

# BACHEM

# PARTNER

FROM RESEARCH TO  
MARKETED API



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## LIST OF ABBREVIATIONS

<b>ANDA</b>	Abbreviated New Drug Application
<b>API</b>	Active Pharmaceutical Ingredient (active substance in medicines)
<b>CDMO</b>	Contract Development and Manufacturing Organization
<b>CEP</b>	Certificate of Suitability to the monographs of the European Pharmacopoeia
<b>CEPS</b>	Chemo-Enzymatic Peptide Synthesis
<b>CMR</b>	Carcinogenic, Mutagenic or toxic for Reproduction
<b>cGMP</b>	current Good Manufacturing Practice
<b>CMC</b>	Chemistry, Manufacturing and Control
<b>DNA</b>	Deoxyribonucleic Acid
<b>DMF</b>	Drug Master File
<b>DMF</b>	Dimethylformamide (solvent used in SPPS)
<b>EMA</b>	European Medicines Agency
<b>FDA</b>	Food and Drug Administration
<b>GDP</b>	Good Distribution Practice
<b>GMP</b>	Good Manufacturing Practice
<b>HPLC</b>	High-Performance Liquid Chromatography (method of analysis and purification)
<b>ICH</b>	International Council for Harmonization
<b>IND</b>	Investigational New Drug (application for the FDA in the US)
<b>LPPS</b>	Liquid Phase Peptide Synthesis
<b>IMPd</b>	Investigational Medicinal Product Dossier (application for the EMA in Europe)
<b>MCSGP</b>	Multicolumn Countercurrent Solvent Gradient Purification
<b>NCE</b>	New Chemical Entities (drug substance not yet licensed)
<b>NDA</b>	New Drug Application
<b>OEB</b>	Occupational Exposure Band
<b>QA</b>	Quality Assurance
<b>QC</b>	Quality Control
<b>RA</b>	Regulatory Affairs
<b>RNA</b>	Ribonucleic Acid
<b>siRNA</b>	small interfering RNA
<b>SPPS</b>	Solid Phase Peptide Synthesis
<b>UPLC</b>	Ultra High-Performance Liquid Chromatography

## WHAT YOU CAN EXPECT FROM US

As the world's leading company in the development and production of peptides and oligonucleotides (TIDES), Bachem is a strategic partner for Biotechnology, Pharmaceuticals, Diagnostics, Cosmetics and Life Science research. We work in close collaboration with our customers to ensure the success of their ambitious product development programs.

Innovation is one of our key success factors. We are not only producing peptides and oligonucleotides in large quantities in modern industrial production facilities; we are also automating our manufacturing processes wherever possible.

We have set new standards in quality, increased efficiency and reduced solvent volumes.

There is an increase in the therapeutic use of oligonucleotide-based drugs. The category is also expanding from rare diseases into chronic diseases, with the potential to make a huge difference to more lives. We identified this need for oligonucleotide therapeutics to address larger-scale patient populations and indications. This is driving our commitment and journey in oligonucleotide NCEs: we want to help build a new future.

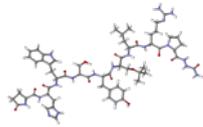
## THE STANDARDS YOU CAN EXPECT BY PARTNERING WITH BACHEM





Founded by entrepreneur Peter Grogg as Bachem Feinchemikalien AG

**1971**



Breakthrough with the commercial production of the decapeptide goserelin, a synthetic analogue of the naturally occurring gonadotrophin-releasing hormone (GnRH)

**1989**



Going public: Bachem shares were now listed on the Swiss Stock

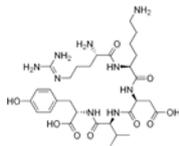
**1998**



Acquisition of Sochinaz SA, a Swiss-based (Vionnaz) specialized manufacturer of active pharmaceutical ingredients

**2001**

**1978**



First contract manufacturer to produce peptides to GMP quality standards, first API produced: Thymopentin

**1996**



Acquisition of the second largest manufacturer of peptides, Bachem California in Torrance, USA, together with its subsidiaries in Germany and the UK

**1999**



Acquisition of Peninsula Laboratories, Inc., based in San Carlos, California, and its subsidiary in England, which is merged with Bachem UK – itself originally a subsidiary of California-based Bachem Inc. in 2000

## An entrepreneurial success story

Every customer project is unique, and, thanks to a wide selection of customizable solutions and efficient processes, we can adapt our services easily to meet our customers' needs. Continuous improvement of our processes makes us more competitive and successful.

Over the years, we have proven that chemical synthesis of pharmaceutical-grade peptides with up to 70 residues can be conducted effectively, on a commercial scale, and in compliance with ever-increasing regulatory requirements. We are also well equipped for small to commercial scale cGMP synthesis of oligonucleotides with a huge variety of possible modifications. For this purpose, we are using solid phase oligonucleotide synthesis and state-of-the-art analytical capabilities for process

development and release testing. We can provide single-stranded and double-stranded oligonucleotides - RNA and DNA including modifications, antisense oligonucleotides and small interfering RNA (siRNA), aptamers and conjugates and other custom-made oligonucleotides.

We consistently comply with Good Manufacturing Practices (GMP), as regulated by Swiss national, European, US and Japanese law. Inspections by national authorities, as well as audits by customers with successful outcome, are proof of our GMP and Good Distribution Practices (GDP) compliance. We have an excellent FDA inspection record with no critical observation or regulatory action during the last ten years. Many FDA inspections even been

passed without the issuance of a Form 483. In addition to the cGMP manufacturing of peptides and oligonucleotides, we offer comprehensive technical and regulatory support.

