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Japan Regulatory Affairs Manager [グローバル製薬企業の品質薬事担当職] 独占求人

成長を続ける世界的な製薬会社における安定的でチャレンジングなキャリア

募集職種

採用企業名
ICE S.p.A

支社・支店
インターナショナル・ケミカル・エンティティ・ジャパン株式会社

求人ID
1529379

部署名
Quality and Regulatory Affairs Division（品質・薬事本部）

業種
医薬品

会社の種類
中小企業 (従業員300名以下) - 外資系企業

外国人の割合
外国人 少数

雇用形態
正社員

勤務地
福島県, いわき市

最寄駅
常磐線3　（仙台-原ノ町-いわき-水戸-上野）、　湯本駅

給与
650万円 ~ 800万円

勤務時間
08:30 - 17:15, 7 hours 45 minutes per day, 1 hour lunch break

休日・休暇
Saturdays, Sundays, National holidays

更新日
2025年04月22日 00:00

応募必要条件

職務経験
6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 (英語使用比率: 50%程度)

日本語レベル
ネイティブ

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

Job Title
Regulatory Affairs Manager

Reporting Line
Head of Quality & Regulatory Affairs

Key Responsibilities
The Regulatory Affairs Specialist is going to be accountable for the following activities:

- Management of contact with Domestic and Overseas Regulatory Authorities
- Redaction and submission of registration procedure to Domestic and Overseas Regulatory Authorities
- Interaction with Official Bodies such us Municipality, prefecture, Consulates.
- Preparation and submission of responses to the DMF Deficiency Letter received from Domestic and Overseas Regulatory Authorities.
- Preparation and submission of documentation relevant to requests for inspections of Pharmaceutical Company by domestic Authorities and submission of Action Plan following inspection.
- Preparation and submission of Dossier in eCTD format and in accordance with guidelines to request a Certificate of Suitability and must interact with the European Directorate for Quality of Medicines Authorities
- Work with cross functional teams (QA, QC, R&D, production) to improve processes and workflows, assessment and management of any regulatory impacts change and verification of the regulatory compliance
- Work with cross functional teams on process and analytical validation activities to support regulatory filings
- Work with IT, QC/QA, and Production, to ensure applicable computer systems are appropriately validated and qualified including SAP
- Regulatory technical assistance to the customer portfolio to support their registrations
- Check for updates on the monographs of the main Pharmacopoeias of reference (EP, USP, JP) and assessment of the impact on products of corporate interest

スキル・資格

- Bachelor’s degree (or equivalent) preferably in Pharmacy or in Scienceor techincal discipline
- At least 10 years of regulatory affairs in a pharmaceutical company and preferably in API company
- Experience in the successful management of regulatory audits
- Fluent in Japanese and English
- Effective communication skills (both written and verbal) Proficiency in the use of IT applications (MS365 - Word, Excel, Outlook/Teams/SharePoint/OneDrive, PowerPoint, etc)
- Excellent attention to detail
- Proven ability to work effectively on own initiatives as well as contributing to the team environment
- Ability to collaborate and influence across the local (Japan) and HQ offices
- Demonstrated experience in managing regulatory affairs tasks for preparation, implementation, and execution of submissions within designated timeframes
- Experience interacting directly with Regulatory Agencies and external providers to meet designated timeframes and maintain regulatory compliance

Location
Iwaki, Fukushima prefecture but partial remote work negotiable
※ Relocation support is provided

About ICE Group
ICE Group is a worldwide multinational Company specialized in natural origin Bile Acids derivates. Founded more than 60 years ago and headquartered in Reggio Emilia (Italy), the Company is now one of the main global players in natural origin bile -related products, with a network of specialist facilities and subsidiaries in Europe, Asia, Oceania, North and South America, which collect and process bile safely and securely.

ICE’s core business includes the manufacturing of Active pharmaceutical ingredients and final dosage forms along with derivatives linked to its bile collection network. Its global and vertical integrated business structure allows the Company to collect bile and process it into ingredients, the most important of which is the Ursodeoxycholic Acid (UDCA), a key ingredient in drugs treating liver diseases and gallstones.

On top of UDCA production, ICE is also committed to enhance the production of almost 20 other APIs that are currently manufactured in our sites in Italy (Reggio Emilia, Basaluzzo), Japan (Iwaki), India (Raichur) and New Zealand, while the FDF production is located in our site in Ivrea (Italy).

ICE has 5 R&D centres, spread across Italy, United Kingdom, India and New Zealand, which allow the Company continuous growth, through the constant development in bile derivatives field as well as in innovative research and development in plant-based bile acid chemistry along with consolidated expertise in carbohydrates. ICE’s Innovation is strongly supported by cutting edge collaboration with worldwide top Universities, leading the identification of bile acid-based molecules and lead candidates for highly significant unmet diseases like Parkinson’s, Alzheimer’s, NASH.

Since October 2019, ICE Group is owned by Advent International, one of the largest and most experienced global private equity investors, that started a vigorous M&A Plan in API and pharmaceutical business.

Corporate Cultural Pillars
Our Cultural Pillars shape the foundations of how we operate as a growing global enterprise. Our Cultural Pillars of :

- Unity
- Evolution
- Achievement

are at the forefront of how we conduct business.

Equal Opportunities
ICE PHARMA operates according to impartiality and does not tolerate any type of discrimination based on age, language, gender, sexual orientation, health status, disability, ethnicity, nationality, political views and religious beliefs.

Our recruitment practices are inclusive and free from discrimination.

会社説明