



【900～1500万円】 Japanese Labelling Artwork Manager

外資系製薬会社での募集です。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

外資系製薬会社

Job ID

1571563

Industry

Pharmaceutical

Company Type

International Company

Job Type

Permanent Full-time

Location

Tokyo - 23 Wards

Salary

9 million yen ~ 15 million yen

Work Hours

09:00 ~ 17:30

Holidays

【有給休暇】初年度 10日 1か月目から付与 【休日】週休二日制 土 日 祝日 GW 年末年始 夏季・冬季休暇

Refreshed

February 20th, 2026 00:00

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 NJB2316386】

Primary Purpose:

Provides Japanese Labelling Artwork Regulatory expertise across a Therapeutic business unit. Delivers strategic and operational regulatory input and guidance to the cross functional teams.

MAJOR RESPONSIBILITIES

- Creation update and maintenance of the Japanese package inserts in line with the CCDS Agency RTQ and most up to date labelling requirements and labelling template required in Japan and according to SOPs

- If applicable for assigned Early development assets deliver competitive labelling searches and contributes to the TCLP for Japan (collaborating with Global Labeling Lead: GLL)
- Key point of contact for the Japanese Package Insert (digital package insert Module 1.8) for internal (GRA + strategic Partners in Japan) and external stakeholders (clinical medical legal commercial safety quality and be the Japan labeling representative in team meetings (DTJ Global RST LET Japan Submission Team ...). Lead Reviews Round Tables Approvals for the Japan Labeling in the appropriate system and according to SOP
- Delivers operational excellence for all labelling activities according to timelines such as appropriate tracking of the Japan labeling in the appropriate system and according to SOP
- Linguistic review process for ensure labelling compliance: Lead with local regulatory lead the Linguistic review according to Green book assist with the preparation of the Closing Sequence and ensure communication of HA approved label to internal and external stakeholders according to SOP
- Lead the Local Labelling Committee (including but not limited to medical legal commercial safety) for the creation review and approval for the Japan Labeling in the appropriate ECMS and according to SOP. This may also include discussion with relevant cross functional SMEs and Japanese Health Authorities
- Key point of contact for the Japan Artwork for GRA and external stakeholders (medical legal commercial safety quality.
- As Japan labelling artwork expert for assigned Therapeutic Business Unit
- the individual will build strong relationships with:
 - Japan and Global Regulatory teams
 - Local business partners (commercial access medical affairs legal and understand their business needs
 - Key partner with SPA for labelling and artwork changes
 - Monitor changes in Japan labelling and artwork requirements • keep the organisation aware of changes in Japanese regulatory requirements.

Required Skills

COMPETENCIES

- Build effective partnerships • identifies opportunities and takes actions to build effective relationships with internal and external stakeholders gains trust and external networking Influencing skills through well thought through rationale and effective communication skills able to influence key decisions. negotiation and influencing skills to develop regulatory strategies contributing to patient value creation
- Flexibility and adaptability Decides what to do based on the situation. Changes behavior or approach to fit the situation or the person. Works effectively in ambiguous situations
- Communication skills • knows when and how to communicate using strong interpersonal skills and written communications when appropriate
- Results focused • ability to overcome obstacles and achieve key outcomes
- Analytical • logically breaking situations or issues down into their essential elements: carrying out diagnosis and developing solutions
- Organizational Skills
- Integrity • Commitment to integrity and high standards in self and others Risk management: Anticipates identifies characterizes and escalates risks associated with our products processes and submissions. Identifies and defines research questions and strategy relevant data sources methodologies and systems for benefit safety and Risk Minimization Measures (RMM) effectiveness analysis in a rapidly evolving environment
- Leadership: Lead transversally beyond organizational borders empower hold accountable drive innovation and engage around vision.

Company Description

ご紹介時にご案内いたします