

Regulatory Affairs Specialist or Senior Specialist

募集職種

人材紹介会社
株式会社 JAC International

採用企業名
Global Oncology Diagnostics Company

求人ID
1618894

業種
その他

雇用形態
正社員

勤務地
東京都 23区

給与
700万円 ~ 経験考慮の上、応相談

更新日
2026年11月05日 01:00

応募必要条件

職務経験
3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
ビジネス会話レベル

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

Position Summary

This role is responsible for leading Regulatory Affairs (RA) and Quality Assurance (QA) activities for a healthcare diagnostics organization in Japan. As an individual contributor, this position will support regulatory submissions and oversee quality and safety management activities across both commercialized products and products under development.

The position provides balanced exposure to both RA and QA functions, including regulatory strategy, submission planning, interactions with regulatory authorities, Quality Management System (QMS) operations, product quality management, and post-market quality oversight.

The role supports a portfolio that includes in vitro diagnostic (IVD) products, companion diagnostics (CDx), oncology-related diagnostics, and Software as a Medical Device (SaMD). Responsibilities include regulatory submissions, maintenance of product approvals, quality management activities, and ensuring compliance with applicable Japanese regulations and industry standards.

Key Responsibilities
Regulatory Affairs
Lead regulatory strategy, submission planning, approval activities, and post-approval maintenance for products marketed in Japan.
Prepare, review, and coordinate regulatory submissions, including new product applications, partial change applications, notifications, and regulatory impact assessments.
Serve as a key contact for interactions with Japanese regulatory authorities, including consultations, reviews, and inquiry responses.
Assess regulatory impact of product, manufacturing, process, specification, and software changes.
Determine and execute required submission, notification, and compliance activities related to lifecycle management.
Collaborate with global RA, QA, Clinical, Medical, Manufacturing, Commercial, and external partners to ensure compliance with Japanese requirements.
Monitor and interpret evolving regulatory requirements and industry trends, assessing business and product impact.

Quality Management System (QMS)
Maintain and continuously improve the Quality Management System in accordance with Japanese medical device and IVD regulations.
Manage core quality processes, including:
SOP management
Change control
Deviations and non-conformities
Complaint handling
Corrective and Preventive Actions (CAPA)
Ensure quality records and documentation remain compliant, accurate, and inspection-ready.
Support quality documentation required for product registrations, lifecycle changes, and post-market activities.

Quality Events and CAPA
Lead investigation and resolution of quality events, complaints, and non-conformities.
Perform root cause investigations and implement corrective and preventive actions.
Maintain appropriate documentation and ensure timely closure of quality records.
Evaluate regulatory impact related to quality events and change controls.
Coordinate with internal stakeholders, manufacturing partners, and external organizations regarding quality matters.

Audits and Inspections
Serve as the primary QA representative for internal audits, supplier audits, and regulatory inspections.
Coordinate audit preparation, audit responses, and follow-up actions.
Partner with global quality teams to maintain alignment with global quality standards and procedures.
Support oversight of manufacturing and supplier quality activities.
Ensure consistency across regulatory submissions, product documentation, and quality records during inspections.

Product Quality and Change Management
Support QA review and approval activities associated with product release and quality records.
Assess quality and regulatory implications of product and process changes.
Ensure appropriate documentation, risk assessment, and compliance activities are completed.
Maintain documentation traceability throughout the product lifecycle.
Support products from development and launch through post-market management.

Training and Quality Culture
Provide internal training on regulatory and quality requirements.
Support cross-functional teams in implementing regulatory and QMS requirements.
Promote a culture of compliance, quality, and continuous improvement throughout the organization.

Employee Benefits:
Employment Type: Full time employee (正社員)
Office Location: Central Tokyo, Japan
Working Model: Hybrid, 2-3 days in office with flex time.
Interviews: 3
Budget: Up to 11 Mil (base+bonus)
Welfare and Insurances: Covered

スキル・資格

Education
Bachelor’s degree or higher in a scientific, engineering, or other relevant technical discipline.
Advanced degree (Master’s, MBA, PhD, etc.) preferred.

Experience
Approximately 5-8 years of Regulatory Affairs and/or Quality Assurance experience within the medical device, diagnostics, life sciences, or healthcare industry in Japan.
Experience supporting RA and QA activities for regulated healthcare products.
Hands-on experience with Japanese regulatory submissions, authority interactions, approval applications, change management activities, and post-approval maintenance.
Experience evaluating the regulatory and quality impact of product, process, manufacturing, specification, or software-related changes.
Experience managing or supporting Quality Management System (QMS) activities, including document control, change control, deviations, non-conformities, complaint handling, CAPA, and audit support.
Experience serving as a Quality Responsible Person or equivalent quality leadership role is preferred.
Experience within a Marketing Authorization Holder (MAH) environment is preferred.
Experience in molecular diagnostics, advanced diagnostics, digital health, personalized healthcare, or other innovative healthcare technologies is a plus.

Technical Expertise
Strong understanding of Japanese regulatory requirements governing medical devices, diagnostics, and related healthcare products.
Knowledge of regulatory and quality requirements applicable to regulated healthcare products, including software-enabled products.
Experience preparing, reviewing, and managing regulatory documentation and authority communications.
Practical experience operating and maintaining Quality Management Systems and associated quality processes.
Experience supporting or leading internal audits, external audits, supplier audits, and regulatory inspections.
Familiarity with internationally recognized quality standards and risk management principles is preferred.

Business Skills
Native-level or fluent Japanese and business-level English communication skills, both written and verbal.
Ability to work independently and manage multiple priorities in a dynamic environment.
Strong attention to detail and commitment to documentation quality, accuracy, and compliance.
Effective stakeholder management skills, with the ability to collaborate across cross-functional and global teams.
Strong problem-solving abilities and capability to assess issues from both regulatory and quality perspectives while implementing practical solutions.

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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