We are a research-driven biopharmaceutical company. Our mission is built on the simple premise that if we "follow the science" that great medicines can make a significant impact to our world. We believe that a research-driven enterprise dedicated to world-class science can succeed by inventing medicine and vaccine innovations that make a difference for patients across the globe.

Our Regulatory Affairs team bring new medical advancements to the world by facilitating communications and procedures that allow swift, organized compliance partnering with external regulatory agencies. We are on the leading-edge of healthcare breakthroughs that help provide new, reliable, and compliant medical products, practices and solutions to the world.

We are continually striving to improve the understanding of health care within the local community. Our site in 1100 Vienna (ICONTOWER) is a strategic location for the distribution of our high quality and innovative health care products, as well as digitally integrated solutions for our patients and clients. To ensure sustainable company growth, we continually aim to offer attractive career opportunities for more than 150 employees at our Vienna site.

Senior Specialist Regulatory Affairs (m/f/d)

Responsibilities

- Ensuring timely preparation and submission of new Marketing Authorization applications
- Taking care of Life Cycle Management of assigned, authorized products
- Ensuring high-quality labeling translations and artwork preparation and management
- Maintaining positive relationship with key players in the regulatory environment
- Collaboration with Director Regulatory Affairs designing and implementing regulatory ad-hoc local action plans, as necessary
- Collecting relevant public available regulatory information (regulatory intelligence) and keeping relevant persons appropriately informed
- Working locally, regionally and globally, to support business initiatives in sub region
- Taking care of Regulatory Affairs Compliance Officer activities

Qualifications

- Post-secondary education in scientific science or equivalent
- Good medical and scientific understanding and knowledge
- Excellent skills and knowledge of local and EU medicines legislation and regulatory procedures
- Solid experience in a Registration Department or equivalent dealing with most aspects of registration and experience in supervising others
- Ability to plan and prioritize regulatory tasks to meet company and local objectives
- Good interpersonal and managerial skills, capability of problem resolution and the ability to work in a team environment
- Commitment, dedication to quality and the ability to handle multiple priorities simultaneously is a key condition
- IT-skills with regard to word-processing, spreadsheets, database applications, and internet
- Fluent in German and business proficient in English



We offer an attractive salary, outstanding social benefits and an exciting work environment with varied tasks in an international environment. The minimum annual salary for this position is EUR 57.000,- (based on fulltime employment) and varies according to the qualifications and experience of the successful candidate. We are looking forward to receiving your application.

Who we are ...

We are known as Merck & Co., Inc., Kenilworth, New Jersey, USA in the United States and Canada and MSD everywhere else. For more than a century, we have been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases. Today, our company continues to be at the forefront of research to deliver innovative health solutions and advance the prevention and treatment of diseases that threaten people and animals around the world.

What we look for ...

Imagine getting up in the morning for a job as important as helping to save and improve lives around the world. Here, you have that opportunity. You can put your empathy, creativity, digital mastery, or scientific genius to work in collaboration with a diverse group of colleagues who pursue and bring hope to countless people who are battling some of the most challenging diseases of our time. Our team is constantly evolving, so if you are among the intellectually curious, join us—and start making your impact today.

To apply today, visit our website: <u>Senior Specialist Regulatory Affairs (m/f/d) job in Wien,</u> Greater Vienna area, Austria | Regulatory Affairs jobs at MSD

