# Regulatory affairs

## Full service for the healthcare industry

**The regulatory affairs team at Diapharm is here to shoulder all of the regulatory responsibilities associated with the pharmaceutical and consumer healthcare markets on your behalf. Our extensive expertise allows us to offer a full range of services to support you right from the very start of the development phase and ensure the marketability of your medicinal products throughout the entire life cycle.**

**Our services include:**

- Evaluating regulatory strategies & GAP analyses
- Preparation and carrying out of Scientific Advices
- National and international marketing authorisation procedures
- Lifecycle-Management (maintenance of marketing authorisations and dossiers), technical documentation
- Advice, assistance and management of Rx-OTC switches
- Preparation of product information texts and readability user testing
- Classification issues regarding medical devices, cosmetics and food supplements
- Responsibility as a pharmaceutical company and applicant
- Temporary staff leasing for client's assignments on site
- Conduction of in-house trainings / workshops

We provide support for all marketing authorisation projects, regardless of whether they are national, MRP, DCP or centralised procedures, renewals or variations. Our services also include updating and reformatting dossiers (NtA to CTD to eCTD) as well as the preparation of expert reports and the handling of deficiency letters.

On request, we can also assume the role of marketing authorisation holder on behalf of our clients or perform the legal roles of qualified person for pharmacovigilance, information officer or qualified person.

**Get in touch with us!**

**Dr. Christoph Buss**
Associate Director Regulatory Affairs & Pharmacovigilance

**Further information:**
Phone +49 (0)251-60935-0
info@diapharm.com

## Your benefits:

- **Targeted advice**
- **Decreased regulatory affairs workload**
- **Efficient realisation of your (marketing authorisation) projects**



Diapharm