

**NEW
CHEMICAL
ENTITIES
BACHEM**

PIONEERING PARTNER FOR PEPTIDES

PIONEERING PARTNER FOR PEPTIDES

With almost 50 years of expertise in peptide synthesis, a track record in process development, large-scale manufacturing and outstanding product quality we hold a leading position.

Bachem is the leading independent supplier of peptidic active pharmaceutical ingredients (APIs) for the human and veterinary pharmaceutical market. Since its foundation in 1971, Bachem's concepts and technologies pioneered the industrial peptide manufacturing.

Our history of firsts drive us to continue developing innovations and we offer a full range of integrated services to bring our partner's breakthroughs to market.

**«BUILDING ON OUR HERITAGE,
WE PIONEER INNOVATIONS TO
DELIVER THE BEST QUALITY
FOR EVERY PEPTIDE NEED.»**

- Process development and custom manufacturing
- From discovery to commercialization
- Milligrams to tons
- Quality you can trust
- Dedicated project management team
- Excellent service and support
- cGMP manufacturing facilities in the USA and in Europe

OLIGONUCLEOTIDE MANUFACTURING

Bachem is strategically diversifying its technology platform to include the manufacture of therapeutic oligonucleotides and nucleic acid-based medicine.

- Custom manufacturing using solid-phase oligonucleotide synthesis (SPOS)
- Huge variety of possible modifications
- State-of-the-art analytical capabilities for process development and release testing, including HPLC, UPLC and high-resolution MS & MS/MS (MALDI, ESI, Q-TOF)

«WE ARE WELL-EQUIPPED FOR SMALL TO COMMERCIAL SCALE cGMP SYNTHESIS OF OLIGONUCLEOTIDES.»

- Single-stranded and double-stranded oligonucleotides
- RNA and DNA including modifications
- Antisense oligonucleotides and small interfering RNA (siRNA)
- Aptamers and conjugates
- Other custom-made oligonucleotides

TURNING TIDES TOGETHER

The fast moving and growing market of oligonucleotide drugs calls for strong and reliable partnerships.

- Full-service oligonucleotide manufacturing facility in Switzerland
- Oligo CMC expertise
- Comprehensive technical and regulatory support
- Dedicated team of experts
- 50 years industry experience





ST. HELENS (UK)

TORRANCE (CA)

VISTA (CA)

GLOBAL BUSINESS

Bachem facilities are located in Switzerland, Europe and in the USA.

All cGMP manufacturing sites are inspected by the FDA and national authorities.

■ GMP MANUFACTURING SITES

■ BUBENDORF (CH)
■ VIONNAZ (CH)

TOKYO (JP) ■

NCE PROJECT PIPELINE



Bachem's pipeline contains more than 150 preclinical and clinical projects.

They all have promising potential: in the last two years, a number of products in phase III trials received marketing authorization and phase II projects progressed to phase III clinical trials.

Our portfolio is completed by oligonucleotide and small molecule projects as well as peptide conjugated NCEs.

BACHEM'S PORTFOLIO

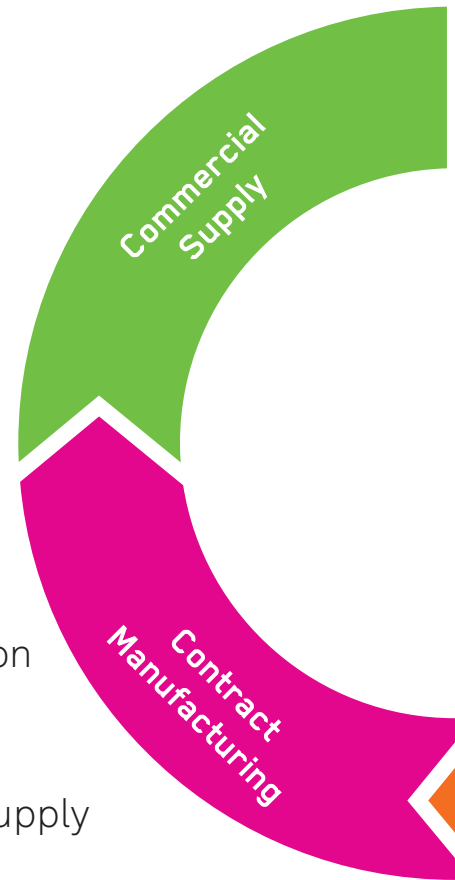
of products and services...

