



Regulatory Affairs Manager at innovative global pharma

Elite pharma company

募集職種

人材紹介会社

ALBERTO株式会社

採用企業名

Global Pharmaceutical Company

求人ID

1532043

業種

医薬品

会社の種類

大手企業 (300名を超える従業員数) - 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 ~ 1500万円

更新日

2025年04月10日 10:19

応募必要条件

職務経験

6年以上

キャリアレベル

中途経験者レベル

英語レベル

流暢

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

Develop and execute regulatory affairs (RA) activities from the development to the life cycle management, with collaborative with global and Japan stakeholders.

Key Responsibilities:

- Lead regulatory affairs interactions with Health Authorities (HAs)
- Oversee New Drug Application (NDA) and supplemental NDA (sNDA) submissions

- Manage Japan NDA preparation and support Health Authority review for approval
 - Prepare regulatory components of the Japan CTD, including the Approval Application Form and Module 1
 - Lead the development and maintenance of electronic Japanese Package Inserts (J-PI)
 - Serve as the Regulatory Affairs representative for SOP/Work Instruction updates and process improvement initiatives
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スキル・資格

- Experience in Research & Development, particularly in Regulatory Affairs
 - Proven track record of collaboration with cross-functional teams and global stakeholders
 - Native-level Japanese and Advanced English
 - Strong stakeholder management skills
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会社説明