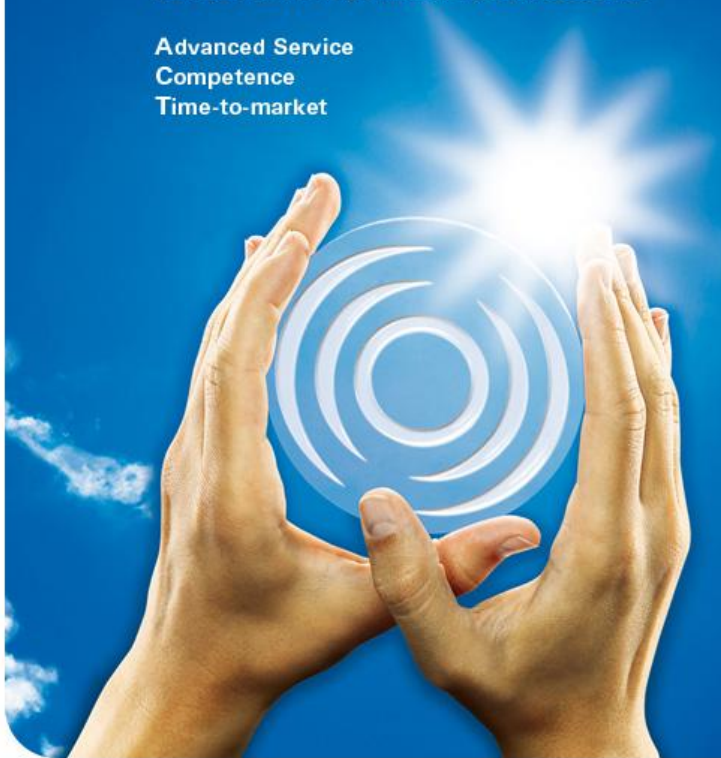


We take you further

Unique competence in biopharmaceuticals

Let us A.C.T. together for your success!

Advanced Service
Competence
Time-to-market



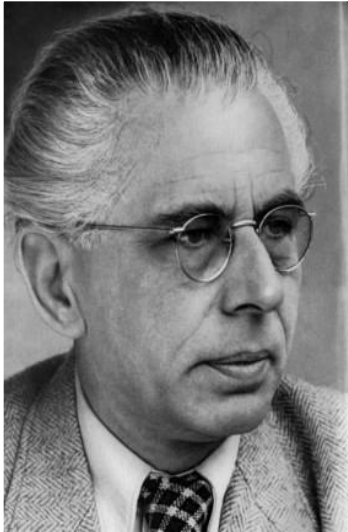
Overview Rentschler Biotechnologie

AusBiotech, Adelaide, 18.10.2011

Klaus B. Schoepe, PhD,
SVP Client Relations

As an independent leading, internationally operating service company, we develop and produce innovative pharmaceuticals and biopharmaceuticals together with our partners.

Our professional services are based on the highest standards in quality and efficiency.