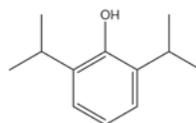
With half a century of experience, we are thrilled to offer our customers end-to-end partnership in commercialization of the respective drug substance: from preclinical and clinical development through worldwide marketing authorization. How did we get to this leading position? For more information, check out our key milestones in the illustration above or visit our website for further details:

<https://www.bachem.com/about-bachem/company-overview/our-history/>



Establishing Bachem Japan K.K. in Tokyo to enhance project and customer support with local presence in Asia

**2018**



Despite the COVID-19 pandemic, we were able to secure the systemically important supply of active ingredients. We even increased in critical areas and did high investments at all sites

**2020**

**50 YEARS**  
**BACHEM**

What started out as a small laboratory has grown into a company that employs over 1,500 people at six locations worldwide

**2021**

**2015**



Acquisition of the American Peptide Company (APC), also specialized in the production of peptides and based in Vista, California

**2018**



Strategic decision to significantly expand the product range and to position Bachem in the future as a supplier in the development and production of oligonucleotides

**2020**



Rated by EcoVadis we received a Silver Rating, indicating that Bachem Group ranks in the top quarter of companies assessed for their Corporate Social Responsibility performance

“

It is an absolute delight to work and collaborate with Bachem. Bachem has a unique ability to develop, manufacture, and supply high-quality products that enable us to develop and commercialize clinically critical therapies. In addition, their entire global and cross functional team – from technical, regulatory, business development, to customer service – are dedicated to ensuring that we are well taken care of! It is safe to say that Bachem sets a high bar for quality and customer delight.”

**Nailesh A. Bhatt,**  
CEO



## PRODUCTS AND SERVICES

### We are a full-service provider

We are partnering to supply both smaller-scale academic and industrial research projects as well as big pharma on a global scale: Bachem offers the full range of TIDES API manufacturing, from small to medium to large scale. We adapt to our customers' needs. For clients who search a CMO partner for manufacturing of approved drugs, we offer a competitive package, taking advantage of the economy of scale we can realize.

For example, we have a new large-scale facility in Bubendorf, Switzerland and we will increase our offer several times by end of 2030 with our nearby new site in Sisslerfeld, Switzerland.

In addition, we have access to different GMP manufacturing sites, covering a wide range of scale for production.

Looking for a CDMO, our clients benefit from the development capacities and -capabilities at Bachem. Here, we support our clients alongside the clinical development process and contribute our part that the new medicines patients are waiting for can be approved rapidly.

Pushing the boundaries of complex API manufacturing – this is what we offer our clients as a trailblazing CDMO. With

innovative technologies and more than 50 years of experience, we go new ways in close collaborations with our customers to produce, quicker and with greener chemistries or, give synthetic access to new, difficult to produce drug substance molecules.

As projects evolve into the next phase, our dedicated team of experienced project managers coordinate activities to facilitate advancement through all scale-up processes right the way up to product registration and commercial production.

Currently, we support over 170 new chemical entities (NCEs) across projects at all developmental stages. We serve the pharmaceutical industry on a global level. On a regular basis, we manufacture well over 30 commercial peptide active pharmaceutical ingredients (APIs) in substantial quantities either in exclusive customer partnership or as multi-customer products. The annual production volumes per API range from several hundreds of grams on the low end to 100 kg and more on the high end. These products are registered worldwide, which speaks to the breadth and depth of our capabilities in terms of manufacturing, quality control (QC), quality assurance (QA), and regulatory affairs (RA).

Research & Specialties	CMC Development	Commercial API
Peptides and chemical compounds for research, early discovery, cosmetics and diagnostics	Supply of APIs and compounds for clinical research with peptides and oligonucleotides and related services	Manufacturing and supply of peptide and oligonucleotide APIs for approved drugs (patent-protected and generics)

**We provide products for research, clinical development and commercial application to support customers from academia, pharmaceutical and biotechnology companies worldwide.**

Not only are we constantly seeking to expand our portfolio for the existing peptide offering, but we are also applying our proven experience in the field of oligonucleotides. At Bachem, we see oligonucleotides as a novel and emerging class of compounds that can treat diseases that were previously considered untreatable. One of our key goals is to continue pioneering manufacturing technologies to help meet increasing demands due to larger patient populations and more indications.

With innovation as one of our strategic pillars, we constantly evaluate all our equipment and processes – often in collaboration with our partners. One example is Chemo-Enzymatic Peptide Synthesis (CEPS), where an enzyme – peptilgase - enables the synthesis of peptides (or better small proteins) with 150 to 200 amino acids residues. We always maintain the highest-quality standards, as well as a competitive edge that helps our partners maintain their market-leading positions, far beyond any exclusivity period.

#### **In close collaboration with our customers**

Every project is handled by a dedicated project manager who ensures that the timelines, budget, and overall goals and deliverables of the project are carefully monitored and met. All our project managers are scientifically minded and experienced in peptide- or oligonucleotide-based NCE development. Their knowledge is a huge asset to early-stage pharma and biotech companies that do not have an in-house development team. Our project manager will work hand in hand with you and guarantee that we meet all your needs and expectations.

We are fast and flexible, and we offer the necessary regulatory support.

#### **Meeting regulatory requirements**

More than 20% of our workforce is engaged in quality control and assurance, as well as in regulatory affairs. We provide 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 to commercialization.

Our 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. Almost weekly, our QA/RA team hosts a quality audit by customers from all over the world. These audits provide valuable input for our continuous quality improvement process, the success of which is reflected in our flawless inspection track record.

Successful inspections by national authorities confirm our high-quality standards and our compliance with the requirements for cGMP. Our GMP manufacturing network consists of facilities in Europe and in the US as outlined on page 20 and on our website. We manufacture peptides and oligonucleotides with excellent batch-to-batch reproducibility. This guarantees good quality and makes us a reliable partner for you.

## RESEARCH AND SPECIALTIES

### A large selection of modifications (N-, C-terminal and backbone) on offer:

- Acetylation, formylation, acylation
- Amidation
- Biotinylation
- Branched peptides
- Chromogenic and fluorogenic carboxypeptidase substrates
- Clickable peptides
- Conjugation to polymers, proteins and small molecules (including imaging agents)
- Cyclizations, head to tail and side chain (lactam bridge, thioether)
- Dye labeled peptides
- Hydrocarbon-stapled peptides
- Incorporation of fluorophores or chromophores

Bachem supports researchers around the world with our comprehensive portfolio of amino acid derivatives and peptides. We offer support at every step of the drug discovery process - from the first reaction in the lab to the large-scale manufacture of an established API (see overview on pages 12 and 13). In addition to an efficient and high-quality custom synthesis service for peptides and amino acid derivatives, we offer research-grade products listed on our website and available from our stock. Our distribution centers in the US and in Europe allow fast delivery worldwide. With an excellent track record in custom synthesis projects, we are a trusted partner and supplier of high-quality research chemicals for our clients.