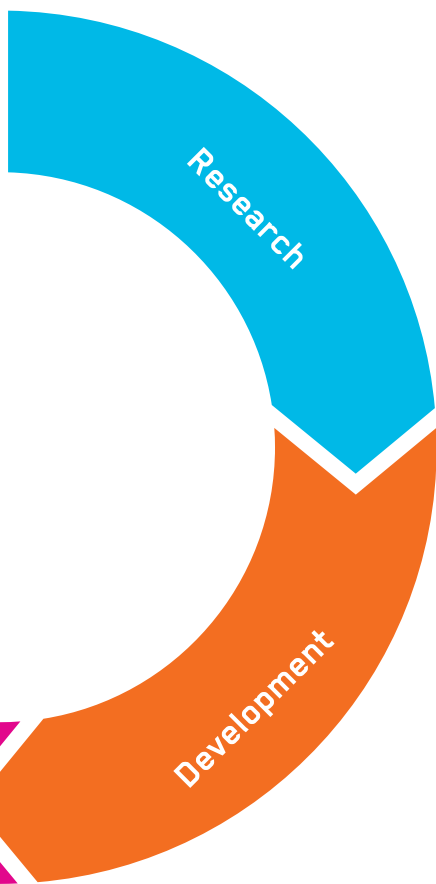
GENERIC APIs

- peptide and small molecule generics
- supply of commercial quantities
- reputation for sustained quality & supply
- high-demand APIs available from stock
- close and long term partnerships

NCEs

- process development, optimization and validation
- comprehensive analytical services
- supply of cGMP material for all clinical phases
- cGMP-manufacturing of APIs for commercial supply





CATALOG PRODUCTS

- more than 5500 products available online
- peptides, amino acids, inhibitors, substrates
- fast & easy ordering @ shop.bachem.com
- bulk quantities according to your needs
- excellent customer and technical support

CUSTOM SYNTHESIS

- from discovery stages to early clinical candidates
- strong focus on quality and timely execution
- development of synthetic routes for scale up
- best industry practice
- highly motivated and experienced team

...from R&D to commercial supply



GMP

PROCESS DEVELOPMENT & MANUFACTURING

Flexible solutions for successful development and production of your product are provided by our dedicated facilities.

Bachem offers cGMP contract manufacturing of active pharmaceutical ingredients (APIs) and advanced intermediates from clinical trial material to product launch quantities and commercialization.

Custom Manufacturing

- Manufacturing of peptide and small molecule APIs (GMP and non-GMP)
- Manufacturing of oligonucleotide APIs (GMP)
- Feasibility studies
- Process development and scale-up
- Process validation

Quality Control

- Analytical method development
- Analytical method validation
- Forced degradation studies
- Indicative stability studies
- ICH stability studies
- Follow-up stability testing

Regulatory Support

- Preparation of CMC documentation
- Preparation and submission of DMFs
- Consulting and regulatory support

QUALITY YOU CAN TRUST

Bachem's quality management system covers the entire production process, from starting materials to production, packaging and delivery of the final product.

Regular audits by customers and authorities systematically verify our quality in terms of equipment, processes and products. Successful inspections by more than 50 customer audits per year and by national authorities confirm our high quality standard and our compliance with the requirements for Good Manufacturing Practices (cGMP).

«WE MANUFACTURE PEPTIDES AND OLIGONUCLEOTIDES WITH EXCELLENT BATCH-TO-BATCH REPRODUCIBILITY.

