

Regulatory Affairs-CMC  Exclusive job

Job Information

Recruiter

[en world Japan K.K](#)

Hiring Company

Global pharma company

Job ID

1207890

Company Type

Large Company (more than 300 employees) - International Company

Non-Japanese Ratio

Majority Japanese

Job Type

Contract

Location

Tokyo - 23 Wards

Salary

6 million yen ~ 8 million yen

Refreshed

April 29th, 2024 10:00

General Requirements

Minimum Experience Level

Over 3 years

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

☞ Serving as a contact point for the company, coordinates for pharmaceutical affairs matters on product development between internal concerned departments and regulatory authority.

☞ Performs pharmaceutical regulatory affairs tasks for obtaining pharmaceutical product approval. ☞ Prepares various pharmaceutical regulatory affairs documents in a timely and appropriate manner according to the product development plan.

☞ Manages pharmaceutical regulatory affairs schedules for product development plan.

☞ Working with internal concerned departments, prepares appendices attached to pharmaceutical regulatory affairs documents to be submitted to regulatory authority and submits them.

✎ Negotiates with subcontractors and external parties about pharmaceutical affairs issues as needed.

✎ Working collaboratively with other departments, reviews the documents (minutes, examination report, etc.) created by regulatory authority, builds a consensus and confirm them with the regulatory authority and obtains the final version of the documents.

✎ Presents pharmaceutical affairs strategies for product development plan to the concerned departments and gains consensus from them.

✎ Support Director's job

Required Skills

Minimum 5 years' work experience in RA.

Company Description

エンワールドについて

エンワールドは、アジア太平洋地域7カ国を拠点に、スペシャリスト・管理職のリクルーティングサービスを提供しています。また、海外拠点との連携によりクロスボーダーリクルートメントでグローバル企業のサポートも可能にします。

エンワールド・ジャパンについて

エンワールド・ジャパンは、外資系企業や、グローバルな視点を持つ日本企業を対象に、業界専任コンサルタントと職種専任コンサルタントとの二軸からのキャリアコンサルティングにより、きめ細かいマッチングを可能にします。

エンワールド・ジャパンは、金融、財務を専門分野とするウォールストリートアソシエイツとして1999年に設立されました。その後、多岐に渡る業界や職種においてサービスを展開、2010年にインターネットベースの採用ソリューションでは国内トップクラスである、エン・ジャパン株式会社のグループ会社となりました。

エンワールド・ジャパン株式会社

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About en world

en world is a group of recruiting consultancies specialising in professional and managerial roles. Operating from 7 countries, we support global companies' recruitment needs through our Asia Pacific network.

About en world Japan

en world Japan supports globally-renowned international and Japanese companies to hire professionals and managers. Our recruitment consultants specialise across both function and industry resulting in deep market knowledge and focused search results.

en world Japan was founded in 1999, operating as Wall Street Associates and specialising in financial services recruiting.

We expanded our coverage and service in response to our customer needs. In 2010 we became a group company of en-japan inc., a leading internet-based provider of recruitment services in Japan.

en world Japan K.K.

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