### Custom-made peptides

We have the expertise you can rely on to produce your peptide needs, from simple peptides to the most complex and challenging molecules. Our chemists can prepare a wide range of compounds according to your specifications. By choosing us as your custom

synthesis partner, you will have access to our knowledge base over 50 years of experience in designing and synthesizing novel peptides and related organic compounds according to customer requirements. We can supply you with

- research to commercial scale quantities, from milligrams to kilograms to tons
- non-GMP to GMP quality
- short peptides to small synthetic proteins
- peptides to peptidomimetics to complex organic molecules

We are experts in producing fluorescently labeled peptides, peptides with multiple disulfide bridges, peptides containing stable isotopes, and long and difficult peptides. Other specialties include multi-step organic transformations and peptidomimetic molecules. Our standard analytical package typically includes mass spectrometric analysis and determination of purity (by RP-HPLC). Additional analytics are offered too.



Additional features are custom synthetic procedures, traceability and change control, as well as customized vialing of your product prior to delivery. If you need a custom peptide, please challenge us with your ideas and take advantage of our expertise! Our highly experienced custom synthesis teams with extensive knowledge in sequence design and modifications will deliver every peptide to the quality you need.

For urgent orders, we also offer an “Express Manufacturing” service. Your project is important to us, therefore our dedicated and experienced technical staff and our state-of-the-art facilities are ready to serve you at a moment’s notice.

#### Catalog peptides

Our catalog products are sold from stock in various pack sizes or in larger quantities. The majority of these are manufactured in St. Helens, UK or in Bubendorf, Switzerland. They can be purchased via the Product Catalog on our website <https://shop.bachem.com/>.

These products are mainly ordered by chemists, but also serve our customers involved in biological and medical research.

Catalog products may only be used for laboratory and research purposes. They must not be used in humans.

#### Fluorescently labeled peptides

Fluorescently labeled peptides are a powerful tool in the elucidation of biochemical processes. In order to support researchers worldwide, we offer a large amount of dye labelled products as part of our catalog portfolio. Additionally, our custom synthesis service offers labeling with various dyes as a standard modification. Our dye selector is the best way to browse the comprehensive range of fluorescently labelled products.

- Incorporation of D-enantiomers and unusual amino acids
- Introduction of C-terminal alcohol and aldehyde moieties
- Introduction of C-terminal ester and thioester groups
- Labeling with stable isotopes
- Labeling with Tide Fluor™ and Tide Quencher™
- Ligations
- Lipidation
- Maleimido peptides
- Methylation, alkylation
- Multiple disulfide bond formation
- Phosphorylation and sulfation
- Retro-inverso peptides
- Stabilizing modifications including PEGylation, N-methylated amino acids and reduced peptide bonds



**Automated microwave-assisted peptide synthesizers are a key of Bachem UK’s toolbox. Microwave technology enables a significant reduction in both amino acid coupling cycle times and solvent consumption compared to conventional synthesis.**

“ We have developed a great partnership with Bachem AG since 2017. Real-time professional communication with Bachem specialists provided us with critical support for our products and allowed us to develop novel diagnostics solutions. High level of service and customer centricity are just a few of the great qualities we experienced with Bachem team. R-Biopharm is looking forward to strengthening this collaboration and, without any doubt, recommends Bachem as a reliable and trustable partner!”

**Yanis Tolstov**  
Chief Medical Officer



### Cosmetic peptides

Thanks to our exclusive Molecular Hiving™ technology, cosmetic peptide manufacturing could be adapted to green manufacturing and processes free of CMR (carcinogenic, mutagenic or toxic for reproduction) substances. We can customize cosmetic peptide manufacturing to meet different needs in terms of scales and specifications. Increasing quality requirements and higher standards in documentation in the cosmetic industry can be met by using our Bachem Quality Grade, which has been established to meet our partners’ needs to comply with the current regulatory standards for cosmetic ingredients.

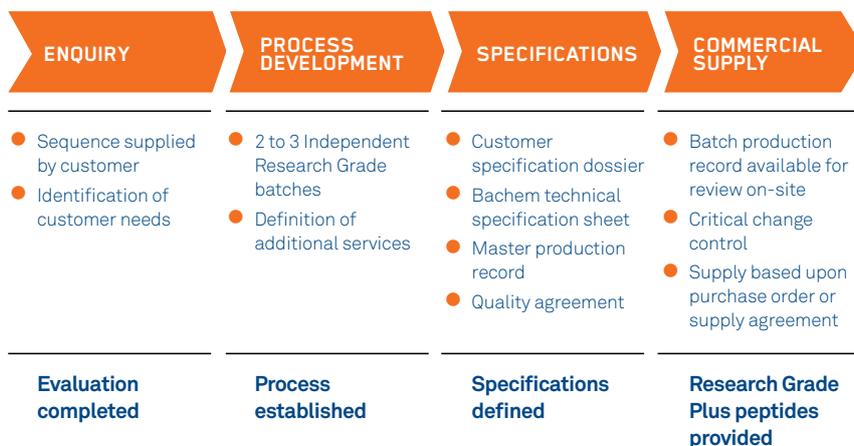
Together with our customers, we accomplish each of the demanding steps in a development project, finally leading to the creation of a successful cosmetic product.

### Peptides for in vitro diagnostics

Over the last 50+ years, we have been the leading partner for peptides for in vitro diagnostics. We assist our partners at every stage of product development, from early-stage R&D all the way through to commercialization. Together with our clients, we define the requirements (e.g., specifications, quality, dedicated equipment) and establish a robust manufacturing process for future commercial supply.

