regenold
Development
Regulatory
Market Access

regenold GmbH

Your partner for development, regulatory and market access.

Introduction to the regenold organisation

- Founded in 1994 by Dr. Jürgen Regenold
- Offering a full suite of regulatory services from development to market access and life cycle management
- Strong international presence with > 50 % sales outside of Germany
- Proprietary network, **regulanet®** which today covers more than 90 countries with over 120 domain and regional experts
- Established medical device division **CE plus** in 2009
- Presence in data science and analytics since 2015
- Offering legal manufacturer and representative services through our subsidiary, **NEXTEC medical GmbH**
- Today regenold has over 100 employees

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Our service offering

Our service range in pharma and medical devices is complemented by Legal Representation services and IT/Data Sciences

- **Full-Range Regulatory Services**
- **Legal Manufacturing & EU Representative Services (NEXTEC)**
- **Data Science/Validated IT/Data Access**

Pharma

- Medicines (Rx & OTC)
- Biopharmaceuticals
- Orphan Drugs
- Vaccines

Devices/IVD

- Active Medical Devices/ Software/Apps
- Non-Active Medical Devices
- IVD & Companion Diagnostics

Other

- Food
- Novel Food Applications
- Cosmetics
- Chemicals

Structure of the network

- Founded in 2001 and owned by regenold GmbH
- Comprised of 60 in-country partners and members who are expert regulatory professionals:
  - 33 Partners
  - 27 Members
- Covering over 90 countries throughout Europe, US, LATAM, Asia (including China, Japan, India) and MENA
- 60 subject Experts and Service Provider Partners

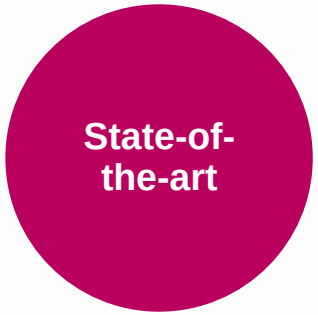
Our Key Differentiators

Throughout the years we have helped over **2000 clients** with more than **10’000 products** and implemented **+100 QM Systems.**

Our Subject Matter Experts possess **extensive practical experience** with backgrounds from industry as well as regulatory bodies.

We offer **short response times** & dedicated contact points and we maintain **close communication** with Authorities and notified bodies.

Flexible roles such as Consultancy, Advisory Board, Regulatory Affairs Manager, Quality Manager, Project Manager etc..



Proven experience with **breakthrough technologies** including the use of AI / Digital Biomarkers.

Active member of **numerous networks**, working groups and standard committees.

We provide tailored solutions for **all phases of the product life-cycle** including acting as Legal Manufacturer as well as European Representative.

Pharma Services

- Strategic Advice
- Pharmaceutical Development
- Preclinical Development
- Clinical Development
- Project Management
- Regulatory Strategy & Implementation
- Pharmacovigilance
- Data Science & Analytics
- Auditing
- Market Access
- Portfolio Analysis
- Due Diligence
- Quality Management & Compliance

We offer customised solutions with a focus on innovative development plans in view of market access

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We cover the full range of regulatory services in medical devices and IVD's with deep product expertise in most categories

CE plus
MEDICAL DEVICES | IVD
Regulatory Affairs & More

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Medical Device & IVD Services

Technical Documentation
- Compilation
- Maintenance

Assessments
- Gap Assessments
- Due Diligence
- Clinical
- Biocompatibility

Quality Management System
- Implementation
- Maintenance
- Auditing

Market Access
- International Registrations in collaboration with regulanet®

Regulatory Strategies
- Design & Development
- Classification, CE marking

Post-Market Services
- Post-Market Surveillance
- Device Vigilance
- Regulatory Intelligence