Dr. h.c. Erwin Rentschler †
Founder & Managing Director
1927 - 1959



Dr. Helmut Rentschler †
Co-Founder & Associate
1929 - 1976

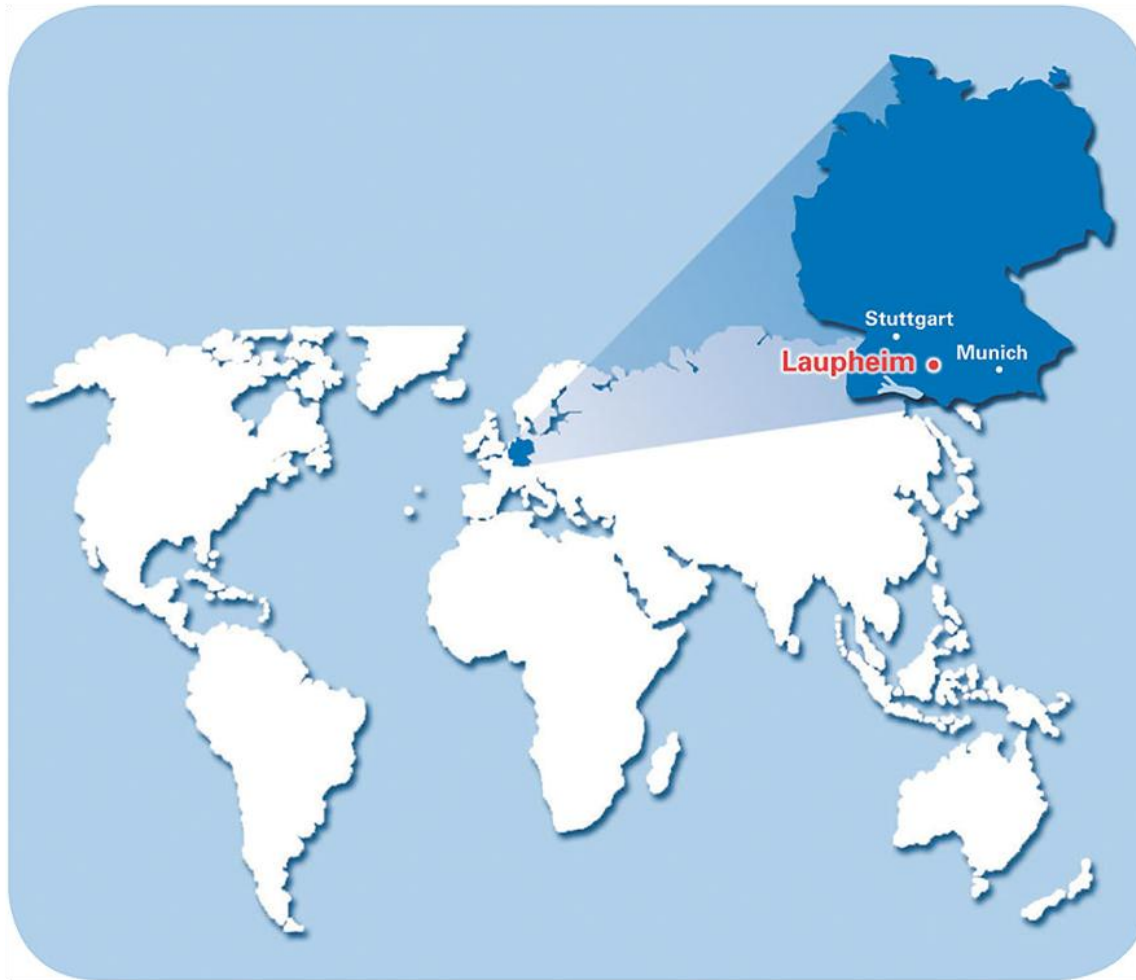


Dr. Friedrich E. Rentschler
Managing Partner
1959 - 1999



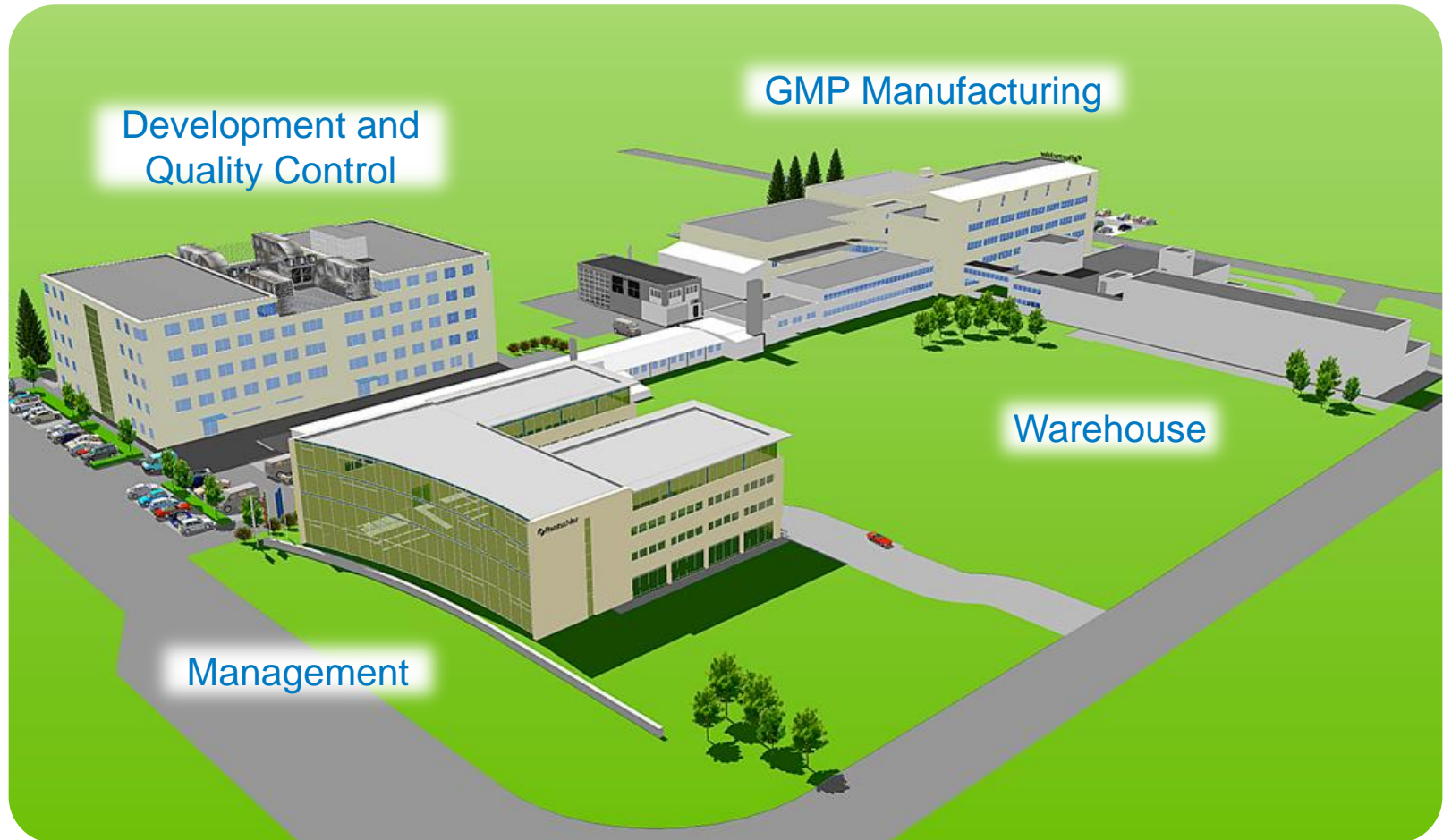
Dr. Nikolaus F. Rentschler
Managing Partner
since 1999

➡ **Family owned company since the foundation in 1927**



- In the South of Germany
- 2h from Munich airport
- 1h from Stuttgart airport
- 2.5 hours from Frankfurt airport

Facilities in Laupheim



Contract Services for Biopharmaceuticals

**Cell Line &
Process
Development**

**Mammalian
Cell Culture
GMP
Production**

**Fill & Finish,
Regulatory
Services**



- 1927 Founding of Dr. Rentschler & Co.
- 1947 Establishment of a bacteriological and virological institute
- 1974 Founding of Rentschler Biotechnologie
- 1983 World's first market approval for a natural IFN- β compound (Fiblaferon®)



