



Pharmacovigilance Reporting Associate

ICONクリニカルリサーチ合同会社での募集です。安全性情報（臨床開発・製販後...

Job Information

Recruiter

JAC Recruitment Co., Ltd.

Hiring Company

ICONクリニカルリサーチ合同会社

Job ID

1522989

Industry

Contract Research Organization

Company Type

International Company

Job Type

Permanent Full-time

Location

Tokyo - 23 Wards

Salary

4.5 million yen ~ 6 million yen

Work Hours

09:00 ~ 17:30

Holidays

【有給休暇】有給休暇は入社時から付与されます 入社7ヶ月目には最低10日以上 【休日】完全週休二日制 【休日】：土曜、日曜、祝...

Refreshed

February 20th, 2025 16:18

General Requirements

Career Level

Mid Career

Minimum English Level

Fluent

Minimum Japanese Level

Native

Minimum Education Level

Technical/Vocational College

Visa Status

Permission to work in Japan required

Job Description

【求人No NJB2204577】

Overview

- ・ Serve as safety reporting processor or lead for multiple safety reporting providing management support as designated.
- ・ Recognize exemplify and adhere to ICON's values which center around our commitment to People Clients and Performance.
- ・ As a member of staff the employee is expected to embrace and contribute to our culture of process improvement with a

focus on streamlining our

processes adding value to our business and meeting client needs.

- Complete all departmental project activities accurately in accordance with ICON SOPs Study Specific Procedures regulatory requirements and client processes.
- Responsible for safety reporting or safety reporting intelligence activities on assigned projects working in a customer focused approach and an audit and inspection ready mindset.
- Demonstrate skills pertaining to client management safety reporting project scope submission compliance quality and budget.

Detail

- The following safety information case processing tasks related to clinical trials/post marketing of pharmaceutical products
- Receipt of information on Adverse event triage numbering confirmation of details entry into database/QC
- Creation of explanatory text for case course (Japanese and English) /QC
- Primary evaluation of the necessity of reporting to the PMDA / QC of the evaluation details
- Preparation of reports to PMDA/QC
- Escalation coordination etc. to customers
- Operations incidental to the above

*Our Safety Reporting team will allow you to experience the ICCC study start up not just safety reporting. At first senior members will support you. You could expand your experience.

Required Skills

- Experience required for any of the following
- PV experience especially PMDA submission experience required.

Experience with ICCC is better.

- 2+ years of CRA experience
- Fluency in Japanese business level English

Company Description

1. 医薬品、医療機器、再生医療等製品、ワクチン等にかかる臨床開発、市販直後調査、製造販売後調査、臨床研究等の受託事業
2. 労働者派遣事業