

【東京｜医療機器｜薬事】 薬事ディレクター/RA Director

募集職種

人材紹介会社
株式会社 JAC International

求人ID
1613051

業種
医療機器

会社の種類
中小企業 (従業員300名以下) - 外資系企業

雇用形態
正社員

勤務地
東京都 23区, 大田区

最寄駅
京浜東北線　(東京-横浜)、　大森駅

給与
1400万円 ~ 2000万円

ボーナス
給与： ボーナス込み

歩合給
給与： 歩合給込み

勤務時間
9:00-17:30 (コアタイム：11:00-14:00)

更新日
2026年11月09日 01:00

応募必要条件

職務経験
10年以上

キャリアレベル
中途経験者レベル

英語レベル
ビジネス会話レベル

日本語レベル
流暢レベル

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

OBJECTIVES/PURPOSE OF JOB
The Senior Regulatory Affairs Manager is responsible for leading regulatory strategy and execution in Japan for a portfolio of medical devices and healthcare products.

This role serves as the primary interface with PMDA, MHLW, and relevant authorities, driving successful product registrations, lifecycle management, and compliance. The position plays a critical role in integrating Japan regulatory requirements into global development programs, while building a high-performing regulatory team and partnering closely with Quality and Commercial functions to ensure business success.

Key Responsibilities

1. Japan Regulatory Strategy & PMDA Submissions (Core Focus)
Lead development and execution of Japan regulatory strategies across the full product lifecycle
Own and drive end-to-end PMDA submissions, including:
o Class II,IV medical device approvals and certifications
o Healthcare product registrations and variations, as applicable
o Lifecycle submissions (partial changes, renewals, updates)
Develop and execute PMDA consultation strategies, including pre-submission interactions, scientific advice, and issue resolution
Ensure submissions are high-quality, compliant, and aligned with business timelines and launch objectives

2. Clinical & Regulatory Integration
Provide regulatory leadership for clinical evidence requirements for Japan, including:
o Evaluation of clinical data needs for device approvals
o Bridging strategies using global data where applicable
o Input into clinical/regulatory pathways for new and modified devices
Partner with global Regulatory, Clinical, and R&D teams to ensure:
o Early incorporation of Japan requirements into development programs
o Alignment of Japan strategy with global submissions

3. Health Authority Leadership
Serve as the primary company representative to PMDA, MHLW, and local authorities
Lead regulatory consultations, negotiations, and formal interactions
Proactively manage regulatory risks and drive issue resolution with authorities
Build and maintain strong, credible relationships to facilitate efficient approvals

4. Cross-Functional Partnership (Critical Success Factor)
Partner closely with Quality to ensure:
o Alignment on QMS requirements, inspections, and compliance
o Successful execution of QMS submissions and foreign manufacturing registration
Partner with Commercial/Marketing to:
o Enable compliant and competitive product launches
o Review and approve promotional materials and claims
o Ensure labeling supports both regulatory and market needs
Collaborate with Supply Chain, Manufacturing, and Technical teams to ensure alignment on regulatory requirements for product changes and launches

5. Labeling, Promotion & Compliance
Lead regulatory review and approval of:
o Labeling, IFUs, packaging, and product claims
o Promotional and advertising materials for compliance with Japan regulations
Ensure compliant implementation of product changes through robust change control processes

6. Regulatory Intelligence & External Engagement
Monitor and interpret changes in Japan regulatory requirements and global standards (ISO, IEC, etc.)
Provide strategic insights to internal stakeholders to guide product development and lifecycle planning
Participate in industry associations and regulatory forums to stay ahead of policy changes

7. People Leadership & Team Development
Build, lead, and develop a high-performing Regulatory Affairs team in Japan
Provide coaching, mentoring, and structured development plans
Drive a culture of accountability, speed, collaboration, and continuous improvement
Ensure strong succession planning and capability building

8. Business & Operational Leadership
Lead regulatory project management for Japan submissions and approvals
Manage the Japan RA budget and resource planning
Support new product introductions and business development from a regulatory feasibility perspective

SUPERVISE DIRECT REPORTS: Yes

SCOPE OF POSITION
Recruitment, education, and team management of RA team staffs
Project Management for regulatory submissions
Responsible for business license maintenance
Manages RA budget.