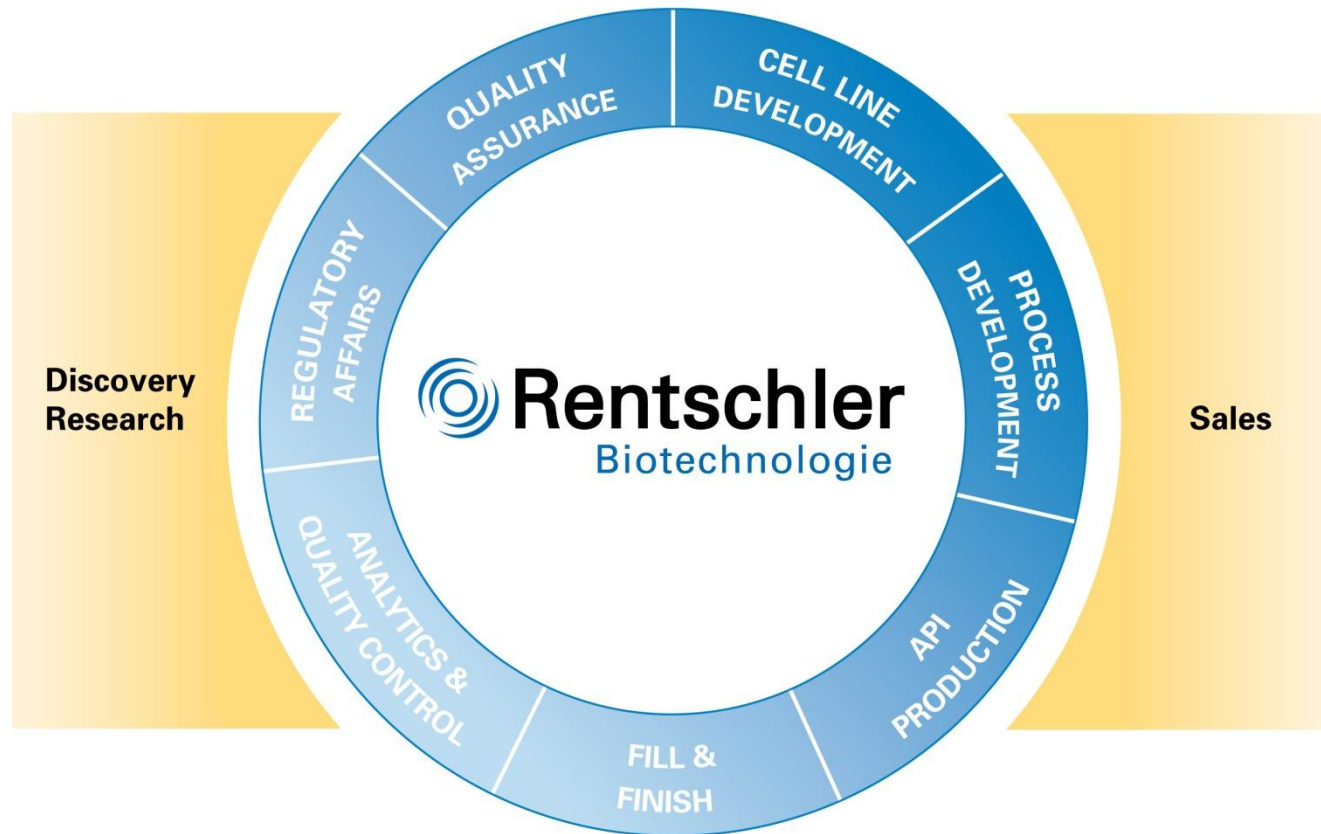
- 1989 Market approval for recombinant IFN- γ and topical IFN- β gel
- 1997 Focus on integrated services for the contract development and manufacturing of biopharmaceuticals
- 2003 New facilities to expand manufacturing capacities in operation
- 2006 US presence with the incorporation of Rentschler Inc. and opening of a sales office



History (3)

- 2007 Two 500 L GMP production lines in operation
- 2008 2,500 L bioreactor in operation
- 2009 New warehouse and administration building
- 2010 First 1,000 L disposable bioreactor in operation
- 2011 Second 1.000 L disposable bioreactor in operation

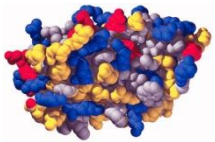




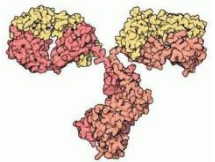
- Development of serum and protein-free cell lines
- Production and storage of Master and Working Cell Banks
- Characterization of Master and Working Cell Banks



- CHO cell line systems for recombinant proteins and antibodies

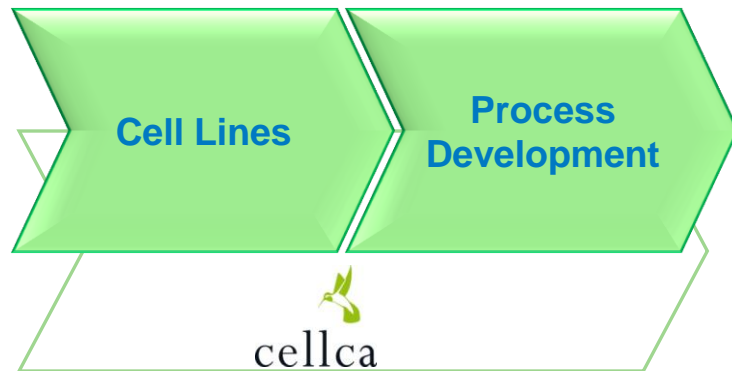


Rentschler's expression system for all **recombinant proteins**



CellCa's high expression system for **antibodies**

Titer 6 - 7 g/L in fed-batch process



- Development and optimization of cell culture processes in stirred tank reactors
- Fed batch and perfusion technology
- Single-use bioreactors (non-GMP)
- Production level scale-up