THIS GUARANTEES CONSISTENT GOOD QUALITY AND MAKES BACHEM A RELIABLE PARTNER FOR YOU.»



REGULATORY COMPLIANCE

- API manufacturing and related services under cGMP
- FDA-inspected since 1997
- Authorized by national authorities (e.g. Swissmedic)
- ISO 13485 certified manufacturing site in St. Helens, UK

PARTNERSHIP

Bachem has established long-term partnerships, being a reliable, independent and financially solid company. Through close collaboration, we enable our customers to bring unique and life changing drug products to the market.

«OUR PARTNERS CAN TRUST IN OUR SUPPORT AND GUIDANCE THROUGHOUT ALL STAGES FROM EARLY DEVELOPMENT, THROUGH CLINICAL TRIALS AND BEYOND COMMERCIALIZATION.»

«Theratechnologies is very pleased to be working with Bachem as a supplier of Tesamorelin. The experience has been very collaborative and contributed to the success of the development program all the way up to market approval. Certainly, Bachem's expertise in peptides, their professional project management and dedication to quality gives us great confidence in knowing we are with the right partner.»

**Pierre Perazzelli, V.P. Pharmaceutical Development
Theratechnologies, Inc.**

«As President and CEO of an emerging biopharmaceutical company, the selection process of a GMP API manufacturer was necessarily exhaustive. We have been pleased with the expeditious development activities and subsequent delivery of our novel API by Bachem. Moreover, Bachem continues to provide professional and timely post-production service.»

**Paul Gunn, President & CEO
Soricimed BioPharma Inc.**

«When entering phase III with our lead product, we want to work with the best in class to assure optimal technical and regulatory support in order to get our therapeutic HPV product to the market as soon as possible. Bachem is our partner of choice since it has a proven track record, as well as the skills and the range of services we need.»

**Gerard Platenburg, CEO
ISA Pharmaceuticals B.V.**



PROJECT MANAGEMENT

As the world's leading peptide manufacturer, we are currently involved in more than 150 cGMP projects centered around New Chemical Entities.

Each project is handled by a dedicated project manager who is ensuring that the timelines, budget, and overall goals and deliverables of the project are carefully monitored and met.

All of our project managers are science-minded and experienced in peptide- or oligonucleotide-based NCE development. Their knowledge of phase appropriate milestones paired with their consultive nature can be a huge asset to early stage pharma and biotech companies that don't have the luxury of an experienced in-house peptide development team.

Your project manager will partner with you and act as an internal voice for your company to guarantee that we meet all your needs and expectations.

**«IN CLOSE COLLABORATION WITH YOU,
WE UNDERSTAND HOW WE CAN BEST
SUPPORT YOUR PROJECTS.**

**WE PLAN AHEAD, WE ARE FAST AND
FLEXIBLE, AND WE OFFER THE NECES-
SARY REGULATORY SUPPORT.»**

REGULATORY SUPPORT

- We provide chemistry, manufacturing, and controls (CMC) information to customers for inclusion in their regulatory submissions or directly to regulatory authorities.
- Our service includes the compilation of the documents and we offer support regarding regulatory requests.
- Through our expertise we enable our partners to meet the regulatory filing requirements from drug development through commercialization.



