Regulatory Affairs Manager (m/f/d)

Are you looking for a patient-focused, innovation-driven company that will inspire you and support your career? If so, be empowered to take charge of your future at Takeda.

Join us as a **Regulatory Affairs Manager** in our Swiss office in **Pfäffikon (SZ)** and later in **Opfikon (ZH).**

Overview

As a **Regulatory Affairs Manager** you will lead the local regulatory product strategy working in collaboration with the Regional and Global Regulatory Leads to successfully deliver the product development and life cycle management plans in accordance with agreed business priorities. Also responsible for ensuring the compliance of registered products with local laws and requirements.

You will serve as the key liaison between the company and the local Health Authority. You will build strong working relationships and conduct yourself with integrity with both internal and external stakeholders to protect and elevate Takeda's reputation.

You will strive for a performance-based culture and deliver operational excellence working in a cross-functional environment within R&D and the Commercial business based on the Takeda values of Patient, Trust, Reputation and Business.

Key Accountabilities

- For new MA registrations provide RA input for launch strategy aligned with commercial plan for timely submissions/approvals and management of national phases of Swiss Procedures. Maintain relevant knowledge of company's pipeline in relevant Therapy Area Units
- Collaborate with Market Access team on the evidence generation and value proposition strategy including preparation of the Pricing and Reimbursement Dossier and follow up Renewal applications.
- Due diligence for locally in-licensed products from RA perspective including support for MA Transfers.
- MA lifecycle maintenance incl. renewals, variations (CMC and non-CMC), labeling updates, blue box requirements, PSUR/PBRERs etc. Ensure national registrations are aligned with global dossier updates and take ownership of regulatory strategies for country specific National registrations. Pro-vide relevant local impact assessments for global dossier changes and initiate change requests for national licenses as per change control processes.
- Submissions of MAA and withdrawals of products after agreement with RA Switzerland Lead, Business and GM
- Manage compliance of labelling (and mock-ups) with CCDS (incl. updates for generics if originator product changes). Local translations of SmPC, labelling, patient information and distribution to internal and external stakeholders (incl. public lists, websites)
- Maintain Global and Local Regulatory databases to ensure accurate records of Regulatory activity and data archives as a key priority.
- Contribute to Regulatory Intelligence, stay up to date on local and EU laws and assess the impact on local business and products.
- Compliance with EU and local laws and Takeda internal processes including EU Food Supplements, Medical Devices, Cosmetics Directives.

Key Accountabilities continued:

- Build relationships with Health Authorities, understand their internal workings, maintain open communication channels and respond with urgency and accuracy to Health Authority requests. Active involvement and participation at Industry Associations
- Promote, encourage and demonstrate commitment to Takeda-ism
- Budget planning, managing RA contractors/CRO´s and oversight of outsourced RA activities in agreement with RA Switzerland Lead.

Experience and Education

- University degree in Pharmacy or other scientific studies
- Minimum of 3 years of experience in Regulatory Affairs
- Minimum 3 years of experience in pharmaceutical industry
- In depth knowledge of applicable laws, regulations and codices for pharmaceutical industry
- Fluent in German and English, French/Italian is a plus

At Takeda, we are transforming the pharmaceutical industry through our R&D-driven market leadership and being a values-led company. To do this, we empower our people to realise their potential through life-changing work. Certified as a Global Top Employer, we offer stimulating careers, encourage innovation, and strive for excellence in everything we do. We foster an inclusive, collaborative workplace, in which our global teams are united by an unwavering commitment to deliver **Better Health and a Brighter Future** to people around the world. Discover more at takedajobs.com.

What Takeda Can Offer You

To further support and inspire our employees, our benefits include: Competitive basic salary, Annual Bonus, Contributory Pension Scheme, Private Health Cover and Life Assurance.

Empowering Our People to Shine

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