KEY RELATIONSHIPS
Internal
Global Regulatory Affairs (core partner for global program alignment)
Quality Assurance and Compliance
Clinical, R&D, and Medical Affairs
Commercial / Marketing / Market Access
Supply Chain and Manufacturing
External
PMDA, MHLW, and local authorities

Industry associations (e.g., device and pharma groups)
Regulatory consultants and external partners

Employee Benefits:
Employment Type: Full time employee
Office Location: Central Tokyo, Japan
Working Model: Hybrid, 2-3 days in office with flex time.
Interviews: 2-3
Budget: Up to 18 Mil (base+bonus)
Welfare and Insurances: Covered

スキル・資格

QUALIFICATIONS/ TRAINING (e.g. professional qualifications, on-the-job training, education)
Bachelor's degree in a scientific or technical field (e.g., engineering, life sciences); advanced degree preferred
Pharmacist license is a plus

Experience
10+ years of Regulatory Affairs experience in medical devices and/or combination products
Strong track record of PMDA submissions and approvals for medical devices (Class II?IV)
Experience with quasi-drug regulatory pathways preferred
Demonstrated experience in Health Authority interactions and regulatory negotiations in Japan
Experience supporting clinical/regulatory strategy for device approvals
5+ years of people leadership experience, including team development
Experience working in global, matrixed organizations

Skills & Competencies
Deep expertise in:
o Japan medical device regulations and PMDA processes
o QMS requirements and regulatory compliance in Japan
o Labeling and promotional review requirements
Strong ability to:
o Lead complex submissions and navigate regulatory ambiguity
o Influence cross-functional and global stakeholders
o Translate global strategy into Japan-specific execution
Excellent:
o Project management and problem-solving skills

会社説明

新たに日本マーケットに参入される外資系企業や、日本でさらなるビジネス拡大をお考えの外資系企業のお客様に、私たちは最適な採用サポートを提供いたします。1975年に英国初の日系人材紹介会社としてロンドンで創業し、その後シンガポール、日本、マレーシア、インドネシア、タイ、中国の7カ国 (また2011 年には香港・韓国にも拠点を新設予定) でグローバル人材紹介会社として事業を拡大してきたジェイ エイ シーは、そのバックグラウンドから、海外文化への深い理解を持ち合わせています。グローバルに事業を展開する日系人材紹介会社のリーディングカンパニーとして、私たちは他に類のない人材ネットワークから、日本人の優秀なバイリンガル人 材や外国人のプロフェッショナル人材をご提供することが可能です。幅広い業種、職種においてのエキスパートである当社のネイティブあるいはバイリンガルコ ンサルタントが皆様のパートナーとなり、適材適所で人材のご紹介をいたします。ジェイ エイ シーが築いてきた特有の歴史、文化、そしてグローバルマーケットでの強みを揺ぎない核として、日本マーケットで躍動する外資系企業のお客様のニーズにさら に的確にお答えするために、ジェイ エイ シー インターナショナルは誕生しました。私たちはアジアやヨーロッパのJAC Recruitment Group海外各社と緊密に連携を取り、お客様の真のニーズを把握した上で、最適なキャンディデイトをご紹介いたします。

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We provide specialized proactive recruitment support tomultinational clients who are setting up new operations or areexpanding existing business and seeking further growth in theJapanese market.As the first Japanese recruitment company to set up operations in theUK in 1975, understanding foreign cultures is second nature to us.With our extensive global network and historically leading position asrecruitment consultancy to Japanese corporations, we have access toan unrivaled pool of bilingual Japanese and foreign professionals.Our professional consultants are experts in a range of Industries andfunctions and all have extensive multicultural experience.Based on JAC's unique history, culture and market strength, JACInternational was founded to provide dedicated support to ourmultinational corporate clients in Japan.

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