



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

BIOLOGICS

NOV2017

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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.

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



SERVICES

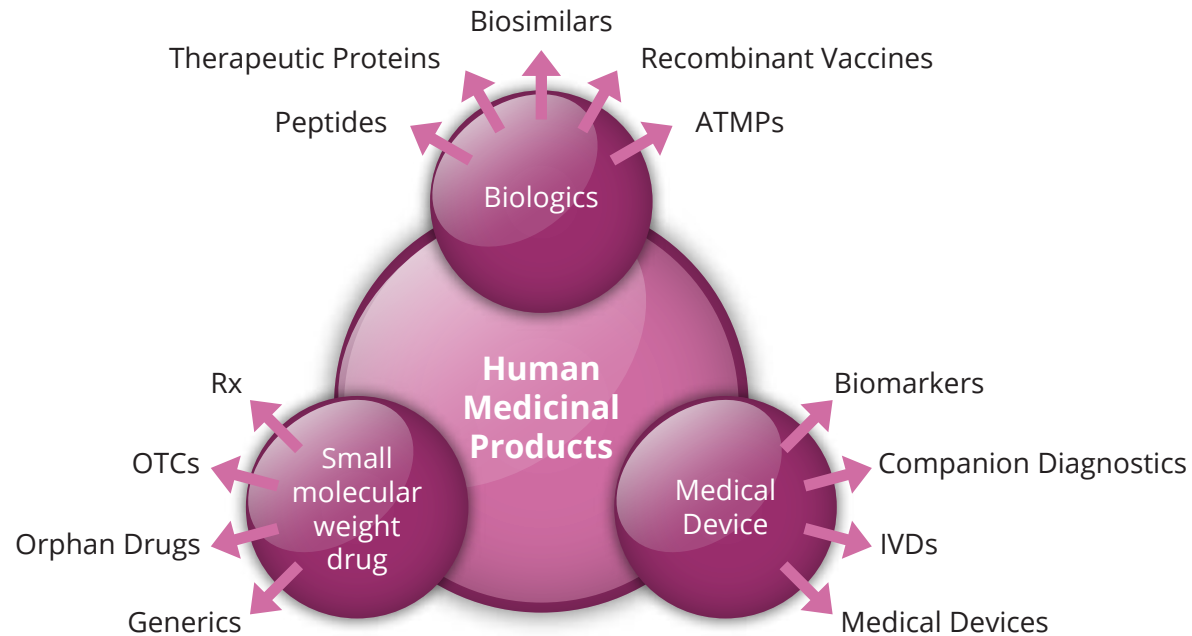
Dr. Regenold GmbH provides a range of services both nationally and internationally.

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:

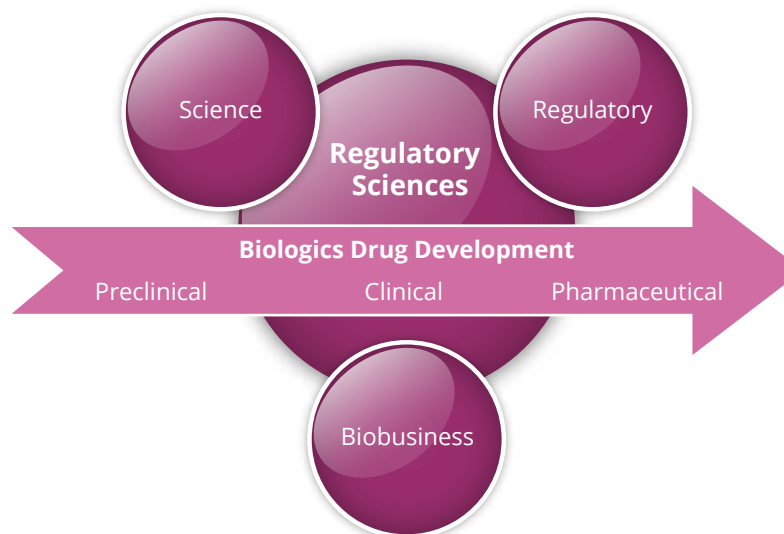
- Strategic advice
- Pharmaceutical development
- Preclinical development
- Clinical development
- Project management
- Regulatory strategy and implementation
- Pharmacovigilance
- Auditing
- Market access
- Portfolio analysis & life cycle management
- Due diligence
- QM systems & licenses
- Brexit preparation

OUR PRODUCT FOCUS



OUR REGULATORY SCIENCE SERVICES FOR BIOLOGICS

- 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

The scientific, technical and regulatory approaches for biopharmaceutical development have a high dynamic. Despite a certain level of harmonization, approval of biopharmaceuticals is based on a case by case approach reflecting drug specific scientific concepts.

Regulatory guidelines need to be interpreted in very close context to the molecular structure and mode of action characteristics of the molecule 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 scientists 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

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

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