Our ISO 13485 certified production site in the UK is dedicated to the manufacturing of peptides as critical raw materials for medical devices using state-of-the-art equipment and offers a comprehensive range of services, including:

- Medical Device File
- Critical change control
- Dedicated equipment
- Customized vialing



**We assist our partners at every stage of product development, from early stage R&D all the way through to commercialization. Together with our clients, we define the requirements and establish a robust manufacturing process for future commercial supply.**

# CHEMISTRY, MANUFACTURING AND CONTROL OF NEW CHEMICAL ENTITIES

For bringing our partners' medical breakthroughs to market, we offer a full range of integrated services based on industry-leading talent, cutting-edge equipment and historical legacy. A clear plan for developing the Chemistry, Manufacturing and Control (CMC) of peptide and oligonucleotide drug substances affords our partners a risk-mitigated approach to any clinical and commercial milestones. Our interactions with regulatory authorities and sponsors around the world lend itself to a general plan (see pages 12-13), which is custom-tailored to every project.

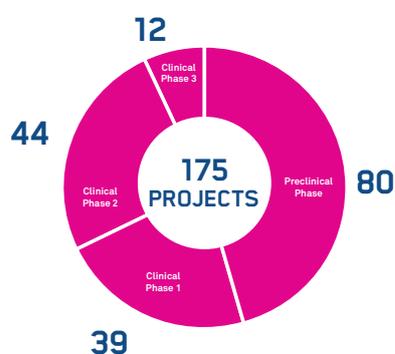
## Peptide new chemical entities

We produce research-grade peptides as well as GMP-grade material, from simple peptides to the most complex peptidomimetics or synthetic proteins. Our pipeline of customer peptide new chemical entities (NCE) projects includes both analytical services and process development for all phases of clinical trials and commercial supply. Our analytical services cover product characterization, development and validation of analytical methods, stability studies, and the identification of impurities.

## Oligonucleotide new chemical entities

With decades of experience in the development, production and regulatory support of APIs, we are a leading CDMO. We have a clear focus on the manufacture of TIDE molecules by expanding our manufacturing platform from peptides to oligonucleotides. As can be expected from any Bachem initiative, this expansion process is done meticulously, with a strong focus on innovation and quality. Our aim is to become the first-choice manufacturer for oligonucleotides.

Like peptides, oligonucleotide therapeutics require expert knowledge in solid-phase synthesis and protecting group chemistry. Downstream processing typically includes purification by chromatography, ultra/diafiltration techniques, precipitation and lyophilisation. The manufacture of peptide APIs follows the same basic principle and has been Bachem's core technology for decades.



**Bachem offers expertise in 175 peptides, oligonucleotides, small molecule or peptide conjugated NCEs projects that are in different phases of preclinical or clinical development.**

We have established long-term partnerships through being a reliable, independent and growing company. Through close collaboration, we enable our customers to bring unique and life-changing drug products to the market. Ultimately, everything we do is with the patient in mind, and we are very proud of this and are committed to playing our part in helping to transform patients' lives. Our partners can trust in our support and guidance throughout all stages from early development through clinical trials, commercialization and beyond.

## We offer:

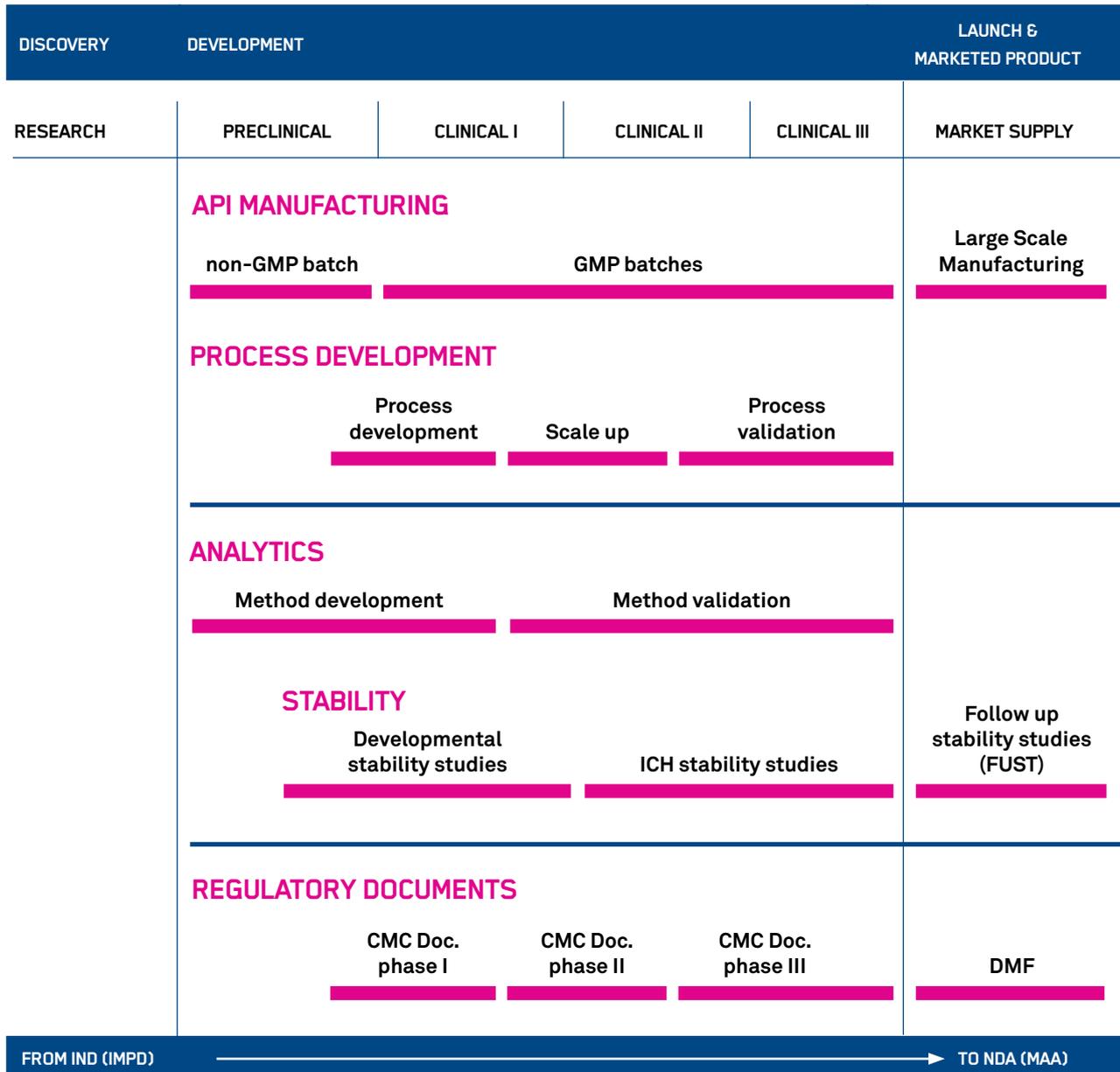
- Custom Manufacturing
- Manufacturing of peptide and small molecule APIs (GMP and non-GMP)
- Manufacturing of oligonucleotide APIs (GMP)
- Feasibility studies
- Process development and scale-up
- Process validation
- Quality Control
- Analytical method development
- Analytical method validation
- Forced degradation studies
- Indicative stability studies
- Stability studies according to the International Council for Harmonization (ICH)
- Follow-up stability testing
- Regulatory Support
- Preparation of CMC documentation
- Preparation and submission of DMFs
- Consulting and regulatory support

