



【800～1300万円】 CMCマネージャー

外資製薬メーカーでの募集です。 CMC薬事のご経験のある方は歓迎です。

## Job Information

### Recruiter

JAC Recruitment Co., Ltd.

### Hiring Company

外資製薬メーカー

### Job ID

1591908

### Industry

Pharmaceutical

### Company Type

International Company

### Job Type

Permanent Full-time

### Location

Tokyo - 23 Wards

### Salary

8 million yen ~ 13 million yen

### Work Hours

08:30 ~ 17:15

### Holidays

詳細は求人ご紹介時にご案内いたします。

### Refreshed

May 14th, 2026 15:56

## 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 NJB2364696】

- ・ Responsible for CMC related regulatory affairs activities to obtain regulatory approval for biosimilars in Japan.
- ・ Activities such as the preparation publication of REG CMC documentation for submissions to Health Authorities (HA) .
- ・ Interaction with HA on REG CMC questions to make new products and/or post marketed products successful.

(Major accountabilities)

- ・ Lead CMC regulatory strategy with a focus on maximizing the business benefit balanced with regulatory compliance

- Lead submission activities (planning authoring reviewing coordination submission) for assigned projects/products.
  - Experience and capabilities are required to personally perform new submission and post marketed products.
  - Lead the submission by identifying required documents/ potential risks which could affect the defied timeline by assessing content and quality etc and by completing the application on time in line with a Global team · aligned project plan to obtain regulatory approval.
  - Authoring and reviewing high quality RA CMC documentation for HA submission ensuring alignment with applying agreed CMC global regulatory strategies and current regulatory trends and guidelines.
  - Prepare and communicate CMC Risk Management Assessments contingency plans and lessons learned on major submissions and escalate with management as appropriate.
  - Initiate and lead HA interactions and negotiations as appropriate; setting objectives preparing/reviewing briefing books coordinating and planning rehearsals and risk mitigation plans.
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## Required Skills

(Work Experience)

- Operations Management and Execution
- Cross functional collaboration

(Skills)

- Preparation of RA CMC related documents for biosimilar marketing authorization applications
- Change Control
- Cross Functional Teams
- Documentation Management
- Negotiation Skills
- Project Management
- Regulatory Compliance
- Risk Assessment
- Risk Management

(Languages)

- English and Japanese
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## Company Description

ご紹介時にご案内いたします