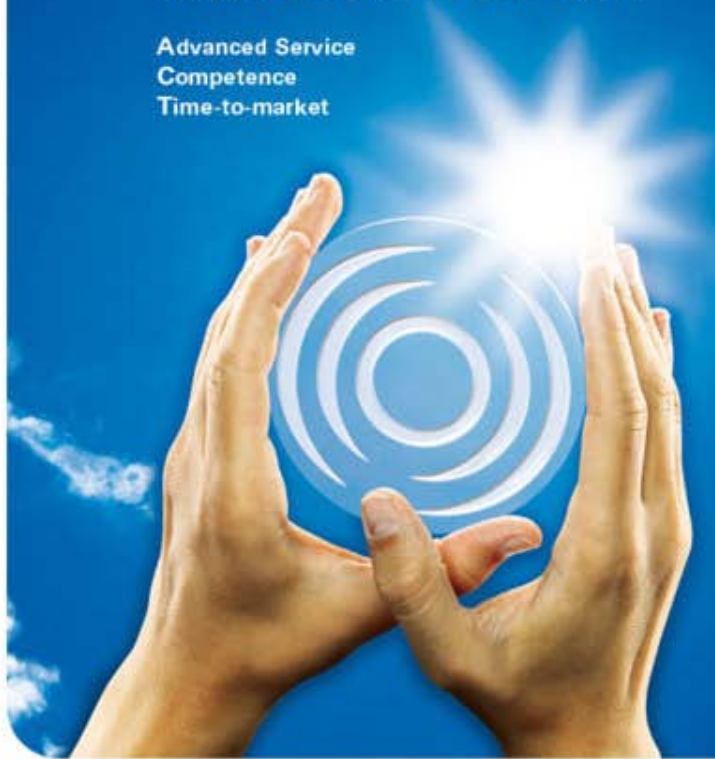


We take you further

Unique competence in biopharmaceuticals

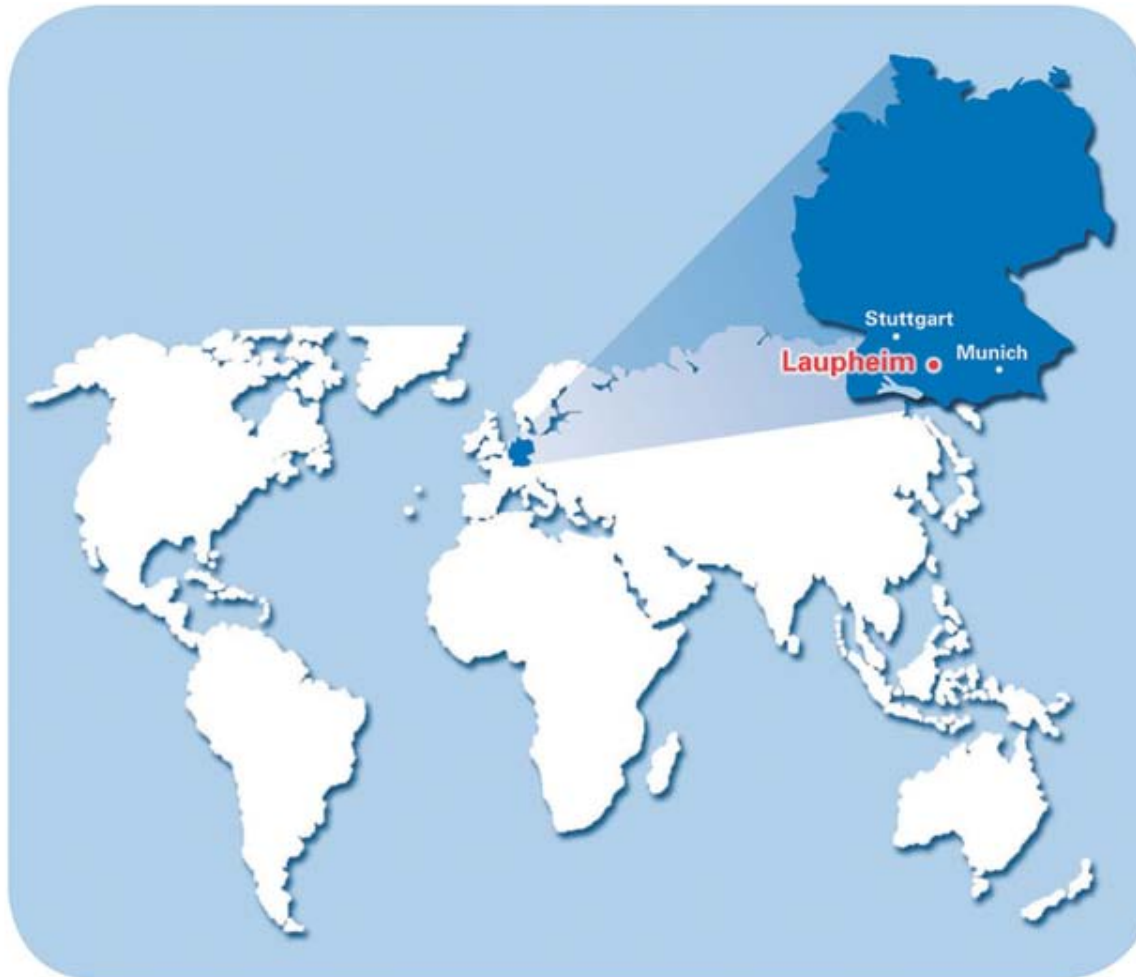
Let us A.C.T. together for your success!