“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



# OUR SERVICES IN THE PROCESS OF DRUG DEVELOPMENT



PRECLINICAL	
<b>CHEMICAL DEVELOPMENT &amp; API SYNTHESIS</b>	<p><b>Feasibility study/manufacturing of non-GMP material</b></p> <ul style="list-style-type: none"> <li>• process development (synthesis and purification)</li> <li>• obtained material can be used for toxicology studies*, stress testing, formulation studies and initial analytical method development</li> <li>• technology transfer from non-GMP to GMP</li> </ul> <p><b>GMP manufacturing</b></p> <ul style="list-style-type: none"> <li>• starts at the end of the preclinical phase</li> <li>• GMP material is mandatory for phase I clinical trials</li> </ul>
<b>ANALYTICAL DEVELOPMENT STABILITY/ANALYTICS</b>	<p><b>HPLC method development</b></p> <p><b>Stress testing</b> (strongly recommended)</p> <ul style="list-style-type: none"> <li>• forced degradation, influence of temperature and moisture in the solid state</li> <li>• hygroscopicity, photostability</li> <li>• essential to get information for determining handling, shipment and storage conditions</li> <li>• prerequisite for the analytical method development of the HPLC purity method</li> </ul>
<b>REGULATORY DOCUMENTS</b>	<b>Preparation of CMC documentation to enter phase I</b>
CLINICAL PHASE I	
<b>MANUFACTURING</b>	<p><b>GMP manufacture</b></p> <ul style="list-style-type: none"> <li>• process development</li> <li>• scale-up</li> </ul>
<b>STABILITY</b>	<p><b>Developmental stability studies</b> (recommended)</p> <ul style="list-style-type: none"> <li>• custom protocols available</li> <li>• stability under different storage conditions at defined periods of time</li> </ul>
<b>ANALYTICS</b>	<p><b>Validation of analytical methods</b></p> <ul style="list-style-type: none"> <li>• purity and assay</li> </ul> <p><b>Characterization of reference standard</b></p> <ul style="list-style-type: none"> <li>• portioning of solid reference material into vials (individually labeled and sealed)</li> <li>• release by QA with Certificate of Analysis</li> <li>• storage under controlled conditions, regularly tested</li> </ul>
<b>REGULATORY DOCUMENTS</b>	<b>Preparation of CMC documentation to enter phase II</b>
CLINICAL PHASE II & III	
<b>MANUFACTURING</b>	<p><b>GMP manufacture</b></p> <ul style="list-style-type: none"> <li>• scale-up</li> </ul> <p><b>MBPR</b></p> <ul style="list-style-type: none"> <li>• manufacturing of confirmation batch according to master batch production record (MBPR)</li> </ul> <p><b>Process validation</b></p> <ul style="list-style-type: none"> <li>• manufacturing of 3 validation batches (demonstrate reproducibility and consistency of process)</li> <li>• batch size should represent batch size of post-market approval</li> <li>• validated analytical methods are prerequisite for the process validation</li> </ul>
<b>STABILITY</b>	<p><b>ICH stability studies</b></p> <ul style="list-style-type: none"> <li>• at least 6 months data required for DMF</li> </ul>
<b>ANALYTICS</b>	<p><b>Validation of analytical methods</b></p> <ul style="list-style-type: none"> <li>• validation according to ICH guideline Q2(R1)</li> <li>• e.g., peptide content, purity, water content, acetate content, residual solvents, bioburden</li> <li>• must be completed prior to release testing of the validation batches</li> </ul>
<b>REGULATORY DOCUMENTS</b>	<p><b>Preparation of CMC documentation for phase III</b></p> <p><b>Preparation of DMF</b></p> <ul style="list-style-type: none"> <li>• at least 6 months data of ICH stability study required</li> <li>• open part of CMC/DMF provided to customer, closed part sent directly to authorities</li> </ul>

## COMMERCIAL ACTIVE PHARMACEUTICAL INGREDIENTS

We are the leading CDMO for the manufacturing of peptide and oligonucleotide active pharmaceutical ingredients (APIs). The development and manufacturing of oligonucleotide-based API is applicable to large-scale production and has strong synergies with peptides.

### Commercial generics

You can choose from our portfolio of generic APIs, which are produced in annual quantities of up to hundreds of kilograms and tons for commercial use. We have multi-kilogram scale cGMP peptide manufacturing facilities in Europe and in the US, where we produce generic APIs for customers around the world. All cGMP manufacturing sites are inspected by the United States Food and Drug Administration (FDA) and national authorities. For more details regarding our sites, please read the chapter starting at page 20 or visit our website.

We provide technical and regulatory support tailored to your needs. Our partners trust in the consistent high-quality of our generic APIs for the manufacturing of their drug products. Among our generic API portfolio, more than 80 Bachem Drug Master Files (DMF) have been submitted and approved around the globe. This includes DMFs at the FDA, European authorities and authorities around the world. Our regulatory dossiers do not only contain information on the manufacturing process, but also detailed information on our facilities used in the manufacturing, as well as the processing, packaging, and storing of APIs. All this comprehensive information is used to support Investigational New Drug Applications (IND), New Drug Applications (NDA), and Abbreviated New Drug Applications (ANDA).

