【980～1600万円】Associate Director Innovative Medicines Regulatory…

外資製薬メーカーでの募集です。 薬事申請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
1566767

Industry
Pharmaceutical

Company Type
International Company

Job Type
Permanent Full-time

Location
Tokyo - 23 Wards

Salary
9 million yen ~ 16 million yen

Work Hours
09:00 ～ 17:45

Holidays
【有給休暇】有給休暇は入社時から付与されます 10日～20日　※勤続年数による 初年度 10日 （入社日3日付与、入社3か月後…

Refreshed
January 8th, 2026 20:00

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 NJB2324367】
■Primary purpose and function of this position
・ Is responsible for developing the regulatory strategy preparation and execution of regulatory submissions （HA consultation documents Clinical Trial Notification （CTN） Marketing applications （MAs）） for innovative products with various tactics to expedite product registrations.

・ Requires a strong understanding and knowledge of local regulatory requirements and also actual experience of leading regulatory activities in Japan （e.g. CTN PMDA consultation J NDA dossier preparation and filing）.
・ Need a strong communication skills and built excellent trust based relationship with HAs （e.g. MHLW PMDA） and with various internal stakeholders （Incl. Innovative Medicines Regulatory Affairs Global development teams and Japan team）.
・ The Associate Director of Innovative Medicines Regulatory Affairs in Japan will lead the document preparation process （incl. Briefing Packages CTN documents J NDA dossier） to ensure high quality and timely submission as per the agreed workplan.

■Essential Duties Responsibilities
The Associate Director of Innovative Medicines Regulatory Affairs in Japan will be responsible for the following:
1. Accountable for the development and implementation of regulatory strategies in Japan. Create proactive and robust regulatory strategies for development products considering the global regulatory strategy through the discussion with the Global project team Global Regulatory Lead （GRL） Innovative Medicines Regulatory Affairs and Japan team members. Recommend such strategies to team members and senior management.
2. Lead implement and drive the regional regulatory strategy submission activities including the planning coordination and submission of Briefing Packages meeting requests CTNs J NDAs and other regulatory filings to ensure compliance with local regulatory standards.
3. Coordinate and lead the team in planning preparation （incl. Briefing Packages） and execution for meetings or teleconferences with HAs in Japan.
4. Coordinate responses to HAs with appropriate personnel and departments to resolve outstanding regulatory issues.
5. Ensure that cross functional activities to support submissions are in compliance with regulatory requirements to achieve timely submissions. Identify gaps and propose/support solutions to address them that are consistent with regulatory requirements. Initiation and/or participation in teleconferences and/or meetings related to the topic/project （to clarify issues solve issues discuss changes and strategy check timelines and availability of documents etc.）.
6. Represent Innovative Medicines Regulatory Affairs in Japan in global teams （Global Regulatory Strategy Team （GRST） project team protfolio/commercial team etc.） and provide regulatory filing strategy and guidance in Japan.
7. Assessment of business development opportunities from Japan regulatory perspective.
8. Update internal electronic systems as applicable.
9. Follows all Teva applicable policies and procedures.
10. Other duties as assigned or as business needs required.

Required Skills

■Position Requirements
・ Required: BSc/MSc in chemistry/biology/biotechnology/pharmacy or similar scientific field.
・ At least 5 years of experience in regulatory affairs for pharmaceuticals/biologics.
・ Knowledge and actual experiences of interaction with the HAs in Japan such as consultation meeting and/or J NDA review.
・ Understanding of the trend and changing regulatory environment surrounding clinical trials in Japan and global. Familiarity with CTD format and ICH requirements for J NDA filing and clinical development.
・ Ability to strategically apply knowledge across a protfolio of products.
・ Good leadership project management and communication skills as well as managerial capability.
・ Self learning Multi tasking capabilities.
・ English both spoken and written ・ business level required.

Company Description

ご紹介時にご案内いたします