

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 1st, 2025 14:52

## 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

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**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.

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**Company Description**