### Proving the sameness of a generic drug

In 2021, the FDA released industry guidance on ANDAs for certain highly purified peptide drug products. Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, lower-cost alternative to the brand-name drug it references. Abbreviated drug applications require no new preclinical and clinical studies; instead, a generic applicant must scientifically demonstrate that its product is bioequivalent to the bio-originator. This includes showing that the primary and secondary sequence of the generic and the original drug are identical, that their oligomer and aggregation state are the same, and that the biological activity remains unchanged. For all these analyses, we use a range of methods to provide substantial proof on the sameness of a generic drug.

**The cGMP site in Torrance, California is the center of excellence of the Bachem Americas organization for the development of peptide new chemical entities by solid phase peptide synthesis. ►**



## GENERIC PEPTIDE APIS

Generic API	CEP/DMF	Application	Site
Atosiban	DMF	Reproductive Medicine	CH
Bivalirudin	DMF	Cardiovascular Disease	CH
Buserelin	DMF	Oncology, Reproductive Medicine	CH
Calcitonin	DMF	Paget's disease, Hypercalcemia and Osteoporosis	USA
Glucagon	DMF	Diabetes Mellitus	CH
Gonadorelin Acetate	CEP,DMF	Oncology, Reproductive Medicine	CH
Goserelin Acetate	CEP,DMF	Oncology, Reproductive Medicine	CH
Icatibant Acetate	DMF	Hereditary Angioedema	CH
Lanreotide	DMF	Oncology	USA
Leuprolide Acetate	CEP,DMF	Oncology	CH
Octreotide Acetate	CEP,DMF	Oncology	CH
Somatostatin	CEP	Gastritis	CH
Teriparatide Acetate / pTH (1-34) (human)	DMF	Osteoporosis	USA
Tetracosactide	DMF	Oncology, Diagnostics	CH
Triptorelin Acetate	DMF	Oncology, Reproductive Medicine	CH
Triptorelin Pamoate	DMF	Oncology, Reproductive Medicine	CH
(Arg <sup>8</sup> )-Vasopressin	DMF	Hypotension after shock	USA
Liraglutide*	DMF	Diabetes Mellitus	USA,CH
Semaglutide*	DMF	Diabetes Mellitus	CH

## SMALL MOLECULE APIS

Generic API	CEP/DMF	Application	Site
Carbidopa	CEP,DMF	Epilepsy and Parkinson's Disease	CH
Etomidate	CEP,DMF	Sedatives and Anesthetics	CH
Propofol	CEP,DMF	Sedatives and Anesthetics	CH

DMF = Drug Master File, CEP = Certification of Suitability

## PIPELINE

Generic API	Application
Glepaglutide*	Short Bowel Syndrome & others
Setmelanotide*	Obesity

Please note: Some products may be restricted in certain countries.

\* Bachem provides this product solely for uses within the scope of any statute or law providing for an immunity, exemption, or exception to patent infringement ("Exempted Uses"), including but not limited to 35 U.S.C. § 271(e)(1) in the United States, the Bolar type exemption in Europe, and any corresponding exception to patent infringement in any other country. It is the sole responsibility of the purchaser or user of this product, and the purchaser or user of this product agrees to engage only in such Exempted Uses, and to comply with all applicable intellectual property laws and/or regulations. The purchaser of this product agrees to indemnify Bachem against all claims in connection with the performance of the respective commercial agreement (e.g., supply agreement) and possible infringements of intellectual property rights.

### Commercial new chemical entities

Throughout the world, about 80 peptide APIs are used in commercial drugs for the treatment of diverse diseases. With confidentiality agreements in place, we are at liberty to say that we manufacture almost one third of those peptide APIs. Therefore, we hold the largest proportion of commercially available peptide APIs. Regarding oligonucleotides, more than ten oligonucleotide APIs are already used as commercial drugs for the treatment of diverse diseases, and we produce several of these commercially available oligonucleotide APIs.

The new ANDA guidelines open new opportunities to offer synthetic peptides as generic APIs. In our pipeline (page 16), you see six peptide-based generic APIs. However, please feel free to reach out to us if you are interested in other peptide-based generic APIs not listed there. With our capabilities to meet the FDA ANDA guideline, we are the leading manufacturer for synthetic peptide APIs.

We have established long-term contracts with important industrial partners. Examples of our long-term supply agreements on generic APIs are Goserelin to AstraZeneca (GB) and Triptorelin to Debiopharm (CH). You will find examples of peptide and small molecule generic APIs available in our portfolio or in our pipeline on our website and in the tables below.



**Customers from all over the world source generic APIs from Bachem.**

### Technical and regulatory support:

We enable clients to meet the requirements of the authorities by providing comprehensive technical and regulatory information for filing. Our service includes the compilation of technical and regulatory documents and we offer support for regulatory requests. Through our expertise, we enable clients to be the first to file their generic drugs in a highly competitive market.



[www.bachem.com](http://www.bachem.com)



I truly feel comfortable selecting Bachem as API partner for our complex formulation need. Bachem always comes with innovative research which make them stand tall in this highly competitive environment. Working with Bachem, I don't recollect any points which were not resolved, and when we have to go open ended for our ANDA submission, their customer service support is indeed superb. I can say that Bachem knows science, Bachem knows regulatory requirements, Bachem knows service which gives ultimate peace of mind to us, and we are always confident that we tied knot with perfect API partner."

**Kushal Shah**  
Manager,



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



## INNOVATING FOR BETTER MANUFACTURING

We drive innovation to bring new solutions for more sustainable and efficient manufacturing processes. Thus, we are supporting customers in achieving short time-to-market for their products and in jointly achieving high sustainability. Please see the following examples of implementing innovative technologies for each step of making peptide or oligonucleotide APIs: synthesis, purification and isolation.

### Automation for faster syntheses

We establish industry standards in innovative and efficient large-scale API manufacturing processes while constantly improving our high degree of automation of SPPS. More automation leads to shorter production cycles, more consistent product quality, higher effectivity and higher precision of documentation. As an example, we have set up a fully automated large-scale SPPS system using a robotic arm for the activation step. The automated system eliminates manual operations and executes repetitive tasks such as carrying vessels, loading and unloading amino acids into the reactor and washing steps. Furthermore, the synthesizer is seamlessly integrated in a manufacturing execution system enabling electronic batch records and analysis of all data collected during synthesis. Fast and efficient responses to any variability in the production process are thus possible.

