Dr. Regenold GmbH

Your partner for development, regulatory and market access.

DR. REGENOLD GMBH

DEVELOPMENT • REGULATORY • MARKET ACCESS

NEXT

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About Dr. Regenold GmbH

Dr. Regenold GmbH is specialised in development, regulatory and market access. Founded in 1994, we have helped many clients progress their product developments, by providing scientific and regulatory advice, through to gaining regulatory approval and marketing authorisation both nationally and internationally.

By gaining an understanding of clients' commercial needs, the key decision makers and route to market, we are able to recommend development, regulatory and market access solutions which help them achieve their milestones or bring their products efficiently to market, thereby maximising value from their asset.

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Our Network: regulanet®

In 2001 we founded regulanet® which is a network of independent regulatory consultancies with representation in over 90 countries throughout the world.

The members offer services to a wide variety of national and international healthcare and pharmaceutical 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.

Please visit www.regulanet.com

regulanet®
THE INTERNATIONAL NETWORK
DEVELOPMENT • REGULATORY • MARKET ACCESS

The services offered by the members have been expanded over the years to now include all aspects of development, regulatory and market access in their respective countries.

In addition, the network has been extended to include several international B2B partners, who are experts in specific topics, which increases the range of services available to our clients.

B2B partners include:

- Contract Research Organisations
- International contract development and manufacturing companies
- Analytical experts and laboratories
- Pre-clinical and clinical investigational units and sites
- Bioanalysis, pharmacokinetic & pharmacodynamic modeling experts and laboratories
- Market access experts
- Patient adherence experts

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Services

Dr. Regenold GmbH provides a range of services both nationally and internationally.

Dr. Regenold GmbH expertise covers development, regulatory and market access. Our aim is to help clients maximise the value of their product or device throughout its development and lifecycle within a constantly evolving regulatory and market access environment. We do this by developing innovative and cost effective development and regulatory strategies and solutions, tailored to the client, to achieve set milestones and thereby optimise regulatory approval and market access.

Our services include:

- **Strategic Advice**
- **Pharmaceutical Development**
- **Preclinical Development**
- **Clinical Development**
- **Dossier Compilation**
- **Project Management**
- **Regulatory Strategy & Implementation**
- **Pharmacovigilance**
- **Auditing**
- **Market Access**
- **Portfolio Analysis & Life Cycle Management**
- **Due Diligence**
- **Quality Management**

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Development

We can assist our clients in all aspects of development from setting up and managing development plans through to preclinical and clinical development and project managing the whole process.

Pharmaceutical Development
Our pharmaceutical development team has many years of experience in all aspects of development and is able to help you with any of the topics listed below:

- Set-up of development plans
- Follow-up and management of pharmaceutical development
- Vendor selection and follow-up of vendors
- Support in GMP requirements for the complete development program including those for investigational medicinal products and drug substances used in their manufacture
- Interaction with competent regulatory authorities as required during pharmaceutical development

Preclinical Development
The preclinical team has long-standing experience in preclinical research, toxicology and regulatory and can therefore help you with:

- Preclinical development planning
- Preclinical study planning and management, evaluation and interpretation of results
- Compilation of the preclinical parts of the CTD
- Compilation of Investigator's Brochures and IMPDs
- Compilation of briefing documentation for scientific advice procedures and discussion of preclinical questions with the authorities
- Feasibility assessment & gap analysis for project assessment
- Due diligence for in-licensing candidates
- Identification of qualified service partners, key opinion leaders and scientific experts
- Biocompatibility assessment for medical devices

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Development

Clinical Development
Our medical team is an international group of experienced professionals, trained in clinical medicine, biology and pharmaceutical sciences which has extensive scientific and hands-on experience in clinical medicine, clinical research and regulatory, both in industry and academia.

Topics where we offer support include:
- Clinical development planning
- Clinical trial planning and management, evaluation and interpretation of results
- Compilation, maintenance and storage of clinical trial masterfiles
- Dossier preparation (CTD, IMPD)
- Consultation with regulatory authorities for scientific advice
- Paediatric Investigational Plans
- Orphan Drug Designation
- PSUR, DSUR, RMP
- Feasibility assessment & gap analysis for project assessment
- Due diligence for in-licensing candidates
- Clinical evaluation of medical devices

Project Management
We provide project management for entire projects or individual steps, including planning, organization, selection of partners, coordination, monitoring and control of the various steps of the development process.

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Regulatory

Regulatory has been core to our business ever since we started 20 years ago, therefore we have an experienced team who can help you with any of the topics below. We pride ourselves in helping clients, not only with strategy, but also implementation, which is key to successful commercialisation.