Advanced Service
Competence
Time-to-market



Corporate Presentation

- Location
- Facilities in Laupheim
- Focus
- Competence
- Advanced Service, GMP certified
- Benefit
- Let us A.C.T. together ...



- In the South of Germany
- 2h from Munich airport
- 1h from Stuttgart 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®)

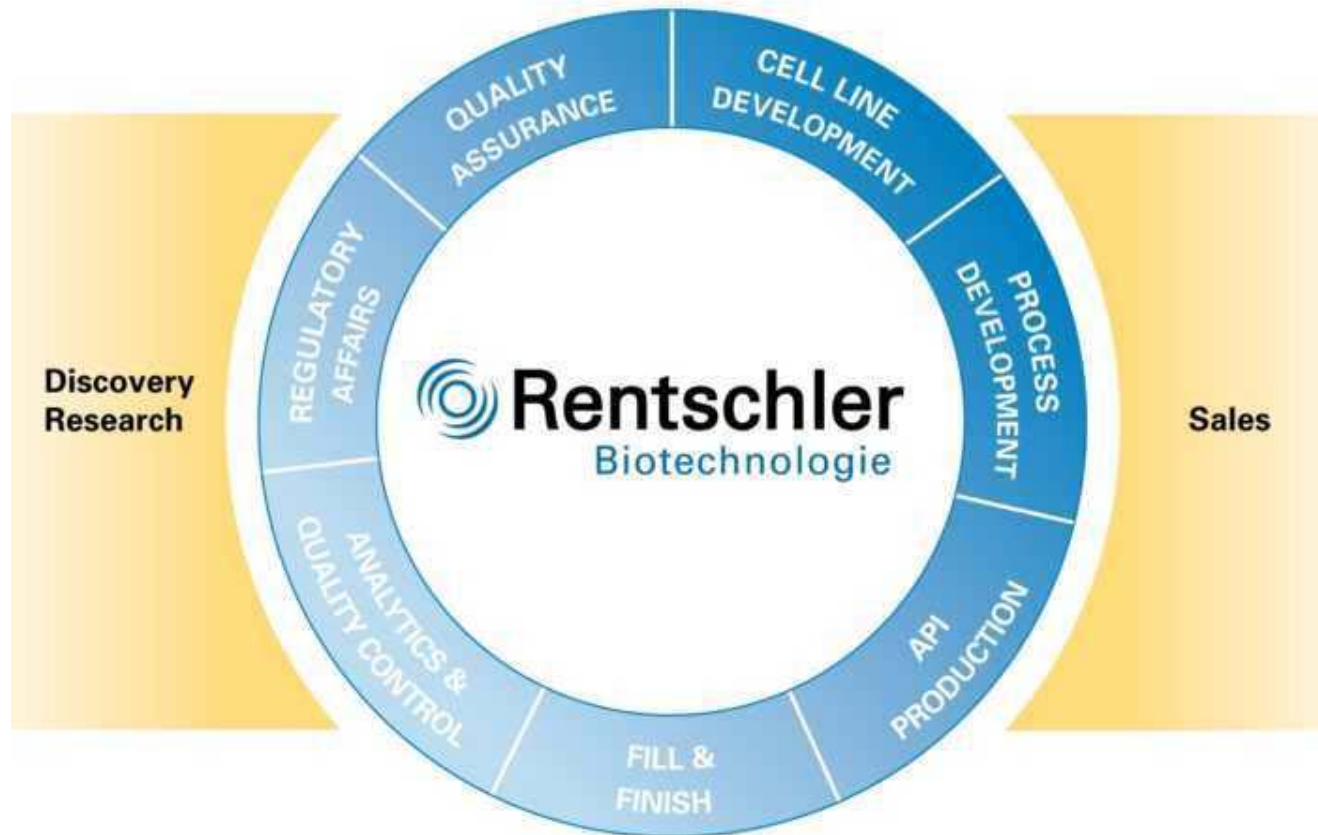


- 1989 Market approval for recombinant IFN- γ and topical IFN- β gel
- 1997 Focus on integrated services for the contract development and manufacturing of biopharmaceuticals
- 2003 New facilities to triple manufacturing capacities in operation
