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CMC Department Senior Manager ~ Rapidly Growing Bio Venture

Job Information

Recruiter

[j Career Co.,Ltd.](#)

Hiring Company

急成長しているバイオベンチャー

Job ID

1315041

Industry

Pharmaceutical

Company Type

Small/Medium Company (300 employees or less)

Non-Japanese Ratio

Majority Japanese

Job Type

Permanent Full-time

Location

Tokyo - 23 Wards

Salary

8 million yen ~ 15 million yen

Holidays

完全週休2日制（休日は土日祝日）年間有給休暇1日～15日（下限日数は、入社直後の付与日数となります）年間休日日数124日

Refreshed

July 31st, 2024 04:00

General Requirements

Minimum Experience Level

Over 6 years

Career Level

Mid Career

Minimum English Level

Business Level

Minimum Japanese Level

Fluent

フレックスタイム制：10:00～15:00 標準的な勤務時間帯：9:00～17:30 休憩時間：60分間

Minimum Education Level

Bachelor's Degree

Visa Status

Permission to work in Japan required

Job Description

Company:

Fast-growing bio-venture

We are developing pharmaceutical products specializing in the areas of "cancer, blood, and autoimmune diseases."

The company is working on the development of new drugs that focus on the "blank treatment area" that is expanding with structural changes in the pharmaceutical industry, and aims for sustainable growth as a company through activities that meet unmet medical needs.

Position:

As a manager of the CMC department of a listed (TSE Growth) pharmaceutical company, you will be involved in the following operations.

- (1) As a person in charge of the investigational drug supply department related to the development theme, you will be involved in the investigational drug supply business in line with the clinical development plan
- (2) Formulation and execution of a technology transfer plans in cooperation with related parties inside and outside the company and related departments.
- (3) Application / notification of approval or change (creation of CMC related documents)
- (4) Provide necessary CMC support for the internal departments related to product maintenance.

Treatment:

Health insurance, welfare annuity insurance, employment insurance, workers' accident compensation insurance (social insurance: Tokyo Pharmaceutical Health Insurance Association)

Commuting allowance: 6-month commuter pass

Severance pay system: Defined contribution pension (~ 60 years old), Contribution reserve (60 years old ~)

72 years old

- In-house study session
- In-house training (invited lecturer)
- OJT
- Attendance of external training

- Comprehensive welfare group term life insurance
- Health checkup assistance: As a general rule, various checkups designated by the health insurance company will be fully borne by the company, and the human dock will be subsidized up to 10,000 yen.
- Employee Stock Purchase System: Incentive 8%

Required Skills

Experience: CMC (formulations, especially injectables) related development, manufacturing, analysis work, CMC for domestic and international applications

Document writing experience

Knowledge: Knowledge of Pharmaceutical Machinery Law, related laws and regulations, GxP (GMP / GQP / GDP), JP, USP, EP, ICH, etc.

Ability: Ability to negotiate with contractors and partners, ability to manage schedules for collaborative work

Basic communication skills with foreign companies in English are required

Company Description

Remembering our Gratitude

For foreigners who chose to come to Japan

We express our gratitude towards international students who chose Japan as their destination of studying abroad by founding this company, with the primary purpose of providing international students and foreigners in Japan with the assistance they need to seize their happiness. In doing so, we hope to contribute to the Japanese society as well as the international community. Due to corporate globalization in recent years, some Japanese companies have adopted English as their official language. However, recruiting in Japan is still possesses unique customs thus presents a challenge to foreigners who are not familiar with it. At j Career, we are dedicated to help foreigners in overcoming such difficulties and support their endeavor in attaining a happy life in Japan.

We set up a job searching website called goojob.jp with the intention to help international students utilize their knowledge and expertise they learned and apply that in their job hunting. We also help people who are working with making a career switch.