Regulatory Strategy & Management of 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
- Determine market access requirements and develop a strategy in the early phases
- Identify and manage external resources/experts

Regulatory Strategy

- Evaluate technical data (chemistry/manufacturing, preclinical, clinical), to help determine the appropriate regulatory procedure and legal status for products
- Pro-actively consult with the regulatory authorities for scientific advice (protocol assistance for orphan drugs)
- Arrange and manage scientific advice meetings with regulatory authorities
- Propose optimal filing and submission strategy
- Establish frequent contact with regulatory authorities to facilitate compliance

Regulatory Management & Implementation

- Clinical trials applications
- Dossier Preparation (CTD, eCTD)
- Translation services
- Submission process
- Liasion with Health Authorities
- Marketing authorisation applications, management of the procedure, and Marketing Authorisation holdership
- Post approval maintenance
- Variations, Renewals, Pharmacovigilance, PSURs
- Technical Expert Services

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Regulatory

Rx to OTC Switches

- Development of strategy to ensure national switches are planned and implemented to an international standard
- Preparation of dossiers with full justification
- Evaluation of the impact of reclassification on product reimbursement and pricing
- Planning and implementation of parallel switches in several countries

Borderline Products

An increasing number of products have to be characterized as borderline products – an ambiguity either due to an overlap between existing regulations or because the product is innovative and does not fall into any prospective regulation.

Borderline Products *continued*

Our services include:

- Demarcation and identification of appropriate regulatory path with applicable legislation
- Development of optimized regulatory strategies, aiming to achieve ideal marketability
- Intermediation and close interaction with Competent authorities, Notified Bodies and other regulatory bodies in order to safeguard chosen strategies

Our fields of expertise are:

- Medicinal products
- Medical devices
- Cosmetics
- Food/food supplements/dietary foods/food for special medical purposes and the relevant borderline areas in between

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Regulatory

Small Medium Enterprises - SMEs

EMA

The European Union recognises the key part that micro, small and medium-sized enterprises (SMEs) play in the innovation of new medicines and the benefit that these provide for patients. At the same time it acknowledges that SME's do not have the same resources as larger companies. So in 2005 the EU introduced financial and administrative help for SMEs.

We can assist companies with applications to achieve SME status and access the incentives available.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

FDA

The Food and Drug Administration (FDA) is a large, complex organization which requires a good understanding of which processes are relevant for a specific project - this requires FDA specific expertise for the different product categories.

In the US we have local expertise and access to experts who have this detailed expertise which includes:

- Representing international companies as the designated US agent
- Liaising with the FDA to resolve issues and expedite marketing approvals
- Preparing and submitting Drug Establishment Registration/Renewals and Drug Product Listings
- Managing and inputting study information into the FDA database of investigational protocols for the treatment of serious and life threatening diseases

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Market Access

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

- Product development strategy
- Liason with the Healthcare Technology Assessment (HTA) agencies
- Development of HTA dossiers
- Negotiations with the HTAs and insurers.
- Patient access and adherence programmes
- Local support for market access through our network, regulanet®
- Development of "route to market" solutions for all types of products
- Marketing plans including regulatory guidance on branding

Portfolio Analysis & Life Cycle Management

Our portfolio team has over 20 years experience with blue chip pharmaceutical companies to help you build and manage your portfolio. Through our network of contacts and knowledge of available dossiers we are able to provide the following services:

- Portfolio and business strategy
- Portfolio analysis, management including process implementation
- Product portfolio completion via licensing in/out and partnering/gap filling
- Product launch facilitation
- Post launch life-cycle management
- Supply chain management

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Product Expertise

We have expertise in the following product categories across our service areas:

- **Medicines**
- **Biopharmaceuticals**
- **Orphan Drugs**
- **Medical Devices**
- **In Vitro Diagnostics**
- **Combination Products**
- **Companion Diagnostics**
- **Borderline Products**
- **Herbal & Traditional Herbal Medicines**
- **Food Supplements**
- **Cosmetics**
- **Chemicals**

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Quality Standards

Quality Assurance System

Our service area is generally not covered by any GxP system. However, in order to guarantee customers a consistent and uniform level of high-quality service, we have a customized quality management system in place. Our system is not only based on state-of-the-art elements of ISO quality norms but also on current GxP guidelines, where appropriate.

Our philosophy is based on an integrated quality perception, covering all aspects of the business process. We aim to continuously improve the quality of our services to the benefit of our clients.

Quality Standards

All regulanet® members maintain a Quality Management System and share a set of common quality standards.

The network developed these standards based on best practices in the industry to ensure high-level services and provide effective management and communication with our clients. As part of regulanet's continuous improvement process, both members and standards are monitored by independent consultants.

regulanet® also works closely with strategic partners which provide the network with skills and expertise to maintain a high level of customer service.

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Contact Us

Name:

Company:

Email:

Telephone:

Message:

Send

Call or contact us today, we'll be more than glad to answer any questions you might have.

Dr. Regenold GmbH
Am Berg 4
D-79410 Badenweiler

Phone: +49 7632 82 26-0
Fax: +49 7632 82 26-22
info@regenold.com
www.regenold.com

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