- 2006 US presence with the incorporation of Rentschler Inc.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

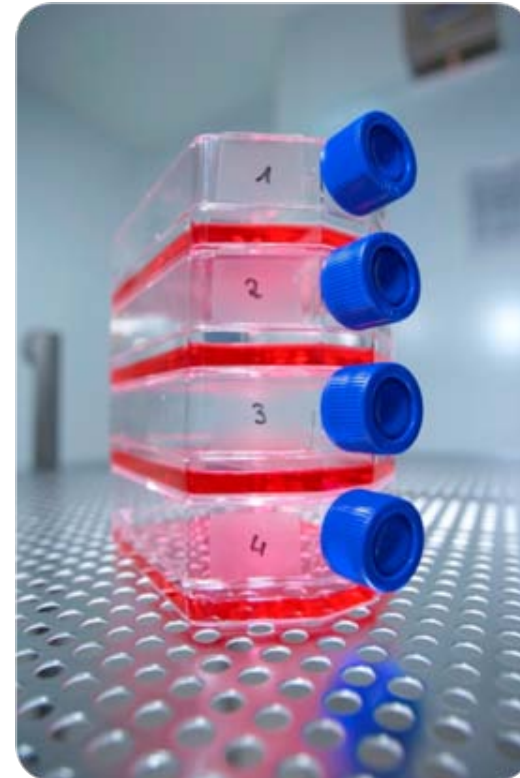


- 2007 Two 500 L GMP production lines in operation
- 2008 2,500 L bioreactor in operation
- 2009 New warehouse and administration building
- 2010 First 1,000 L disposable bioreactor in operation

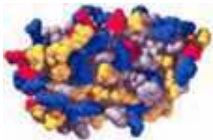




- Development of serum and protein-free cell lines
 - Rentschler's system
 - Cellca's system
- Production and storage of Master and Working Cell Banks
- Characterization of Master and Working Cell Banks



