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:

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

Purpose of the function:

Provide European regulatory guidance and strategy for assigned marketed products and represent Regulatory Affairs in internal and external interactions (e.g. project teams, working teams, authorities, affiliates, partners).
Support or lead the preparation of regulatory documents and submissions in a manner that is scientifically sound, commercially viable and in accordance with regulatory standards and ensure regulatory compliance. May act as a specialist with regard to specific field of regulatory or therapeutic knowledge.

Roles and Responsibilities:

- Provide regulatory strategy and guidance to product teams and Daiichi Sankyo Europe affiliates.
- Define and implement European regulatory strategy for assigned marketed products. Lead and coordinate all required life-cycle management and maintenance processes for like variations and renewals including affiliate and partner management. Respond

to issue management and queries from Health Authority agencies to satisfactory conclusions.
- Act as regulatory contact person for authorities.
- Provide regulatory expertise in participating assigned due diligence opportunities.
- Lead and participate 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 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
- Minimum of 5 years of experience in the pharmaceutical industry and minimum of 3 years of experience in regulatory affairs with emphasis on life-cycle management and maintenance of marketing authorisations in Europe
- Experience of working in an international environment as well as with National Health Agencies and EMA
- Proven ability to plan, coordinate and lead activities simultaneously on multiple projects
- Excellent personal and intercultural skills paired with the ability to work cross functionally in a multinational organisation
- Ability to develop and maintain good relationships, challenge views, present and argue cases in a professional and respectful manner
- 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 specific questions please contact our reception: +49 89 78080 and ask for Dr. Ines Grimm or Heike van Kampen.