Dr. Regenold GmbH

Your partner for development, regulatory and market access.

DR. REGENOLD GMBH
DEVELOPMENT • REGULATORY • MARKET ACCESS

Regenold Group

Introduction to the Regenold Group

- 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 separate medical device division, CE plus GmbH in 2009
- Started developing our presence in data science and analytics in 2015
- Offering legal manufacturer and representative services through our subsidiary, NEXTEC medical GmbH
- Today, Regenold has over 90 employees

Product Expertise

Pharma

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

Devices

- Active Medical Devices/Software/Apps
- Non Active Medical Devices
- Combination Products
- Borderline Products
- In Vitro Diagnostics
- Companion Diagnostics (CDx)

Other

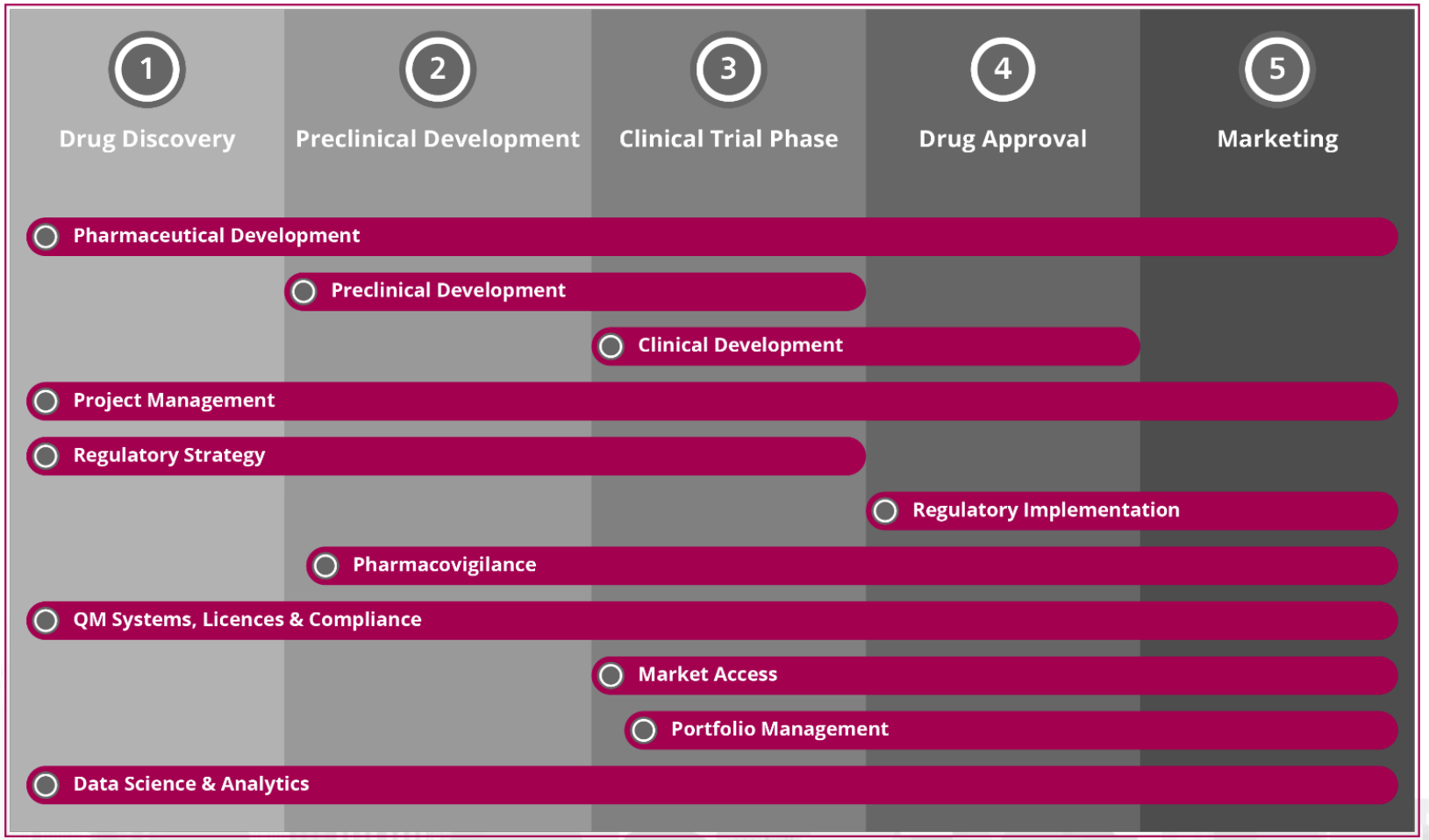
- Food Supplements
- Cosmetics
- Chemicals
- Biocides

