



Dr. Regenold GmbH and regulanet® - the International Regulatory Affairs Network

Dr. Regenold GmbH is specialised in national and international regulatory affairs. Founded in 1994, Dr. Regenold GmbH has helped many clients gain marketing authorisations, both nationally and internationally, for their product developments.

Recognising clients' needs for pan-European and global product registrations, Dr. Regenold founded regulanet®, a network of regulatory affairs consultancies with members in over 80 countries throughout the world. Established in 2001, member companies offer services to a wide variety of national and international healthcare and pharmaceutical clients, helping them understand the complexities of the different regulatory requirements and providing solutions.

Services

The core service of Dr. Regenold GmbH is regulatory affairs specialising in several product categories from prescription medicines, OTCs, medical devices through to food supplements. Building upon this and in response to client feedback and demand, the services have now been expanded to include **Market Access, Portfolio Analysis and Life Cycle Management**.

By gaining an understanding of clients' commercial needs, the key decision makers and route to market, we are able to recommend regulatory and market access solutions which help our clients bring their products efficiently to market and maximise value from their asset.

Dr. Regenold GmbH is therefore a 'one stop shop' for national and international regulatory affairs, strategic advice and implementation.

Specifically as part of our regulatory affairs we offer:

- **Regulatory strategy and management for drug development**
 - Provide regulatory advice in the early phases of development projects
 - Define the product concept
 - Interpret regulations and guidelines
 - Develop strategies for technical aspects of drug development (quality, preclinical and clinical)
 - Design and manage drug development programmes
 - Identify and manage external resources/experts
 - Determine market access requirements and develop a strategy in the early phases
- **Regulatory strategy**
 - Pro-actively interface with regulatory bodies
 - Recommend and advise clients on legal classification
 - Propose optimal filing and submission strategies
- **Regulatory management and execution, including Marketing Authorisation holdership**
- **Pharmacovigilance**
- **Rx to OTC switches**
- **Project management**
- **Regulatory due diligence for mergers and acquisitions**
- **EMA SME status facilitation and FDA access and liaison**



Product Categories

We have expertise in the following product categories and the respective industries:

- Prescription reimbursed medicines (Rx) including orphan drugs
- Over The Counter medicines (OTC)
- Generics, including niche generics
- Medical Devices and Medtech Applications
- Biotechnology derived products
- Herbals
- Food Supplements/Nutraceuticals
- Cosmetics and Cosmeceuticals
- Biocides
- Veterinary

regulanet® - the International Regulatory Affairs Network

regulanet® is a network of regulatory affairs consultancies with members throughout the world. Founded in 2001 and led by Dr. Regenold GmbH, member companies offer services to a wide variety of national and international healthcare and pharmaceutical clients.

The network uses state-of-the-art tools to ensure efficient communication and access to information, between members and clients. regulanet® provides advice and assistance on national and international projects and marketing authorisation procedures, including the decentralised, mutual recognition and centralised procedures within Europe.

Contact

If you would like to find out how we could help you contact us via our websites:

www.regenold.com

www.regulanet.com

or directly by phone or email:

phone: +49 7632 82 26-0

e-mail: info@regenold.com

Dr. Jürgen Regenold and Jutta Schnirring, Managing Directors