### Replacing and reducing solvents

We aim to redesign our processes to minimize the use and generation of hazardous substances and their environmental impact. That's why we have implemented new solutions for greener peptide synthesis by replacing potential harmful solvents whenever possible. Jitsubo's Molecular Hiving™ technology is one example of how we are already achieving this. It is a liquid phase peptide synthesis using a hydrophobic tag onto which the peptide is assembled in the same way as onto the resin in SPPS. Solvents and reagents classified as carcinogenic, mutagenic or toxic for reproduction can be entirely avoided. Many

washing and filtration steps are not necessary with this technology, resulting in a reduction of organic solvents in the production of peptides by up to 60%.

### More efficient purification

Purification is not only paramount for achieving a high purity but also a major determinant for the productivity of the whole manufacturing process of APIs. The innovative Multicolumn Counter-current Solvent Gradient Purification (MCSGP) technology represents great progress in the downstream process for peptide and oligonucleotide manufacturing; compared to single-column batch purification, solvent consumption is typically decreased over 30%, thus contributing to a higher level of sustainability.

Whereas with batch processes achieving the target purity often goes with a decrease of yield and productivity, MCSGP provides high yields of product without negative impact on purity. The automated system runs 24/7 and has potential for additional reductions in cycle time of up to 70%. More details are given on our website.

### Isolation with patented lyophilization-trays

Lyophilization of bulk material is a common step in improving the stability and handling of APIs. Innovations in the lyophilization process mean key improvements for API manufacturing. We have developed our own closed lyophilization tray made from stainless steel, a material well established in API production and not prone to issues with leachables. Our new technology fits in perfectly with our existing equipment and allows for the lyophilization of high volumes of GMP material. The loading and unloading are easy and convenient. These patented lyophilization-trays allow for a constant monitoring of temperature during the lyophilization of products. With these unique closed lyophilization trays, we can handle highly active peptides and oligonucleotides down to Occupational Exposure Band (OEB) levels of 100 ng / m<sup>3</sup> safely.

**With our patented closed lyophilization trays developed in-house, we handle high volumes safely with a strict containment protocol. ►**



## EXPERTISE AND EQUIPMENT AT OUR SITES

We manufacture APIs with excellent batch-to-batch reproducibility. This guarantees consistent high quality and makes us a reliable partner for you. Our facilities are located in Switzerland, the UK, Japan and the USA. All cGMP sites are inspected by the FDA and national authorities, such as the Swissmedic.



**We are close to our customers with local presence in Asia, Europe and America and manufacturing sites in the US and in Europe.**

### Large-scale production of peptides and oligonucleotides



**Bachem AG, Switzerland, Bubendorf**

Our headquarters has the largest GMP production facility for peptides and oligonucleotides with capacities for large-volume production of commercial APIs and possible batch sizes over 15 kg. Here we also produce selected research and specialty products and manage products and services for Europe, Africa, India and the Middle East. In fact, most of our research facilities and experts involved in a wide range of services for our customers are located here: that means that our cGMP process development and manufacturing, project management, regulatory support and supply chain management are all based here. For peptide production, we use SPPS,

LPPS and the Molecular Hiving™ technology: the latter is advantageous for producing shorter peptides (up to 10-15 amino acids) which are required in larger quantities with up to 10-20 kg batch size. In Bubendorf, we have a record of producing luteinizing hormone-releasing hormone (LHRH) agonists like goserelin, leuprolide or triptorelin and generic APIs such as liraglutide\* and semaglutide\*.

The analytical capabilities for peptides and oligonucleotides at this site include high and ultra-high performance liquid chromatography (HPLC and UPLC) high-resolution mass spectrometry (MS), electrospray ionization MS (ESI MS) and matrix-assisted laser desorption ionization-time of flight mass spectrometry (MALDI-TOF MS).

To strengthen our position as a leading center of excellence, we are expanding our production capacities with the world's most modern facility for producing peptides and oligonucleotides by 2024. The site is licensed for the manufacture of APIs for the Japanese market.

### Medium-range production of APIs



**Bachem Americas Inc., Vista, California, US**

This site is a medium-to-large-volume cGMP manufacturing facility for commercial API, peptide NCEs and intermediates. The necessary infrastructure has been installed to support a full array of large-scale manufacturing capabilities for SPPS and LPPS. Here we produce APIs like liraglutide\*. The site is licensed for the manufacture of APIs for the Japanese market.

### Small-range production of APIs



**Bachem Americas Inc., Torrance, California, US**

The cGMP site is the center of excellence of the Bachem Americas organization for the development of peptide NCEs by SPPS. Furthermore, here we have the in-depth CMC knowledge and expertise needed to successfully achieve commercialization. This site delivers efficient peptide API development and custom manufacturing on a small to medium scale with an annual capacity of tens of kilograms. Here we produce peptides such as vasopressin, desmopressin, exenatide and vasoactive intestinal peptide (VIP). The site also constitutes a center of excellence for the

characterization of peptidic APIs for the US organization. The analytical capabilities for peptide characterization include HPLC and UPLC equipped with UV and Corona CAD detection, high-resolution MS, and multi angle light scattering (MALS). The site is licensed for the manufacture of APIs for the Japanese market.

### Center of competence for small molecules



**Bachem SA, Vionnaz, Switzerland**

At this GMP site we produce small organic molecules, short peptides in large quantities, and amino acid derivatives for the peptide production on other sites. There is broad expertise in process development, amino acid chemistry, chiral synthesis, metal catalysis, hydrogenations, heterocyclic chemistry, oxidations and reductions using various reagents, enzymatic reactions, high-pressure reactions, pyrogen-free production and high temperature reactions as well as continuous flow technology. The annual capacity to produce APIs is over 200 tons. Here we produce the anesthetic propofol, of which we are the world leader. Thanks to innovative technologies and highly automated equipment, our manufacturing process is sustainable and solvent-free. The 2007 decision by the product's inventor to purchase the substance from us was another major milestone. Being told that our manufacturing process was vastly better than the original was one of the greatest compliments we could receive. The site is licensed for the manufacture of APIs for the Japanese market as well.

