【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
June 11th, 2026 06:00

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.

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

Company Description

ご紹介時にご案内いたします