Pharma Services

Our 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

Our Pharma Services



CE plus medical devices & IVD

Medical Devices / IVD

CE plus

- Regulatory support for medical devices and in vitro diagnostics
- Associated company of Dr. Regenold GmbH
- Integrated into Dr. Regenold GmbH and regulanet® network

CE plus GMBH
MEDICAL DEVICES • IVD
Regulatory Affairs & More

Medical Device & IVD Services

Technical Documentation
- Creation
- Maintenance

Quality Management System
- Implementation
- Maintenance
- Auditing

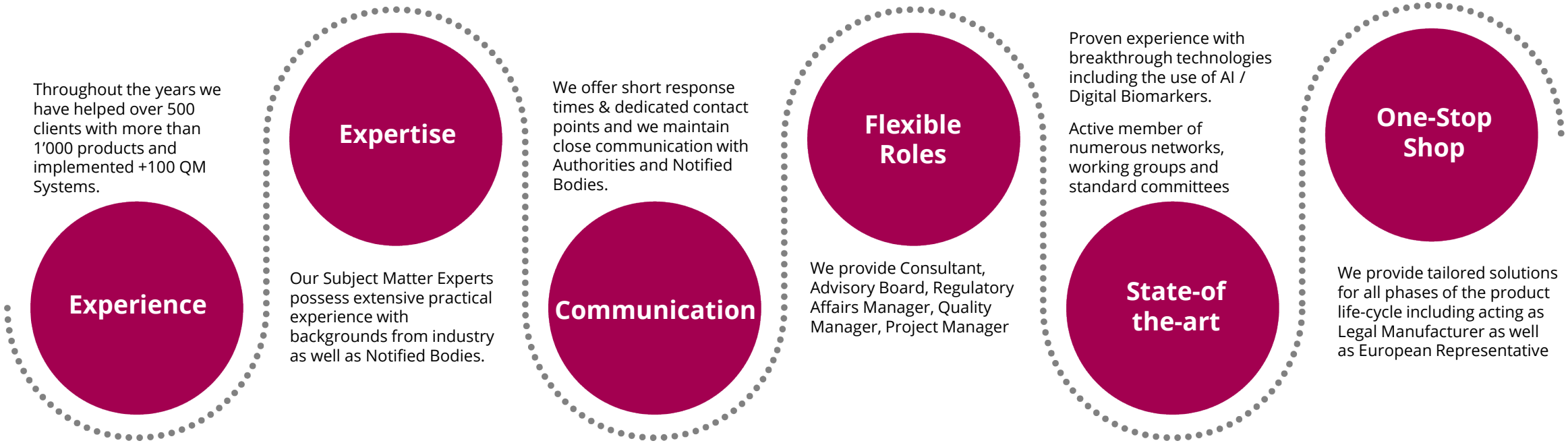
Regulatory Strategies
- Development
- Demarcation

Assessments
- Gap Assessments
- Due Diligence
- Clinical
- Biocompatibility

Market Access
- International Registrations in collaboration with regulanet®

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

Medical Device & IVD Services



NEXTEC medical GmbH

Service portfolio of NEXTEC

- NEXTEC is a company providing regulatory affairs services and takes over legal responsibility for medical devices under MDR 2017/745 and in-vitro diagnostics under IVDR 2017/746.
- “Legal” manufacturer service according to MDR/IVDR Article 10
- EU REP services according to MDR/IVDR Article/IVDR 11
- Importer Service according to MDR/IVDR Article 13
- Contract development for Medical device Software and Combination products according to MDR/IVDR and EN ISO 13485:2016

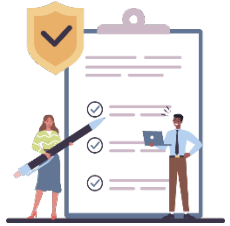
NEXTEC medical GmbH
Implement. Place. Sustain.

