Safety Assistant Manager

CSLベーリング株式会社での募集です。 安全性情報（臨床開発・製販後GVP）の...

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
CSLベーリング株式会社

求人ID
1585119

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
650万円 ~ 1000万円

勤務時間
08:45 〜 17:30

休日・休暇
【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】週休二日制 土 日 祝日 夏季休暇 年末年始 年...

更新日
2026年05月02日 17:00

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 NJB2361432】
■Responsibilities:

Handling and assist management of safety related information of investigational products in accordance with GCP and support development tasks.・

Handling and assist management of safety related information of marketed products in accordance with GVP

Planning and implementation of measures for securing safety such as information providing/disseminating and assist management of those tasks

Implement and assist management・ of other GVP/GCP activities・ （archiving SOP management Training Outsourcing etc.）

Managing GVP/GPSP SOPs/WIs/other documents in Japan

Managing Vender including sign GVP agreement and PVA

Managing Organized Data Collection System （ODCS）

■Main Responsibilities and Accountabilities

1. Implement and assist management of collecting and evaluating safety management information such as AEs or infection cases and reporting to authorities. （Evaluating safety management information preparing reports submitting to authorities and archiving records）

2. Implement and assist management of exchanging safety information with relevant global organization and business partners.

3. Implement and assist management of preparing periodic reports and submitting them to authorities.

4. Planning and implementation of measures for securing safety such as information providing/disseminating and assist management of those tasks

5. Implement and assist management of creating and updating CTD1.11（J RMP） in the safety part receiving global approval and answering PMDA inquiries.

6. Implement and assist management of other GVP/GCP activities （archiving SOP management Training Outsourcing etc.）

7. From safety perspective join JPT and support development tasks.

8.・Implementing and managing procedure documents according to GVP/GPSP and confirming global SOPs/WIs/other documents （SOP management etc.）

9.・Managing Organized Data Collection System （ODCS） including the website in Japan according to GSPV standards

10.・Coordinating PVA signing in Japan in cooperation with GSPV

スキル・資格

■Job Qualifications and Experience Requirements

◇Education
Bachelor’s degree science is preferable;

◇Experience
Experience of PV activities under GCP and/or GVP; 3 years or more experience of safety is preferable.

◇Competencies
・knowledge of GCP/GVP/GPSP related laws and regulations in Japan
・Proficiency in written and spoken Japanese
・Good communication skills in English
・Good communication skills both internally and externally
・Problem solving / logical thinking

会社説明

血漿分画製剤、バイオ医薬品の輸入・製造・販売