TIEFENBACHER GROUP

We are Tiefenbacher Group – Health Pioneers since 1963.

100% family owned since 1963, we are a leading healthcare company providing innovative and best-in-class solutions along the entire pharmaceutical value chain. The distribution of APIs and the development, manufacturing, and registration of finished dosage forms are our core competencies. The world´s most trusted brands count on our pioneer spirit as well as our pharmaceutical excellence. Leveraging our global presence, including own laboratories and manufacturing sites, we are driven to make pharmaceuticals more affordable, more available, and better than before. There is one purpose driving our about 800 employees day by day: improving the life of millions of patients worldwide.

Your expertise and commitment can make a difference to patients all over the world. Join us at our global headquarters in Hamburg and become a part of AET at the earliest possible date.

We look forward to hearing from you!

Send your application package today and check out our website (https://careers.tiefenbachergroup.com/eng) for more information. We look forward to hearing from you!

Regulatory Affairs Manager (all genders) Labelling & Own Brands

As Regulatory Affairs Manager in the "Labelling & Own Brands" team, you will be responsible for all regulatory tasks relating to our marketed products in the relevant European focus markets. You will be part of a team that coordinates the regulatory strategy for the implementation of variations or new submissions. This includes processing product information texts as well as taking full responsibility for the change control process and coordinating artwork activities.

A challenging task

- Independent coordination of change control processes for marketed products
- Preparation and submission of variations
- Review and update of product information texts (SmPC, PiL, labelling) in the context of marketing authorisation applications and variations
- Timely implementation of safety-related text changes and coordination of internal implementation
- Maintenance of marketing authorisation
- Collaboration in the planning and implementation of national and European marketing authorisation procedures (MRP, DCP)
- Contact person for regulatory issues
- Direct contact person for European regulatory authorities and an international group of partners

A convincing background

- Successfully completed scientific degree or comparable training in the pharmaceutical/natural sciences field
- Ideally, initial professional experience in the field of regulatory affairs
- Independent working style, good time management
- Strong communication skills and solution-oriented mindset
- Enjoy working with people from different backgrounds and cultures
- Ability to keep a cool head and sense of humour even in hectic times
- High level of commitment and sense of responsibility
- Very good knowledge of German and English as well as confident use of MS Office

Our mindset

We strive towards developing curious team members from all over the world who love to challenge the status quo, take on responsibility, enjoy collaborating and have an affinity and passion for health care. At Tiefenbacher, you will meet a fast-paced work environment where everybody is welcome to suggest new ideas and take ownership of their realization. On a daily basis, we are working towards a culture characterized by curiosity, high energy levels and openness to mutual feedback. We also value a good sense of humor and optimism, especially during hectic times.

An exciting environment

You will be working in an internationally successful company in the buzzing heart of Hamburg, directly at the Elbe river. We offer flexible working hours and a hybrid 60/40 working model with 60% office presence and 40% mobile working. You can expect a varied job in a motivated and friendly team, an uncomplicated interaction with each other and many opportunities to contribute your own ideas. Come and convince yourself!