



## 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

July 8th, 2024 02:00

### 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

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## Required Skills

Minimum 5 years' work experience in RA.

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## 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ーションにより、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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