



Regulatory Affairs Manager at innovative global pharma

Elite pharma company

Job Information

Recruiter

ALBERTO K.K.

Hiring Company

Global Pharmaceutical Company

Job ID

1532043

Industry

Pharmaceutical

Company Type

Large Company (more than 300 employees) - International Company

Job Type

Permanent Full-time

Location

Tokyo - 23 Wards

Salary

8 million yen ~ 15 million yen

Refreshed

April 10th, 2025 10:19

General Requirements

Minimum Experience Level

Over 6 years

Career Level

Mid Career

Minimum English Level

Fluent

Minimum Japanese Level

Native

Minimum Education Level

Bachelor's Degree

Visa Status

Permission to work in Japan required

Job Description

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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Required Skills

- 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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Company Description