



【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。

募集職種

人材紹介会社

株式会社ジェイ エイ シー リクルートメント

採用企業名

外資製薬メーカー

求人ID

1591908

業種

医薬品

会社の種類

外資系企業

雇用形態

正社員

勤務地

東京都 23区

給与

800万円～1300万円

勤務時間

08:30～17:15

休日・休暇

詳細は求人ご紹介時にご案内いたします。

更新日

2026年06月11日 06:00

応募必要条件

キャリアレベル

中途経験者レベル

英語レベル

ビジネス会話レベル

日本語レベル

ネイティブ

最終学歴

大学卒：学士号

現在のビザ

日本での就労許可が必要です

募集要項

【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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スキル・資格

(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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会社説明

ご紹介時にご案内いたします