



YOUR PARTNER FOR  
**DEVELOPMENT,  
REGULATORY &  
MARKET ACCESS.**



NEXT 

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## ABOUT DR. REGENOLD GMBH

Dr. Regenold GmbH specializes 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 authorization 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 maximizing value from their asset.



## 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 of the network offer services to a wide variety of national and international healthcare and pharmaceutical clients by providing advice and assistance on national and international projects and marketing authorization procedures, including the decentralized, mutual recognition and centralized procedures within Europe.

Please visit [www.regulanet.com](http://www.regulanet.com)

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

In addition to founding **regulanet®**, Dr. Regenold GmbH has built relationships with several international B2B partners to extend the range of services available to our clients.

B2B partners include:

- Contract research organizations
- International contract development and manufacturing companies
- Analytical experts and laboratories
- Pre-clinical and clinical investigational units and sites
- Bioanalysis, pharmacokinetic and pharmacodynamic modeling experts and laboratories
- Market access and launch optimization experts
- Patient adherence experts
- Big data, analytics and machine learning experts



## 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 maximize 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 optimize regulatory approval and market access.

Our services include:

- Strategic advice
- Pharmaceutical development
- Preclinical development
- Clinical development
- Project management
- Regulatory strategy and implementation
- Pharmacovigilance
- Auditing
- Market access
- Portfolio analysis & life cycle management
- Due diligence
- QM systems & licenses
- Brexit preparation

## 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

## DEVELOPMENT *continued*

### 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
- Pediatric 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.



## REGULATORY

Regulatory has been core to our business ever since we started over 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 commercialization.

### 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 programs
- 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
- Proactively 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 trial applications
- Dossier Preparation (CTD, eCTD)
- Translation services
- Submission process
- Liaison with Health Authorities
- Marketing authorization applications, management of the procedure, and Marketing Authorization holdership
- Post approval maintenance
- Variations, Renewals, Pharmacovigilance, PSURs
- Technical Expert Services

## REGULATORY *continued*

### 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



## REGULATORY *continued*

### Small Medium Enterprises - SMEs

#### EMA

The European Union recognizes 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 to 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

## 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 to ensure payer and regulatory requirements are incorporated into clinical programs
- Liaise with Healthcare Technology Assessment (HTA) agencies
- Development of HTA dossiers
- Negotiations with the HTAs and insurers
- Patient access and adherence programs
- Local support for market access implementation 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

## QM SYSTEMS & LICENSES

Whilst the process of obtaining Marketing Authorization for a medicinal product in the EU is well harmonized, the quality management system and license requirements for companies handling medicinal products (manufacturing, import, distribution etc.) differ considerably between EU member states. The requirements depend mainly on the specific set-up between the involved companies and the ownership of products at the different points in time.

Achieving an optimal quality system which fulfills EU country specific requirements and fits to your company internal strategy and processes is mandatory for successfully proceeding with high internal compliance and achieving the required licenses. Our team, involving local expertise where necessary, supports you with any service that will benefit your existing or intended system, be it for gaining a wholesaler or import license, establishing a system according to DIN ISO 900x, DIN ISO 13485 or fulfilling GMP requirements.

Our services include:

- Background information on the system and license requirements in the EU member states
- Strategic advice on the optimal solution for your company (including Brexit considerations)
- Complete system set up or adaptation of your existing system for a principal with several subsidiaries in several EU member states
- System set up or adaptation of your existing system for a single company in one EU member state
- Support during implementation of your system
- Training
- Compilation and submission of applications for the required licenses, including follow up with the authorities
- Mock inspections and support during inspection preparation
- Support during inspection
- Support during follow up of authority inspections until granting of the intended license(s)

## BREXIT

The Pharma and Biotech industry is likely to be significantly affected by Brexit. The joint notice and Q&A document from EMA and European Commission along with the CMDh in May 2017 have provided an indication of the changes that the Pharma and Biotech industry may need to consider to meet the new situation. For EU/EEA licenses there will probably be an impact on the Marketing Authorization Holder (MAH) and pharmacovigilance activities.

If you consider that your company may be impacted by these changes we recommend that you begin to prepare a risk management plan ahead of the March 2019 timeline.

Over the last few months we have been assessing with some of our clients the different options and alternatives to address these issues. Some clients are affected more than others and we have been helping them prepare individual risk management plans as necessary. We have offices throughout the EU and UK, as part of our **regulanet**® network, and are therefore able to understand the issues and provide solutions depending on your particular situation and strategy.

Several topics which could be impacted include:

- **UK is/or will be the RMS** - For medical products authorized/planned to be submitted via MRP/DCP the company will need to change the location of the RMS to an agency of a member state of the EU (EEA).
- **Marketing Authorization Holdership** - MAHs located in the UK will need to transfer their EU MAs to a holder established in the EU (EEA) and for a UK license a UK located MAH will be needed.
- **Batch release site in the UK** - The MAH will need to transfer its current UK batch release site to a location established in the EU (EEA) whilst for a UK license a site in the UK is required.
- **PV** - PSMF & QPPV location must be inside EU/EEA for EU27 whilst for the UK the PSMF & QPPV location must be in the UK.
- Generic/Hybrid type of application.

## PRODUCT EXPERTISE

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

- Medicines
- Biologics
- Orphan drugs
- Medical devices
- In vitro diagnostics
- Combination products
- Companion diagnostics
- Borderline products
- Herbal & traditional herbal medicines
- Food supplements
- Cosmetics
- Chemicals



## 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**<sup>®</sup> members use a shared Integrated Management System based on a set of common quality standards for best practices.

As part of regulanet's aim to continually improve, both its members and the standards they follow undergo internal and external audits to demonstrate their suitability and receive constructive feedback.



## CONTACT

Email:

Message:

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

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