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...

Job Information

Recruiter
JAC Recruitment Co., Ltd.

Hiring Company
CSLベーリング株式会社

Job ID
1585119

Industry
Pharmaceutical

Company Type
International Company

Job Type
Permanent Full-time

Location
Tokyo - 23 Wards

Salary
6.5 million yen ~ 10 million yen

Work Hours
08:45 ~ 17:30

Holidays
【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…

Refreshed
May 16th, 2026 04:00

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 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

Required Skills

■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

Company Description

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