CareerCross by JAC Recruitment

【800～1250万円】Senior Regulatory Writer

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Job Information

Recruiter
JAC Recruitment Co., Ltd.

Hiring Company
非公開

Job ID
1530568

Industry
Pharmaceutical

Company Type
International Company

Job Type
Permanent Full-time

Location
Tokyo - 23 Wards

Salary
8 million yen ~ 12 million yen

Work Hours
09:00 ～ 17:45

Holidays
【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・…

Refreshed
April 17th, 2025 06:00

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 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.

Required Skills

■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）

Company Description

ご紹介時にご案内いたします