GMP production for clinical studies and the market

- Stainless steel bioreactors
 - 3 x 30 L
 - 1 x 50 L
 - 2 x 250 L
 - 2 x 500 L
 - 1 x 2,500 L
- Single-use bioreactors
 - 2 x 1,000 L
- Cultivation methods
 - Batch, fed-batch & perfusion mode



- Development at lab scale
- Scale-up to pilot and production levels
- Process validation
- Validation of viral safety



Protein production and purification under GMP

- Chromatographic separation: IEX, HIC, Affinity, SEC, other
- Filtration: microfiltration, UF, DF
- Membrane adsorption
- Extraction: aqueous two phase
- Virus inactivation and removal: pH, solvent/detergent, nanofiltration
- Protein modification: PEGylation

Fill & Finish for clinical trials and market supply

- Aseptic filling of vials and pre-filled syringes
- Lyophilization
- Terminal sterilization for diluent and placebo fills
- Labeling, packaging and GMP logistics

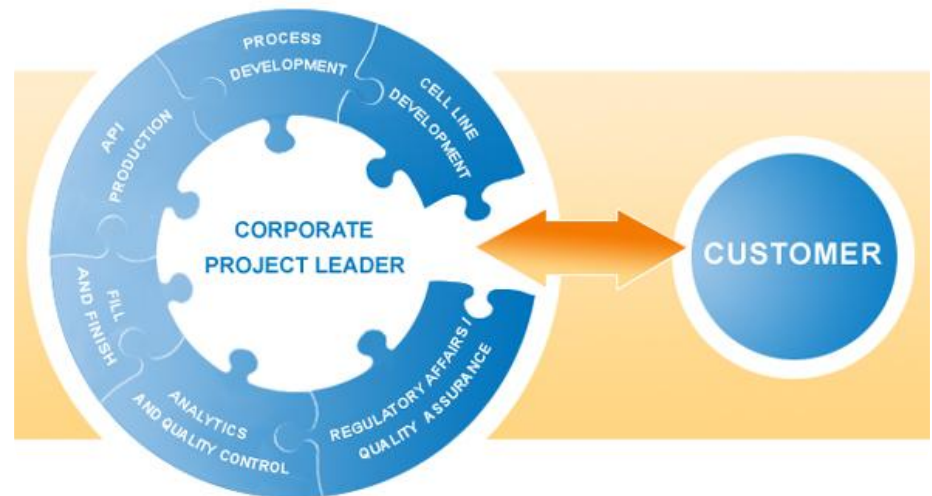
Approved by EMA and US FDA

- Chemical, biological, pharmaceutical, and microbiological analysis
- Protein structure analysis, identity and purity testing
- Protein quantification and qualification via immuno- and bioassays
- Glycoprotein characterization, oligosaccharide mapping
- Residual analysis for DNA, host cell proteins, processing chemicals
- Stability studies under ICH conditions

- Contacts within the authorities
- Regulatory consulting and registration services
- Assurance of regulatory compliance from lab scale to commercial scale
- Preparation of registration dossiers (market approval)
- Advice on biological and virological safety questions

- Securing EU and cGMP compliance
- Management of regulatory inspections and client GMP audits
- Qualification of suppliers and subcontractors
- Development and administration of the GMP quality systems
- Batch Record Review
- Administration of controlled documents (SOPs, Reports, BPRs...)

- One designated contact person for client
- Project management including planning and control
- Proactive communication and transparency
- Monitoring of project goals and timelines



- Full service from an experienced and reliable CMO partner
 - From phase I to market
- State-of-the-art facilities and suitable capacities
 - High expression systems for antibodies and recombinant proteins
 - Highly efficient processes and bioreactors up to 2,500 L working volume
- All services from one hand
 - From gene to vial
 - In-house Fill & Finish
- 100 % historical project success rate
 - Well established track record
 - Outstanding expertise in development and manufacturing of biopharmaceuticals

The growing knowledge in molecular medicine continuously opens new chances and opportunities to cover unmet clinical needs.

Together with our international partners we will use these opportunities for the development of new biopharmaceutical products and thus contribute to the advancement of medicine and human health.

Phone: +49 7392 701-810

Fax: +49 7392 701-400

Email: klaus@rentschler.de

Internet: www.rentschler.de

Rentschler Biotechnologie GmbH
Erwin-Rentschler-Straße 21
88471 Laupheim
Germany

