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ALBERTO RECRUITMENT

Regulatory Affairs Manager for global pharmaceutical

global pharmaceutical 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
July 31st, 2025 02:00

General Requirements

Minimum Experience Level
Over 3 years

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

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

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

Company Description