

Associate Director of Regulatory Affairs

募集職種

人材紹介会社
株式会社 JAC International

採用企業名
New Market Entry CRO

求人ID
1617147

業種
その他

雇用形態
正社員

勤務地
東京都 23区

給与
経験考慮の上、応相談

更新日
2026年10月29日 22:00

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

The position supports the subordinates and the unit in development, implementation, and achievement of the department goal, strategy and financial metrics.

Uses his/her project and submission management experiences to provides the overall supervision and guidance for the regulatory affairs to the project and/or the regulatory subordinates.

Supports the account manager to identify and develop sales opportunities and generates the regulatory strategy and/or relevant service scope and budget tailored to client's need.

Personnel Management
-Provides supervision and guidance to the subordinates for the project execution and/or identifies the resources needed to ensure the success of the team and/or their project(s)
-Responsible for the quality and consistency of work across the department
-Evaluate the project and backlog to generate and execute the staffing strategy (recruitment, training, and development of

talents and evaluate the performance in a fair fashion per role/position with less guidance from Line Manager)
-Build teams in different disciplines and services by training and mentoring from each subject matter expert through the relevant methodologies, techniques, frameworks, etc.
-Engage the team and minimize the turnover rate
-Provide the leadership for the unit and across the department with support from LM as applicable
-Ensure the subordinates carries the same standard/role model to their direct reports for the department to reach the final goals with support from LM as applicable

Department Affairs
-Accountable for Regulatory Intelligence Management with the inputs from the senior management and/or technical experts and share the impact analysis and execution plan to the impacted department(s), as needed, with the guidance from the LM.
-Independently responsible, accountable, training and mentoring on Standard Procedure Management and initiate the change management to improve the service delivery, as applicable, with the guidance from the LM.

Project Execution
-Independently accountable/responsible and/or providing training/mentoring for different regulatory services included but not limited to CTD authoring, CTD document preparation and publishing, country submission, gap analysis, consultation, Regulatory project coordination, management and strategy.
-Responsible for the regulatory project governance, client's pipeline management and maintain/engage client's relationship with minimum guidance/support from LM

Commercial Support
-Support Account Manager to identify/develop sales opportunities and to generate the service scope and corresponding budget for regulatory related services as well as deliver sales presentations and participates in id defense meetings when needed
-Contributes information to support the account planning process and integrated marketing programs

Employee Benefits:
Employment Type: Full Time Employee
Office Location: Tokyo or Osaka
Working Style: Remote
Salary Range: Up to 16mil.
Welfare and Insurances: All Covered
Reporting Language: Japanese

スキル・資格

Requirements:
-9+ years RA experiences and/or equivalent competencies in pharmaceutical industry/clinical research.
-Leadership skills that include the ability to gain trust with a variety of clients as well as within the department
-Familiarity with ICH/GCP and all different regulatory guidance.
-Excellent interpersonal, verbal and written communication, organization and planning skills with an attention to detail.
-Ability to role model behaviors and ethics in line with company Mission, Vision and Values.
-Ability to work effectively with internal and external team members.
-Previous managerial experience required and demonstrate ability to manage and motivate direct reports
-Strong and proven negotiation, problem resolving, and management skills.
-A flexible attitude with respect to a fast-paced and rapidly changing environment and ability to adapt the changes
-Demonstrated ability to communicate and write English clearly, concisely, and effectively.
-Provides a full range of regulatory consulting services Provides a full range of regulatory consulting services

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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