

Your Partner for Product Development from Bench to Market!
Our Expertise – Your Benefit

GMP Product Development Services

Development of vaccines and biopharmaceutical products from bench to market has been Rhein Biotech's business for over 20 years, supporting its partners to bring to market:

- Hepatitis B vaccines
- Combination vaccines
- Human insulin
- Human IFN α -2a
- Hirudin

Rhein Biotech delivers expert support in the development and manufacturing of vaccines and biopharmaceutical products.

Rhein Biotech offers unique expertise in product development, including:

- State-of-the-art laboratories, pilot plant, EU-GMP production plant
- Strain, process and analytical development
- Manufacturing of products for clinical and commercial use
- Experienced team with demonstrated expertise
- Proven project management and technology transfer track record

Rhein Biotech - Partnership in Product Development!



Office, Laboratories and Production Building

Process Development
Pilot Facility and EU-GMP certified Production
Classified Areas of Grade D, C, and A (Isolator)
Molecular Biology, Immunology and Cell Culture
Analytics and Microbiology
OECD-GLP certified Laboratories

Please contact Business Development

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GMP Product Development Services

Strain Development

- Strain generation (bacteria, yeast, cell lines)
- Strain characterization (GLP)
- Cell banking (GMP)

Process Development

- Fermentation
- Down stream processing
- Formulation
- Process characterization

Analytical Development

- Raw material test methods
- In process control methods (IPC)
- QC methods
- Protein characterization
- Virus-like particle characterization

Immunology

- Vaccine development: identification of antigen targets, evaluation of adjuvants and immune modulators
- Virology
- T cell and antibody response profiling
- Biomarkers: assessment and validation

Preclinical Efficacy and Safety

- Novel *in vitro* and animal immunology models for preclinical proof of concept
- Initiation and coordination of preclinical safety trials (pharmacology, toxicology)
- Serological testing (GLP)

Clinical Development

- Support of clinical trial applications in EMEA countries
- Collaboration with selected CROs
- Clinical immunology (GLP)

Manufacturing (EU-GMP)

- Up- and downstream
- Formulation and aseptic filling
- Process validation
- Preclinical testing material
- Clinical testing material
- Commercial API

Quality Management (GLP, EU-GMP)

- QM system, staged approach according to development phase
- Batch release by Qualified Person

Quality Control

- Method validation
- Raw material control
- Intermediate testing (IPC)
- Stability studies
- Microbial QC
- QC testing of API and final product

General Support

- Project management
- Technology transfer
- Engineering support

Production Capabilities and Equipment

Fermentation

- Fermentation screening system
- Microbial fermentation units (fed-batch) ranging from 0.3 to 10 L working volume
- 2 PLC controlled fermentation lines 5-50 L
- Online fermentation monitoring (pH, pO₂, exhaust gas composition)

Downstream Processing

- Continuous flow centrifuge with automated supernatant and solid harvest (0.5 - 10 L/min; up to 20000 g)
- Automated cross flow filtration units (micro and ultrafiltration; up to 3 m² membrane)
- Cell disruption units (glass bead mills, sonifier and high pressure homogenizer up to 50 L/h and 1600 bar)
- Automated preparative HPLC System (up to 1 L/min)
- Automated preparative low pressure chromatography systems (Äkta®, BioProcess®)
- Preparative centrifuge and ultracentrifuge, continuous centrifuge (up to 40000 g, zonal operation)

Formulation and Aseptic Filling

- High pressure homogenizer
- Formulation at 2 to 100 L scale
- Class A isolator

Analytics

- Total organic carbon analyzers
- Several HPLC systems: DAD, MALLS, UV, refractive index
- Capillary electrophoresis
- Gas chromatography
- Field flow fractionation
- Particle analyzers (Malvern, online static & dynamic light scattering, Coulter Counter)
- Threshold system for residual DNA quantitation
- FTIR
- Cell culture/virology, Guava cell counter, IMX, FACS, ELISpot, ELISA analysis

Infrastructure

- HVAC system
- Purified water
- Clean steam
- WFI
- Clean compressed air
- Central gas supply (O₂, CO₂, N₂, H₂, He)
- Media preparation
- Environmental monitoring
- Utility monitoring
- Central CIP station
- Continuous waste water inactivation