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 cardiovascular diseases, under the Group's 2025 vision to become a "Global Pharma Innovator with Competitive Advantage in Oncology," Daiichi Sankyo is primarily focused on providing novel therapies in oncology. Our European headquarters are in Munich, Germany and we have affiliates in 13 European countries including Denmark, where Copenhagen acts as the Nordic headquarter. For more information: www.daiichi-sankyo.eu.

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

Manager Regulatory Affairs - Product Support & Maintenance (m/f/x)

Purpose of the function:

To provide European regulatory guidance and support for assigned products and non-product related projects. Maintain and vary assigned marketing authorisations in a manner that is scientifically sound, commercially viable and in accordance with regulatory standards. Ensure regulatory compliance. May act as a specialist with regard to specific fields of regulatory or therapeutic knowledge. Representing RA in internal and external interactions (e.g. EU project and working teams, authorities, affiliates, partners).

Roles and Responsibilities:

- Provide regulatory guidance and support to product teams and Daiichi-Sankyo Europe affiliates.
- Implement European regulatory strategy within the Product Support & Maintenance area. Support and coordinate all required life-cycle management and maintenance processes for assigned marketed products as variations and renewals including affiliate management.
- Act as regulatory contact person for authorities.

- Support or lead assigned non-project tasks and process improvements.
- Keep current with, review and interpret regulatory and scientific regulations, directives, guidelines and initiatives, communicate important changes and trends with the relevant stakeholders.

Personal skills and professional experience:

- Bachelor degree in Life Science or Medical Science; Degree in Pharmacy, Master and/or PhD preferred; Master Degree in Regulatory Affairs is a plus
- 2-3 years of experience in the pharmaceutical industry and first experience in regulatory affairs with emphasis on life-cycle management and maintenance of marketing authorisations in Europe
- Understanding of drug development and regulatory processes
- Ability to develop and maintain good relationships and to communicate effectively.
- Ability to plan, coordinate and lead activities simultaneously on multiple projects
- Solution and detail-oriented; well organised and self-motivated
- Excellent written and oral communication skills in English, second language preferred

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.

We are looking forward to your application. Please apply online on our homepage www.daiichi-sankyo.eu under *Career* and visit our *Job Portal*. If you´ve questions please contact our reception: +49 89 78080 and ask for Dr. Ines Grimm or Heike van Kampen.