NEXT

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To request additional information, please see here.

THE NETWORK

regulanet® is a network of independent regulatory consultancies with representation in over 90 countries throughout the world.

Founded in 2001 by Dr. Regenold GmbH, **regulanet®** offers services to a wide variety of national and international health care and pharmaceutical clients. The members of the network provide 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**

regulanet®
THE INTERNATIONAL NETWORK
DEVELOPMENT • REGULATORY • MARKET ACCESS

Over the years the services offered by members have been expanded and now 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 & pharmacodynamic modeling experts and laboratories
- Market access experts
- Patient adherence experts
- Machine learning, AI and analytics experts

SERVICES

regulanet® provides a range of services both nationally and internationally.

Our expertise covers development, regulatory and market access. We 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. In response to client feedback and demand we have expanded our services beyond development and regulatory to include market access, portfolio analysis and life cycle management.

Our services include:

- Strategic advice
- Pharmaceutical development
- Preclinical development
- Clinical development
- Medical writing
- Project management
- Regulatory strategy and implementation
- QM systems, licenses and compliance
- Pharmacovigilance
- Data science & analytics
- Market access
- Portfolio analysis & life cycle management
- Due diligence
- Brexit preparation

DEVELOPMENT

We can assist our clients in all aspects of development from setting up and managing development plans, including pharmaceutical development, preclinical and clinical development.

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
- Liasion 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:

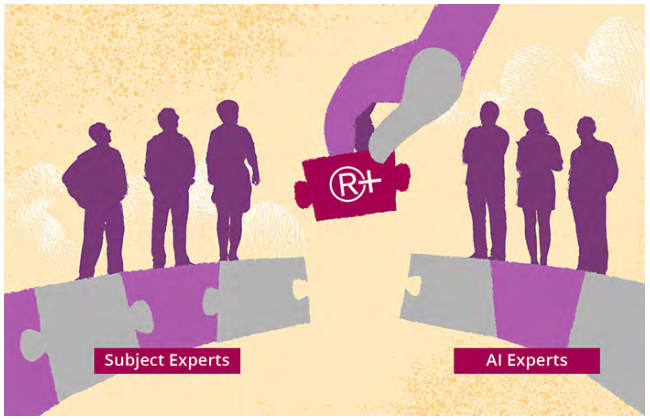
- Representing international companies as the designated US agent
- Liaising with the FDA to resolve issues and expedite marketing approvals
- Preparing and submitting Drug Establishment Registration/Renewals and Drug Product Listings
- Managing and inputting study information into the FDA database of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

DATA SCIENCE & ANALYTICS

Dr. Regenold GmbH has entered into a strategic partnership with the analytics market leader SAS to provide organisations with tailored solutions to speed up time-consuming processes. Artificial intelligence, natural language processing, text mining and analytics on data, even if conveyed in multiple languages, all facilitate faster and more targeted knowledge retrieval which help automate processes.

The Regenold AI/Analytics team bridges the gap between regulatory and/or pharmacovigilance requirements and technology, supported by the highly innovative SAS platform.

It is increasingly important for your business to receive the information you are looking for in a speedy and precise manner. We speak your language and know the guidelines and regulations to retrieve and process targeted information as desired. We provide guidance on how to interpret your results and compile reports targeted to the needs of the various departments within your organisation. Some examples of analytics use cases include screening of literature articles, text mining for report automation and social media screening.



sas Silver Partner

MARKET ACCESS

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

- EU establishment, QM systems, licences and compliance
- 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
- Regulatory guidance on branding
- Local support for market access implementation through our network, **regulanet®**

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 & COMPLIANCE

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

All **regulanet®** 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, its members and the standards they follow undergo internal and external audits to demonstrate their suitability and receive constructive feedback.

NETWORK MEMBERS

The **regulanet®** network covers over 90 countries in Europe, North America, Asia, Australia/New Zealand, Latin America, Middle East and Africa.

See full listing at **www.regulanet.com**

Dr. Regenold GmbH, the founder of **regulanet®**, is based in Germany and the network has 25 full members, five of which are joint ventures, Farmavita R+, JensonR+, Montrose R+, PTR+, and **regulanet®** Switzerland.

CONTACT

Email:

Message:

Send

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

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