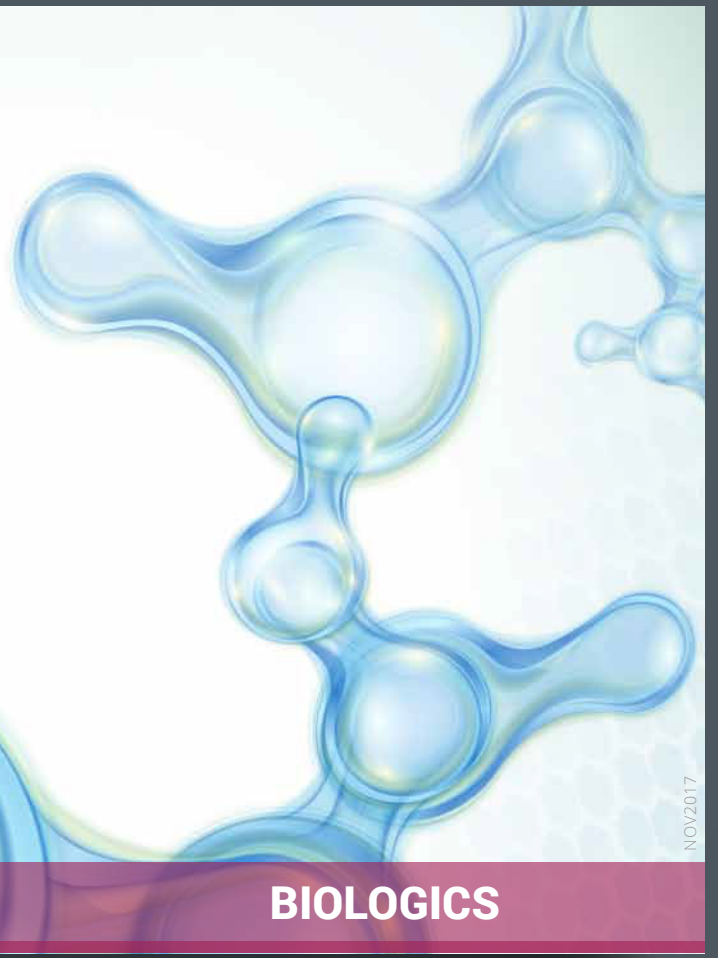
DR. REGENOLD GMBH

DEVELOPMENT • REGULATORY • MARKET ACCESS

YOUR PARTNER FOR

DEVELOPMENT, REGULATORY & MARKET ACCESS.



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BIOLOGICS

NEXT

www.regenold.com

ABOUT DR. REGENOLD GMBH

Dr. Regenold GmbH is specialized 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.

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 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**

regulanet®
THE INTERNATIONAL NETWORK
DEVELOPMENT • REGULATORY • MARKET ACCESS

SERVICES

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

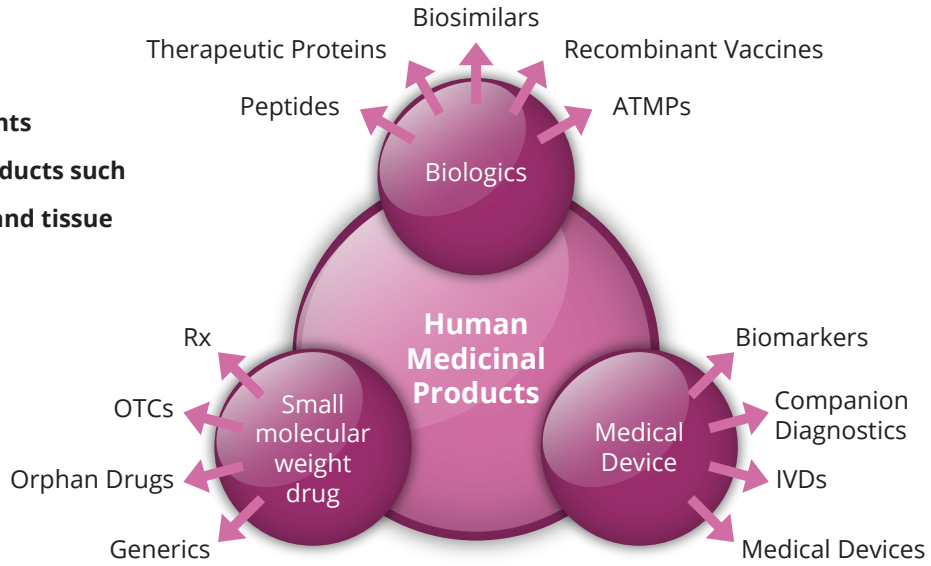
Dr. Regenold GmbH expertise covers development, regulatory and market access. Our aim is to help clients maximize the value of their product or device throughout its development and lifecycle within a constantly evolving regulatory and market access environment. We do this by developing innovative and 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
- 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

