Passion for Innovation. Compassion for Patients.™

Daiichi Sankyo and its 15.000 employees in more than 20 countries are dedicated to the creation and supply of innovative pharmaceutical products. In addition to a strong portfolio of medicines for hypertension and thrombotic disorders, under the Group's 2025 Vision to become a "Global Pharma Innovator with Competitive Advantage in Oncology". Our European headquarters are in Munich, Germany and we have affiliates in 13 European countries. For more information: www.daiichi-sankyo.eu.

For our headquarter in Munich we are seeking highly qualified candidates to fill the position

Regulatory Operations Associate (m/f/x)

The position:

In this role, you will be part of a highly competent team resided in Munich and also in Basking Ridge/US. You will be responsible for electronic submissions to Regulatory Health Authorities regarding Daiichi Sankyo products. You will collaborate with different functions on either side at the company.

Key responsibilities:

- Good knowledge of EU, Swiss, GCC regulatory electronic submission standards is required, US would be a plus
- Preparation of submissions in collaboration with Regulatory Affairs in EU and Regulatory Operation counterparts in the US
- Responsible for confirmation that Daiichi Sankyo document standards are adhered
- Ensuring on-time delivery of high quality, compliant and valid submissions
- Familiar with dispatch of submissions via different electronic submission channels (e.g. CESP, EMA Gateway,)

- Knowledge of Health Authority guidelines concerning electronic submissions and ensuring their proper application
- As needed, participating in special projects (e.g. developing processes within the team's area of responsibility)

Personal skills and professional experience:

The following is required:

- Bachelor's degree or equivalent work experience is required
- At least 3 years of pharmaceutical experience in a global regulatory environment, including hands-on experience with a document management system (e.g. Veeva), provision of eCTD ready documents for submissions as well as electronic publishing tool like LORENZ docuBridge is a plus
- Collaborative, well organized and thorough team player
- Working towards deadlines combined with a professional, flexible, service-oriented mindset
- Very good written and verbal communication skills in English, German would be an advantage
- Strong working knowledge of Microsoft Office

What we offer:

We offer an interesting, diversified and challenging position, good contractual conditions, flexible working models, all the social benefits of a modern company and a professional environment where you will have the opportunity for personal growth.