



安全管理責任者

医療機器メーカーでの募集です。薬事申請のご経験のある方は歓迎です。

Job Information

Recruiter

JAC Recruitment Co., Ltd.

Hiring Company

医療機器メーカー

Job ID

1573827

Industry

Pharmaceutical

Company Type

International Company

Job Type

Permanent Full-time

Location

Tokyo - 23 Wards

Salary

7 million yen ~ 9 million yen

Work Hours

09:00 ~ 17:30

Holidays

【有給休暇】入社7ヶ月目には最低10日以上 【休日】完全週休二日制 年末年始 年末年始（12/30 1/3）祝日、夏季休暇、特...

Refreshed

February 5th, 2026 17:00

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 NJB2346093】

本ポジションは、製品の安全性と有効性を担保するため、国内外の規制対応と安全管理を統括します。安全管理責任者として、医薬品安全監視システムの構築・維持、報告義務の遵守、リスク管理、教育訓練の実施を行います。添付文書の作成・改訂や、外部安全管理委託先の監督も担当。製品登録申請や承認取得、開発プロジェクト支援、グローバルデータベースの活用、内部監査のリードも含まれ、チームと連携し事業目標達成に貢献します。

Required Skills

■Person Specification (Experience Academics Organizational Knowledge Personal Style)

○Experience Academics

- ・ 3+ years of experience in Pharmacovigilance of Pharmaceuticals in a multinational company
- ・ General Knowledge of PMD Act. GVP MHLW Ordinance ICH and relevant regulations
- ・ Experience in English business communication
- ・ Communication with governmental bodies

○Organizational Knowledge

- ・ Understand the company systems and processes ・ QA QC Marketing Sales Customer service IT HR GA Finance

Manufacturing Supply chain

- ・ Ability to communicate effectively across all operational levels of the organization as well as with suppliers and customers exercising appropriate tact and diplomacy to accomplish objectives
- ・ Effective interpersonal skills with the ability to present recommendations and ideas and to summarize issues
- ・ Strong interpersonal communication and analytical skills
- ・ Ability to work independently

○Personal Style

- ・ Take the initiative Leadership to achieve goals
- ・ Coordinate closely with concerned parties (internal and external)
- ・ Hear other opinions and get mutual consent
- ・ Positive and logical thinking
- ・ Stay calm in any trouble case

■COMPETENCIES REQUIRED

○Behavioral Competencies

- ・ Communication / Presentation / Negotiation / Influential skills (Japanese / English)
- ・ Inter functional leadership skills and team player
- ・ Problem analysis and solving skills
- ・ Strategic thinking and planning
- ・ Sound judgement ・ Attention to detail
- ・ Customer oriented ・ Spontaneity
- ・ Cross cultural communication skill
- ・ Team Building skill

○Functional Competencies

- ・ Ability to understand internal/external customer technologies and problem resolution techniques.
- ・ Ability to communicate effectively with customers
- ・ Ability to listen to symptom descriptions; to analyse problems; to respond effectively and to provide constructive feedback to the customer on problem resolution
- ・ Grasp overview of business project
- ・ Business market awareness
- ・ Negotiation Skills

Company Description

ご紹介時にご案内いたします