### Preferred partner for diagnostics



**Bachem UK Ltd., St. Helens, England, Europe**

At the UK site, our ISO13485 certified center of excellence for research chemicals, we manufacture over 1,500 products ranging from milligram to gram quantities annually via SPPS. We are continuously developing tools to improve the efficiency, robustness and performance of our processes, reduce timelines, and manage increasing quality standards required by our customers. The site has been ISO13485 certified for the manufacture of peptides used as raw materials in medical devices since 2017 and specializes in products for use in in vitro diagnostics (IVD) with a full range of associated services. To serve the growing demand for customized peptides aliquots, particularly for IVD peptide sets, we have an automated powder dispensing system to facilitate our efforts in improving the speed of the aliquoting pro-

cess for all finished goods. This upgrade reduces delivery times of peptide sets without compromising weighing accuracy, all while ensuring full traceability and eliminating risk of transcription errors.

### Service for our partners in the Asia Pacific region



**Bachem Japan K.K., Tokyo, Asia**

The office in Tokyo is our gateway to providing excellent service to our partners in the Asia Pacific region. With a highly motivated local team, we engage with the Asia Pacific market more directly and serve our partners on site. The local sales organization focuses primarily on the API business such as generic APIs, peptides and oligonucleotide NCEs. It is important for us to be as close to our customers as possible in terms of language and culture, as well as being physically present.

## OUR COMMITMENT TO SUSTAINABILITY

At Bachem, we are committed to sustainability by taking responsibility for our employees, the society, and the environment. We take responsibility for future generations through careful handling of resources and avoiding environmental risks. This commitment is reflected in our corporate social responsibility (CSR) strategy, which is aligned with United Nations sustainable development goals. Our CSR goals and measures are updated on an annual basis. Thus, we have excellent environmental figures with a comparatively low environmental impact, as well as a level of resource consumption relative to economic output. After participation in the Responsible Care® program for more than 20 years, we introduced a new program for CSR in 2020 and received an EcoVadis Silver Rating. In 2022, we got a EcoVadis Platinum Rating. This indicates that we are one of the top 1% of EcoVadis' list of most sustainable enterprises. More information on this is on our website.

With our commitment to sustainability, we demonstrate that we are not only a leader in the production of peptides and oligonucleotides for research, clinical development, and commercial application, but also in delivering on our broader promise to meet the highest standards possible in corporate social responsibility for a better world tomorrow.

## FOR MORE INFORMATION: OUR KNOWLEDGE CENTER

We offer a wide range of documentation and practical information on our various products and services in the knowledge center on our website (<https://www.bachem.com/knowledge-center>). Here you will find:



### Brochures

Our brochures present peptides for research and products for peptide synthesis, organized by specific topics or applications. You can also find information on our offer of generic APIs and related services to the pharmaceutical and biotechnology industries.



### Technical Notes

Take advantage of lots of useful facts on our products, such as technical notes on care and handling of amyloid peptides, solubilization of peptides, or peptide-based enzyme substrates linked to chromophores or fluorophores.



### Flyers

Our flyers offer insight into selected groups of products in peptide and oligonucleotide research. They are each dedicated to a particular class or family of products and contain regularly updated product lists. The scientific description can range from a brief product summary to in-depth information.



### Frequently Asked Questions

This section provides you with answers to numerous questions you may have concerning the world of peptides and oligonucleotides. Here you will also find answers to your questions regarding conditions of sales and the delivery of our products.



### White Papers

We offer complimentary white papers on innovative products, services or processes in peptide and oligonucleotide research, as well as technical information on peptide synthesis. They are the first step in your search for insightful scientific or technical information towards a certain field or research topic.



### Peptide calculator

Our peptide calculator is a convenient tool for scientists as a molecular weight peptide calculator, which can be used as an amino acid calculator as well. Additionally, the tool includes a hydrophobicity calculator, a net charge calculator at different pH, isoelectric point calculator and the hydrophilicity ratio.



### Posters

Download useful overview posters like our Chart of Unusual Amino Acids, Poster of Di- and Tripeptides or Periodic Chart of Amino Acids and find very interesting scientific posters from our participation at various meetings.



### Peptide content calculator

The peptide content is the amount of pure peptide (net weight) in a product. The peptide content calculator uses the analytical data documented in the respective analytical data sheet for our products.



### Webinars

Benefit from the knowledge of our experts and our collaboration partners. Here you will find links to access the recordings. You can also join our webinars and participate in live discussions; upcoming webinars are listed in our calendar.



### Oligonucleotide calculator

Our oligonucleotide calculator will provide the molecular weight of the desired oligonucleotide.



### Publications

Find the scientific articles where our scientists have reported on our contributions to innovative and sustainable peptide chemistry and technology.



### Glossary

Find explanations for abbreviations for peptides, biochemicals, solvents and protection groups involved in peptide synthesis.

# BACHEM

## GLOBAL BUSINESS

Bachem facilities are located in Switzerland, the UK, and in the US. All cGMP manufacturing sites are inspected by the US-FDA and national authorities.



### About Bachem:

Bachem is a leading, innovation-driven company specializing in the development and manufacture of peptides and oligonucleotides. The company, which has over 50 years of experience and expertise, provides products for research, clinical development, and commercial application to pharmaceutical and biotechnology companies worldwide and offers a comprehensive range of services. Bachem operates internationally with headquarters in Switzerland and locations in Europe, the US and Asia. The company is listed on the SIX Swiss Exchange. For further information, see [www.bachem.com](http://www.bachem.com).



## 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](mailto:sales.us@bachem.com)

### Asia Pacific

**Bachem Japan K.K.**  
Tel. +81 3 6661 0774  
[sales.jp@bachem.com](mailto:sales.jp@bachem.com)

### EMEA and India

**Bachem AG**  
Tel. +41 58 595 2020  
[sales.ch@bachem.com](mailto:sales.ch@bachem.com)

Visit our website [www.bachem.com](http://www.bachem.com)  
or shop online [shop.bachem.com](http://shop.bachem.com)



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