Service portfolio of NEXTEC

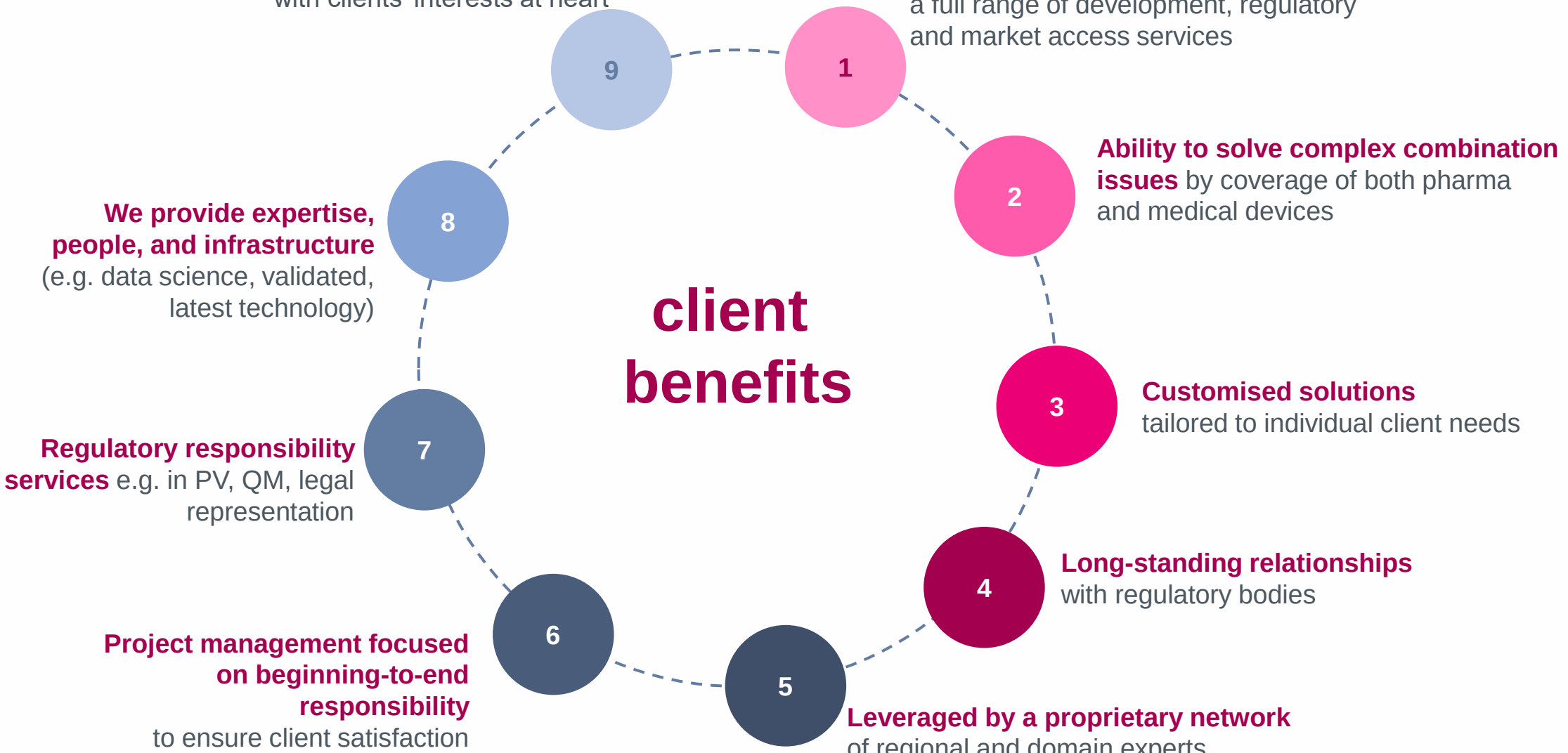
- Our subsidiary NEXTEC is providing regulatory affairs services and takes over legal responsibility for medical devices and in-vitro diagnostics (MDR 2017/745 and IVDR 2017/746)
- “Legal” manufacturer service (MDR/IVDR Article 10)
- EU REP services (MDR/IVDR Article/11)
- Contract development for Medical device Software and Combination products
  (MDR/IVDR and EN ISO 13485:2016)

Data Science & Analytics complementing our regulatory service range

- Experienced team and validated AI platform (SAS & open source) geared towards custom development
- Targeted towards development of tailored solutions in GxP and medical device area
- Strong partnership with SAS with technical and business development support
- Regenold AI solutions range from R&D to commercial, some of our focus areas are:
  - Digital diagnostics
  - Business analytics for critical insights into drug and device development stages
  - Automation of regulatory processes
  - Market analysis & decision support
  - Clinical decision making

We address the following needs:

client benefits



We are passionate about regulatory – that is the reason why we provide a full range of development, regulatory and market access services

Ability to solve complex combination issues by coverage of both pharma and medical devices

Customised solutions tailored to individual client needs

Long-standing relationships with regulatory bodies

Leveraged by a proprietary network of regional and domain experts (regulanet®)

Project management focused on beginning-to-end responsibility to ensure client satisfaction

Regulatory responsibility services e.g. in PV, QM, legal representation

We provide expertise, people, and infrastructure (e.g. data science, validated, latest technology)

A private company with clients' interests at heart

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Thank you.

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