤務時間
09:00 ～ 17:45

休日・休暇
【有給休暇】初年度 20日 1か月目から 【休日】完全週休二日制 土・日・祝日、ゴールデンウィーク（4/29 5/5）、夏季・…

更新日
2025年05月15日 14:00

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 NJB2290704】
Major Accountabilities
1. To author review and manage high quality clinical documents and safety documents: complex Clinical Study Reports （CSR） submission documents [clinical portions of the Common Technical Document （CTD）] other documents for health authorities [e.g. Briefing Books （BB） answers to questions PMS and re examination related documents].
2. Extended member of Japan Project Team （JPT） and Integrated Clinical Trial Team （iCTT）. Core member of Japan

Submission Team （JST）.
3. Major contributor to planning of data analyses and presentation used in CSRs and submission documents.
4. Documentation specialist in iCTTs and JSTs to ensure compliance of documentation to internal company standards and external regulatory guidelines. Provide content expertise and guidance for clinical portions of the CTD.
5. Lead Writer for submissions contributing to key messaging and pooling strategy providing content guidance and ensuring compliance of documentation to internal company standards and external regulatory guidelines.
6. Contribute to process improvement in RWS and/or cross functional initiatives or activities.
7. Coach and/or mentor less experienced writers.
8. Leader in cross functional communication to optimize feedback and input towards high quality documents.
9. Maintain audit SOP and training compliance.
10. Ensure adequate reporting of adverse events / technical complaint / compliance issue in accordance with company procedures.
11. 100% timely delivery of all training requirements including compliance.

スキル・資格

■Education:（minimum/desirable）
Minimum university life science degree or equivalent is required. Advanced degree or equivalent education/degree in life sciences/healthcare is desirable.

■Languages:
Fluent Japanese/English （oral and written）.

■Experience / Professional Requirement:
・ ・ 4 years medical writing experience or other relevant pharma industry experience combined with scientific and regulatory knowledge plus in depth knowledge of medical writing processes.
・ Advanced knowledge of global regulatory environment and process （key regulatory bodies key documents approval processes）.
・ Advanced knowledge and experience and demonstrated record of accomplishment in Japan local registering of drugs.
・ Excellent communication skills （written verbal presentations）

会社説明

ご紹介時にご案内いたします