Senior Specialist Regulatory Affairs (m/f/d)

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 offer long-term career opportunities in a company which values innovation, efficiency, diversity and respect. Today, we are building a new kind of healthcare company – one that is ready to help create a healthier future for all of us. Our ability to excel depends on the integrity, knowledge, imagination, skill, diversity and teamwork of an individual like you. To this end, we strive to create an environment of mutual respect, encouragement and teamwork.

For our Swiss subsidiary in Global Human Health based in Lucerne, we are currently looking for a **Senior Specialist Regulatory Affairs (m/f/d)** who will be responsible for new marketing authorizations, variations, renewal applications and maintenance of assigned, authorized products of our Company's franchise *(full-time, indefinite).*

As a Senior Specialist Regulatory Affairs, you will develop local action plans for new products and maintain strong positive business relationships with the pharmaceutical organization, the local agency and further key players in the regulatory environment. Furthermore, you will participate in subsidiary product and launch teams to provide regulatory input and strategy advice. Embedded in an active team of regulatory affairs experts, you will closely collaborate with stakeholders in Medical, Finance, Customer Service, Marketing and External Affairs. Regulatory Affairs colleagues on sub-regional, regional and global level, Manufacturing Division, Pharmacovigilance and Labeling colleagues will be further key contact points within the company.

Please apply directly online here.

THE PRIMARY ACTIVITIES INCLUDE BUT ARE NOT LIMITED TO:

- Ensure timely preparation and submission of new local Marketing Authorization applications for assigned products as well as appropriate follow-up with the local authorities.
- Track process and manage answers to objections from the regulatory authorities on products registration and major new indications, involving negotiations to achieve best conditions.
- Ensure timely preparation and maintenance of local Product Circular, Patient Package Inserts, local physicians' circulars, packaging material and other applicable regulatory documents according to our Company's and local standards.
- Ensure high quality translations and check of Product Circular and Patient Package Leaflets including linguistic and format check of these documents.
- Design and implement local action plans for new products, involving selection and regulatory training of external experts and closely interacting with the regulatory authorities, with continuous interface with regulatory affairs experts.
- Participate in subsidiary product and launch teams to provide regulatory input and strategy advice.
- Ensure maintenance of assigned, authorized products through timely submission of variations, renewal applications, and supplemental marketing authorizations.
- Develop and maintain positive relationship with key players in the regulatory environment.
- Work with Business Development to support business initiatives on local, regional and global level.
- Ensure efficient and consistent implementation and use of internal and external regulatory databases and systems in Switzerland.
- Ensure that files and archives related to Regulatory are kept updated and complete.
- Participate in establishing and maintaining of relevant Standard Operating Procedures to secure that the current regulations are complied.
- Keep abreast of local and international laws; maintain a scientific knowledge and expertise for our Company's therapeutic areas.
- Shape the regulatory environment through liaising with the local agency, local pharmaceutical organization and other stakeholders.

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QUALIFICATIONS:

- Bachelor's or Master's Degree in a Life Science Discipline or equivalent qualification.
- Minimum of 2 years' experience in a Registration Department including hands-on experience in dealing directly with regulatory Agencies (Swissmedic). Alternatively, experience working within a regulatory agency or other related environment.
- Familiarity with Swiss legislation procedures and guidelines governing pharmaceutical products. Knowledge of the regulatory framework for vaccines, oncology or primay care would be preferred.
- Proficient use of MS Office suite and related Software.
- Hands-on expertise in database application.
- German knowledge at a native level, both spoken and written, including review and regulatory submission of complex medical texts.
- English knowledge at a Business fluent level, both spoken and written, including translation of complex medical texts.
- Additional French knowledge is highly beneficial. Italian knowledge would be desired.
- Strong communication and Stakeholder management skills, diplomacy and assertive skills in communicating with internal and external parties.
- Very good organizational and planning skills; proven ability to successfully handle conflicting deadines.
- Meticulous attention to detail
- Pronounced client focus and business orientation; sound appreciation of the interactions and relationships of the department with other internal groups

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.

THE COMPANY…

Our company has had a presence in Switzerland since 1963. With a regional office and manufacturing/packaging facility, Lucerne is considered the center of operations. Approximately 1,000 people work collaboratively at the four Lucerne locations (Tribschenstrasse, Citybay, Schachen and Kriens). A fifth location has been recently established in Zurich, aimed at accelerating the development and commercialization of many of our company's medicines and vaccines, which supports our mission to save and improve lives around the world. The new location has a target date of 2021 for operational readiness.

We are proud to be certified as a "Top Employer Switzerland" and "Top Employer Europe" showing the company's commitment to our employees and the community around us.

The Switzerland Head Office of our company's Swiss Subsidiary is based in Lucerne's city centre. Located in the heart of the city, employees work collaboratively across many departments including commercial, market access, medical affairs, clinical research, regulatory affairs, and policy & communications.

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 …

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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.
We are proud to be a company that embraces the value of bringing diverse, talented, and committed people together. The fastest way to breakthrough innovation is when diverse ideas come together in an inclusive environment. We encourage our colleagues to respectfully challenge one another's thinking and approach problems collectively for the common good. We are an equal opportunity employer, committed to fostering an inclusive and diverse workplace.

Search Firm Representatives Please Read Carefully
Merck & Co., Inc., Kenilworth, NJ, USA, also known as Merck Sharp & Dohme Corp., Kenilworth, NJ, USA, does not accept unsolicited assistance from search firms for employment opportunities. All CVs / resumes submitted by search firms to any employee at our company without a valid written search agreement in place for this position will be deemed the sole property of our company. No fee will be paid in the event a candidate is hired by our company as a result of an agency referral where no pre-existing agreement is in place. Where agency agreements are in place, introductions are position specific. Please, no phone calls or emails.

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