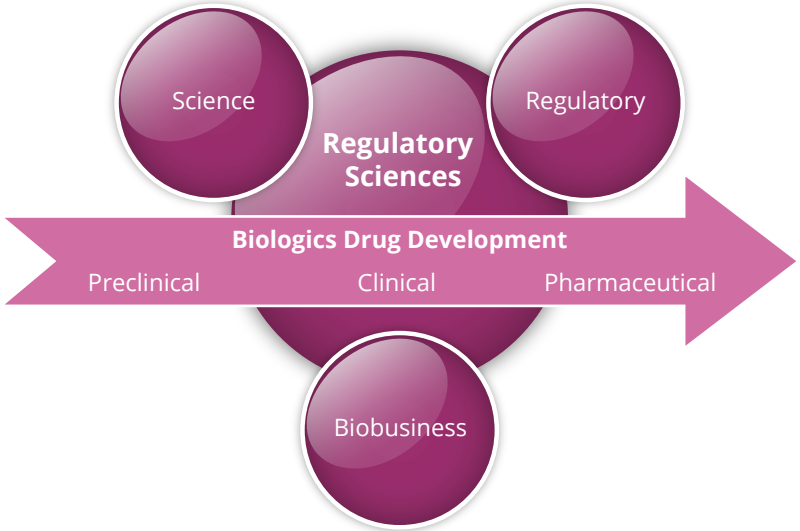
OUR PRODUCT FOCUS

- **Proteins**
- **Antibodies and antibody fragments**
- **Advanced-therapy medicinal products such as somatic cells, gene therapies and tissue engineered products**
- **Peptides**
- **Biosimilars**
- **Recombinant vaccines**



OUR REGULATORY SCIENCE SERVICES

- **Regulatory due diligence**
- **Scientific due diligence**
- **Scientific advice with regulatory agencies**
- **Regulatory & development strategy**
- **Regulatory project design**
- **Clinical trial applications**
- **Marketing authorization applications**
- **Vendor qualification**
- **Audits (GMP, GLP, GCP)**



REGULATORY SCIENCE APPROACH

Biologics are not only the fastest growing area in drug development, but also one of the most complex concerning CMC, mode of action and safety.

The scientific and technical approaches develop very fast and differ widely. Despite efforts of harmonization approval of biologics is based on a case by case approach reflecting drug specific scientific concepts.

The challenge of biologics drug development is the need to scientifically interpret regulatory guidelines in very close context to the product characteristics and mode of action of the drug candidate of interest.

Dr. Regenold is fulfilling this high demand for **"regulatory sciences"** by combining worldwide regulatory experience with a continuously growing network of cutting edge experts from academia and industry.

COMPANION DIAGNOSTICS

Due to their specific modes of action, biologics development requires new routes of patient stratification with drugs that are more likely to be effective and safe.

Implementation of biomarker programs during drug development is mandatory to stratify the patient cohort. Results of biomarker programs may lead to the development of a diagnostic tool (Companion Diagnostic-IVD) which then needs to be available at the time of the marketing authorization of the biologics. Regulatory concepts and authorizations of companion diagnostics are provided by our associate company, CEplus GmbH.

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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