



**DR. RIETHMÜLLER M/R/S**  
MEDICAL RESEARCH SERVICES  
ACCESSING GLOBAL HEALTH MARKETS

**INTERNATIONAL CONSULTANTS  
FOR THE DEVELOPMENT, EVALUATION,  
REGISTRATION AND MARKETING  
OF MEDICINES**

**TAILOR - MADE SOLUTIONS FOR  
A FASTER RETURN ON INVESTMENT**

## ABOUT DR. RIETHMÜLLER M/R/S

*On the strength of our long-standing success, in-depth knowledge and experience in drug development, we can focus on our mission:*

**DR. RIETHMÜLLER M/R/S** is committed to offering the best possible solution and thus aims to shorten the time-to-market in order to enrich and strengthen the product portfolio of its valued customers, while improving patients' quality of life and respecting their dignity.

**DR. RIETHMÜLLER M/R/S** provides straightforward strategies, know-how and services in the development, registration and marketing of medications, emphasizing the outstanding features of your products.

## ADVANTAGES OF WORKING WITH US

**DR. RIETHMÜLLER M/R/S** effectively supports the successful and rapid market entry of your innovative medicines thanks to a highly experienced and qualified team with longstanding

### KNOW-HOW IN

- Clinical Research and Marketing
- Pharmaceutical / galenic development
- Pharmacology
- Toxicology.

**DR. RIETHMÜLLER M/R/S** can look back on over 25 years of successful and skilled expertise in international drug development in the aforementioned fields.

**DR. RIETHMÜLLER M/R/S** has achieved numerous international and national registrations (EMA, MRP, FDA, Japan) of innovative and generic drugs in the shortest possible time as well as orphan drug designations.

The Company has successfully organized and managed international clinical trials in various indications, including topical drug delivery systems.

## YEARS OF EXTENSIVE EXPERIENCE

enables the Company to provide the optimal solution in the shortest possible time, while respecting

- Best possible quality
  - Ethical, cultural and regulatory principles
  - Safety of patients and healthy subjects
- thus enhancing clients' effectiveness and profitability.

**DR. RIETHMÜLLER M/R/S** is committed to high quality standards, flexibility and state of the art performance.

Competent, reliable and entrepreneurial consulting and services are provided by a highly qualified and dedicated staff coming from the pharmaceutical industry, with a focus on clinical and preclinical drug development in a fast changing environment.

Clients benefit from **DR. RIETHMÜLLER M/R/S'** personal and undivided attention and emphasis on tailor-made solutions.

The Company's expertise and strength assist you in securing the enduring success of your valued and novel medications throughout the entire product life cycle.

## WHO ARE OUR CLIENTS

- Pharmaceutical industry companies
- Biotechnology companies
- Clinical research organizations (CROs)
- University clinics
- Venture capital companies and banks
- Associations and scientific societies.

**WE ARE WHAT WE REPEATEDLY DO.  
EXCELLENCE, THEN, IS NOT AN ACT, BUT A HABIT.**

ARISTOTLE, THE NICOMACHEAN ETHICS

**DR. RIETHMÜLLER M/R/S**

*is able to provide all of the services listed below. Please feel free to contact us should you require any additional information.*

**SCIENTIFIC AND STRATEGIC CONSULTING****Preclinic and clinic**

Preparation and evaluation of detailed development plans, including pharmaceuticals, pharmacology, toxicology, pharmacokinetics and clinical Phases I to IV.

We respect ICH-GMP, GLP, GCP and regional guidelines (FDA, CHMP).

**COST CALCULATIONS** of developments.

**SET UP OF FILES FOR**

**Marketing authorization** approval

**Orphan drug designation**

**Product pricing.**

**SUBMISSIONS/NOTIFICATIONS**

to conduct clinical studies:

- Investigational Medicinal Product Dossier (IMPD)
- EudraCT Number, Ethic Committees.

**IMPLEMENTATION**

Project management

Cooperation with

- Clinical investigators and experts
- Health authorities
- CROs: monitoring of studies, statistics.

**INDICATIONS**

Oncology and non-oncology, e.g. CNS, pain, cardiovascular, respiratory, metabolic, endocrine, infectious, immunologic, gastro-intestinal, gynecologic and urologic diseases.

**COMPOUNDS**

New chemical entities, recombinant drugs, antibodies, generics, phytopharmaceuticals.

**MEDICAL WRITING** (English language)

- Common Technical Document (CTD)  
Clinical and preclinical Overviews and Summaries
- Integrated Summaries (FDA, Canada)  
ISE, ISS, ISCP, ISPK
- Investigators' Brochure (IB)
- Study reports, study protocols, study outlines
- Patient Information, SPC, US-PIL.

**PREPARATION**

- Product Profiles, Scientific Drug Brochures
- Publications
- Patents (incl. Medical Use patents)
- SWOT analyses
- Benefit/risk profiles.

**PHARMACOVIGILANCE**

- Serious adverse events (SAE) evaluation
- Defense of drugs vis-à-vis health authorities
- Periodic Safety Update Reports (PSUR).

**TROUBLE SHOOTING**

e.g. support in finishing studies on time  
Preparation of files for health authorities.

**ORGANIZATION OF SYMPOSIA/WORKSHOPS**

e.g. on national and international congresses.

**CURRICULUM VITAE**

**DR. HILDE RIETHMÜLLER-WINZEN**

Study of human medicine and license as a Specialist in anesthesiology and intensive care at a German University Hospital. First performance of clinical studies.

Senior physician in anesthesiology for several years. Substitution for general physicians.

**EXPERIENCE IN THE PHARMACEUTICAL INDUSTRY**

Since 1984 international management duties in medical research and marketing in the pharmaceutical industry. Established and managed the corporate Phase I Unit of the research based company ASTA Medica AG, Frankfurt, Germany.

**MANAGED PHASES I-IV**

working on various indications.

Director of Medical Services of the Spanish subsidiary of ASTA Medica (Madrid):

Set-up and supervision of a medical division with emphasis on Marketing.

Active participation in the implementation of restructuring measures for business units.

Obtained numerous national and international **REGISTRATIONS** of medicines for various indications: Central European Registration (EMEA-CHMP), European Mutual Recognition Procedure (MRP), U.S. Federal Food and Drug Administration (FDA), Japan (KOSEIROSOSH, KIKO).

**NATIONAL AND INTERNATIONAL LAUNCHES**

and new positioning of medicinal and health products.

**PRESENTATION**, advocacy and defense of medications before national and international health authorities.

**DR. RIETHMÜLLER M/R/S GMBH**

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*Dr. Hilde Riethmüller-Winzen, M.D., Anesthesiologist  
Managing Director DR. RIETHMÜLLER M/R/S GMBH*

**ORGANIZATION** of scientific symposia at international medical congresses.  
Set-up of new scientific medical associations.

**EVALUATION** of the adverse effects and benefit/risk profile of drugs.

Numerous publications and presentations on endocrinology, gynecology, human pharmacology (kinetic, dynamic), immunology, neurology, oncology, urology as well as on metabolic, pulmonary and cardiovascular indications.

**DR. RIETHMÜLLER M/R/S GMBH  
WAS ESTABLISHED IN JANUARY 2001.**