Legal Manufacturer Service – All-in-one solution

Development

Manufacturing

QMS
ISO 13485
Legal
Manufacturer
(NEXTEC)



Regulatory
Compliance

Post-Market

Technical
Documentation

Maintenance

Compilation

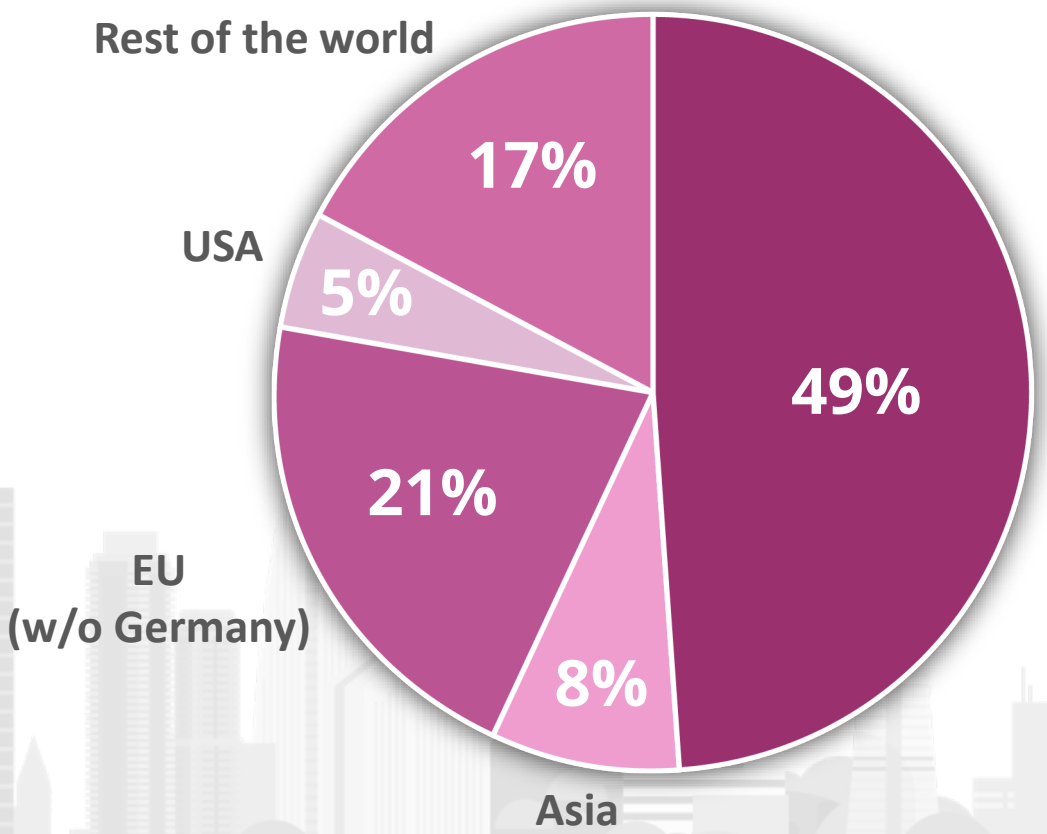
regulanet® The Network

Our Network

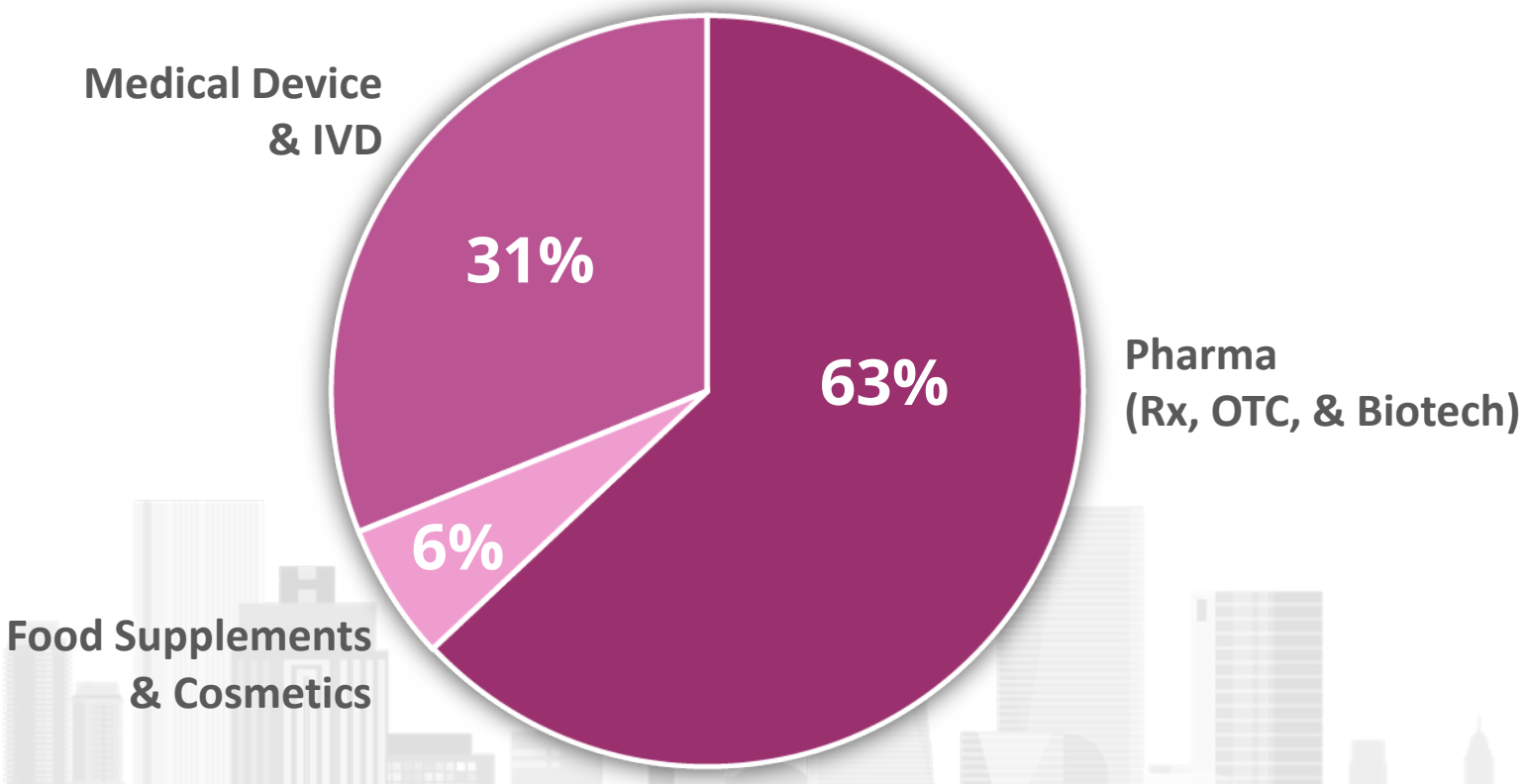
regulanet®

- Founded in 2001 and owned by Regenold
- Comprised of 58 in-country members and partners who are expert regulatory professionals (5 Joint Ventures, 19 Full Members and 34 Partners)
- Cover over 90 countries in Europe, US, LATAM, Asia (including China and Japan) and MENA
- 60 subject Experts and Service Provider Partners

Regenold Turnover 2019 by region



Regenold Turnover 2019 by product category



Our Clients

- Pharma (Rx and OTC), Biotech, Medical Device, Food and Cosmetic companies
- Developers and manufacturers of proprietary and generic medicines
- Large international corporates and SMEs
- Financial institutions, including Private Equity firms
- Relationships and business is primarily driven by recommendation and repeat business

Key benefits of working with Regenold

- Provide a full range of development, regulatory and market access services
- Cover pharma and medical devices and are therefore able to help clients with complex needs
- We listen to client's needs then develop specific solutions to solve their problems
- Personalized approach supported by a network and contacts so we are a truly one-stop shop
- Each project is allocated a project manager who will manage the task from beginning to end
- We are prepared to take responsibility also in critical roles (regulatory responsibility services e.g. in PV, QM, legal representation…)
- We provide expertise, people **and** infrastructure (e.g. data science, validated, latest technology)
- Our team of over 90 internal staff are supported by our international network, regulanet®
- A private company with clients' interests at heart

Contact us for more information! or just Thank you

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Founder of

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