# Dr. Regenold GmbH

Your partner for development,
regulatory and market access.

DR. REGENOLD GMBH
DEVELOPMENT • REGULATORY • MARKET ACCESS

## Biopharmaceuticals

NEXT

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# About Dr. Regenold GmbH

Dr. Regenold GmbH is specialised 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 authorisation both nationally and internationally.



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In 2001 we founded regulanet® which is a network of independent regulatory consultancies with representation in over 90 countries throughout the world.

The members offer services to a wide variety of national and international healthcare and pharmaceutical clients. The network uses the latest tools to ensure efficient communication and access to information between members and clients. regulanet® provides advice and assistance on national and international projects and marketing authorisation procedures, including the decentralised, mutual recognition and centralised procedures within Europe.

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regulanet®
THE INTERNATIONAL NETWORK
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# Services

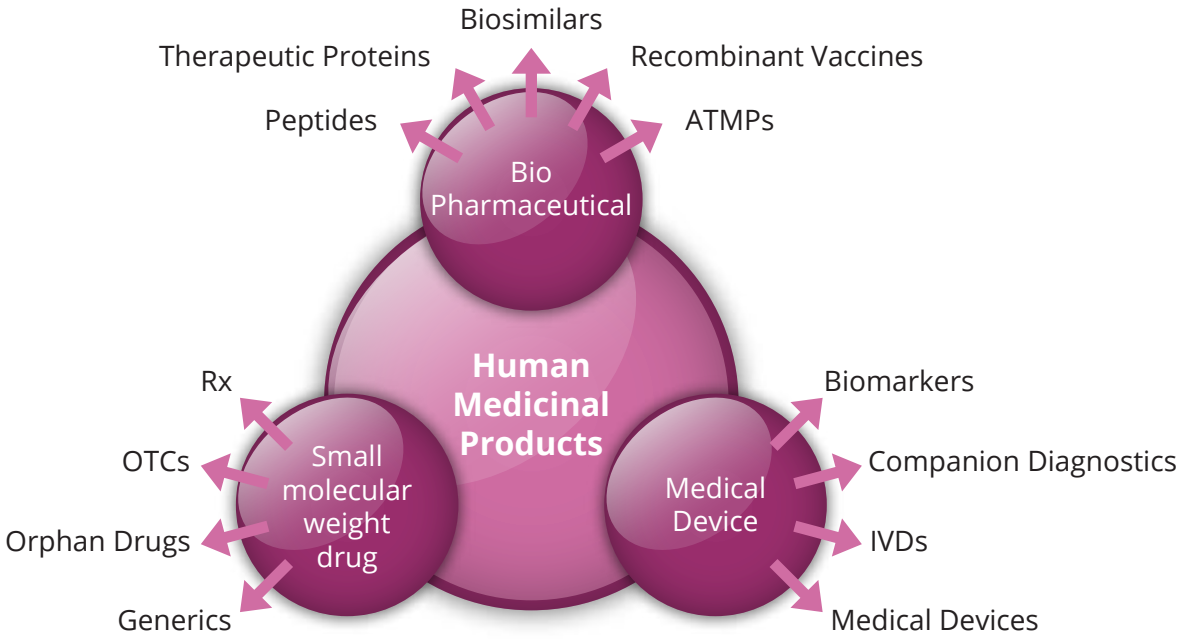
Dr. Regenold GmbH provides a range of services both nationally and internationally.

Dr. Regenold GmbH expertise covers development, regulatory and market access. Our aim is to help clients maximise 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 optimise regulatory approval and market access.

**Our services include:**

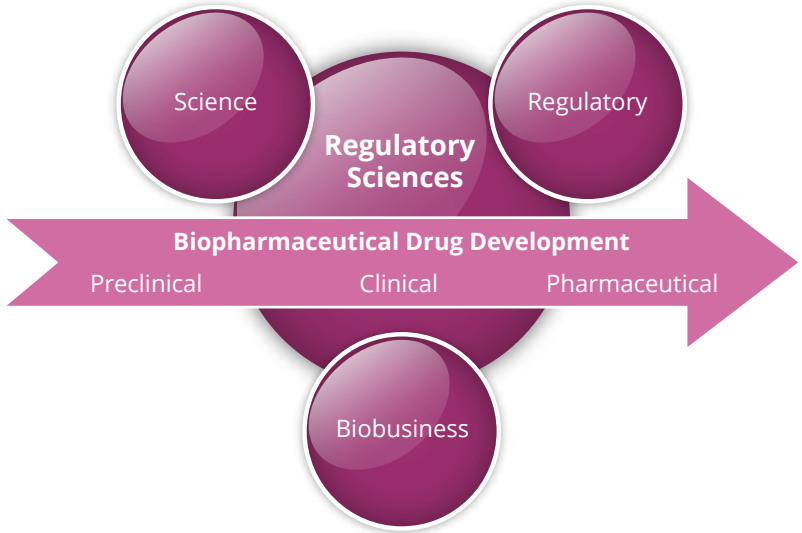
- **Strategic Advice**
- **Pharmaceutical Development**
- **Preclinical Development**
- **Clinical Development**
- **Dossier Compilation**
- **Project Management**
- **Regulatory Strategy & Implementation**
- **Pharmacovigilance**
- **Auditing**
- **Market Access**
- **Portfolio Analysis & Life Cycle Management**
- **Due Diligence**
- **Quality Management**

# Our Product Focus



# Our Regulatory Science Services for Biopharmaceuticals

- **Regulatory Due Diligence**
- **Scientific Due Diligence**
- **Regulatory & development strategy**
- **Regulatory project design**
- **Marketing Authorisation Applications**
- **Vendor qualification**
- **Audits (GMP, GLP, GCP)**



# Our 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, biopharmaceutical drug 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 biopharmaceutical. Regulatory concepts and authorizations of companion diagnostics are provided by our associate company, Medical DeviCE+ GmbH.

# Contact Us

Name:

Company:

Email:

Telephone:

Message:

Send

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

**Dr. Regenold GmbH**
Zöllinplatz 4
D-79410 Badenweiler

Phone: +49 7632 82 26-0
Fax: +49 7632 82 26-22
info@regenold.com
**www.regenold.com**

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