

Japan Regulatory Affairs Manager [グローバル製薬企業の品質薬事担当職] [Exclusive job](#)

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

Job Information

Hiring Company

ICE S.p.A

Subsidiary

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

Job ID

1529379

Division

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

Industry

Pharmaceutical

Company Type

Small/Medium Company (300 employees or less) - International Company

Non-Japanese Ratio

Majority Japanese

Job Type

Permanent Full-time

Location

Fukushima Prefecture, Iwaki-shi

Train Description

Joban Line 3 (Sendai-Haranomachi-Iwaki-Mito-Ueno), Yumoto Station

Salary

6.5 million yen ~ 8 million yen

Work Hours

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

Holidays

Saturdays, Sundays, National holidays

Refreshed

April 22nd, 2025 00:00

General Requirements

Minimum Experience Level

Over 6 years

Career Level

Mid Career

Minimum English Level

Business Level (Amount Used: English usage about 50%)

Minimum Japanese Level

Native

Minimum Education Level

Bachelor's Degree

Visa Status

Permission to work in Japan required

Job Description**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 as 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
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Required Skills

- Bachelor's degree (or equivalent) preferably in Pharmacy or in Science or technical 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 derivatives. 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.

Company Description