- CHO cell line systems for recombinant proteins and antibodies

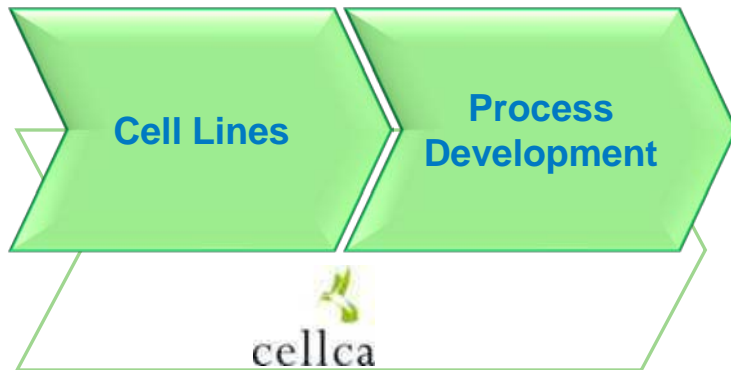


Rentschler's expression system for all **recombinant proteins**



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

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





Upstream Processing (USP) Development

- Development and optimization of fermentation processes in stirred tank reactors
- Fed batch and perfusion technology
- Single-use bioreactor processes
- Production level scale-up





Upstream Processing Production

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
 - 1,000 L
- Cultivation methods
 - Batch, fed-batch & perfusion mode





Downstream Processing (DSP) Development

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





Downstream Processing Production

- Centrifugation
- Filtration
- Membrane technologies
- Chromatographic separation





Fill & Finish

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

Meeting requirements of EMA and FDA

Aseptic filling in vials

- With and without lyophilization
- Volumes: 0.5 mL to 30 mL
- Batch size: 100 to 70,000 vials
- Filling line for small batch sizes and development work



Aseptic filling of pre-filled syringes

- Volumes: 0.5 mL to 20 mL
- Batch size: 100 to 15,000 syringes





Analytics & Quality Control

- 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

■ Core competencies

- Method development and validation acc. to ICH guidelines
- GMP analytics

■ Methods

- Chromatographic separation
- Glycan analyses
- Capillary electrophoresis
- Peptide mapping
- Gel electrophoresis and isoelectric focusing, etc.



■ Core competencies

- Assay development and validation acc. to ICH guidelines
- GMP analytics

■ Methods

- Immuno assays (ELISAs, Gyrolab Technology)
- Host cell DNA analyses
- BIAcore analytics
- Bioassays



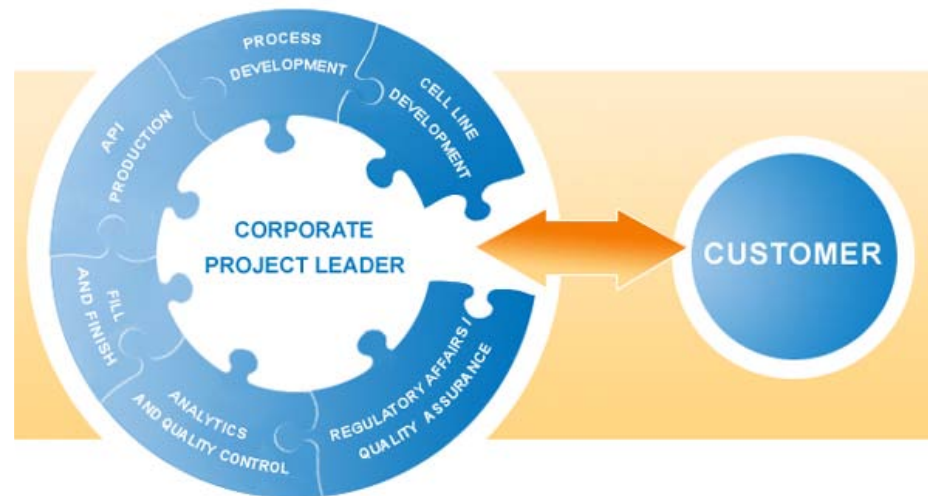


Regulatory Affairs & Quality Assurance

- 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
- Corporate 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

Let us A.C.T together ...

ADVANCED SERVICE

From the cell line to
registration

COMPETENCE

A biotech pioneer with
30 years of experience

TIME-TO-MARKET

Turn your vision into a
successful product

... for your market success!

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