BACHEM'S SERVICES FOR NCE-PROJECTS IN THE PROCESS OF DRUG DEVELOPMENT



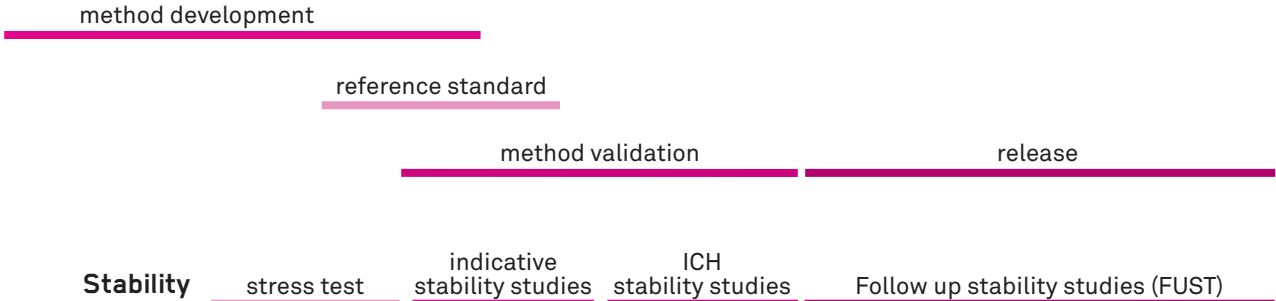
API MANUFACTURING



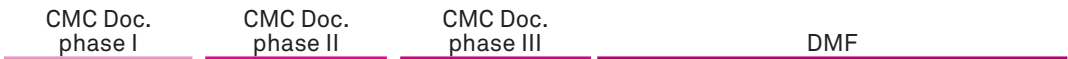
PROCESS DEVELOPMENT



ANALYTICS



REGULATORY DOCUMENTS



PRECLINICAL

CHEMICAL DEVELOPMENT & API SYNTHESIS

Feasibility study/manufacturing of non-GMP material

- process development (synthesis and purification)
- obtained material can be used for toxicology studies*, stress testing, formulation studies and initial analytical method development
- technology transfer from non-GMP to GMP

GMP manufacturing

- starts at the end of the preclinical phase
- GMP material is mandatory for phase I clinical trials

ANALYTICAL DEVELOPMENT STABILITY/ANALYTICS

HPLC method development

Stress testing (strongly recommended)

- forced degradation, influence of temperature and moisture in the solid state
- hygroscopicity, photostability
- essential to get information for determining handling, shipment and storage conditions
- prerequisite for the analytical method development of the HPLC purity method

REGULATORY DOCUMENTS

Preparation of CMC documentation to enter phase I

CLINICAL PHASE I

MANUFACTURING

GMP manufacture

- process development
- scale-up

STABILITY

Indicative stability studies (recommended)

- custom protocols available
- stability under different storage conditions at defined periods of time

ANALYTICS

Validation of analytical methods

- purity and assay

Characterization of reference standard

- portioning of solid reference material into vials (individually labeled and sealed)
- release by QA with Certificate of Analysis
- storage under controlled conditions, regularly tested

REGULATORY DOCUMENTS

Preparation of CMC documentation to enter phase II

CLINICAL PHASE II & III

MANUFACTURING

GMP manufacture

- scale-up

MBPR

- manufacturing of confirmation batch according to master batch production record (MBPR)

Process validation

- manufacturing of 3 validation batches (demonstrate reproducibility and consistency of process)
- batch size should represent batch size of post-market approval
- validated analytical methods are prerequisite for the process validation

STABILITY

ICH stability studies

- at least 6 months data required for DMF

ANALYTICS

Validation of analytical methods

- validation according to ICH guideline Q2(R1)
- e.g., peptide content, purity, water content, acetate content, residual solvents, bioburden
- must be completed prior to release testing of the validation batches

REGULATORY DOCUMENTS

Preparation of CMC documentation for phase III

Preparation of DMF

- at least 6 months data of ICH stability study required
- open part of CMC/DMF provided to customer, closed part sent directly to authorities

Marketing & Sales Contact

Americas

Bachem Americas, Inc.

Tel. +1 888 422 2436 (toll free in USA & Canada)

+1 310 539 4171

sales.us@bachem.com

Asia Pacific

Bachem Japan K.K.

Tel. +81 3 6661 0774

sales.jp@bachem.com

Europe, Africa, Middle East and India

Bachem AG

Tel. +41 58 595 2020

sales.ch@bachem.com

Visit our website

www.bachem.com

or shop online

shop.bachem.com

All information is compiled to the best of our knowledge.
We cannot be made liable for any possible errors or misprints.
Some products may be restricted in certain countries.



www.bachem.com



shop.bachem.com