piCHEM

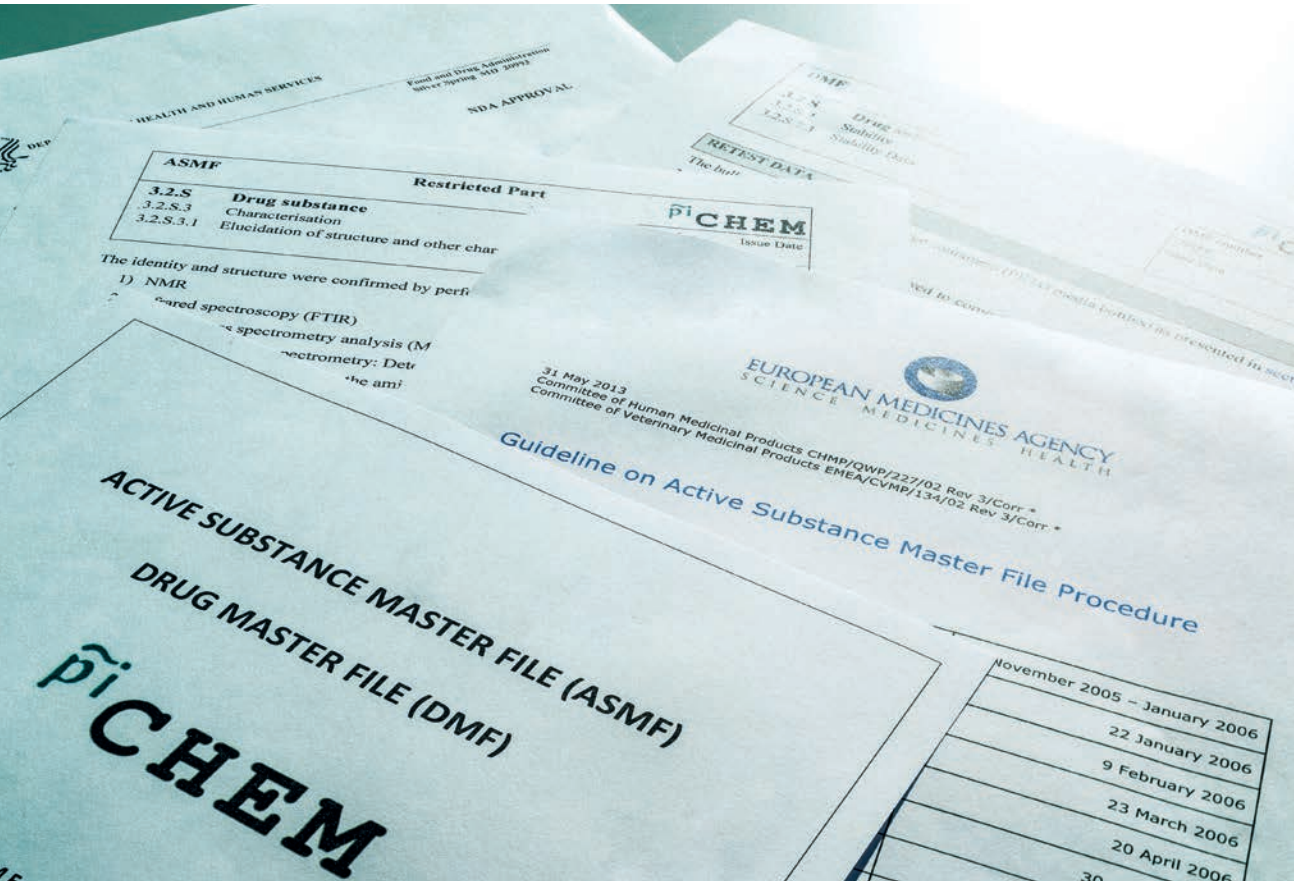
Regulatory Affairs Service

piCHEM accompanies your drug development in every phase of an application from pre-IND/IMPD meetings to the final marketing authorization.

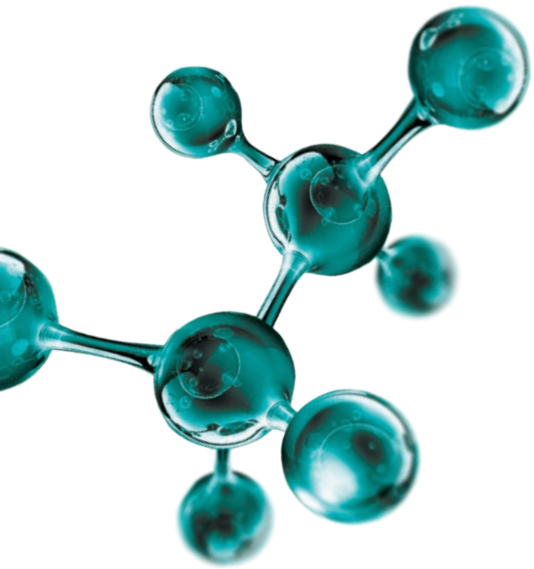
We provide proven experience in all submission procedures (CP, DCP, MRP, national procedures) to national and international authorities to support your application process.

In compliance with relevant regulations and laws (ICH, USP, Guidance for Industry, Ph. Eur., PIC/S) the regulatory support includes:

- Strategy development and guidance throughout the complete authorization process
- Preparation of CMC/ Quality documentation for IND/IMPDs (phase I to III)
- Filing of DMF/ASMF in eCTD format for NDA/MAA
- Submission of regulatory documents to the FDA, EMA and national authorities according to regulatory requirements (e.g. CESP portal)
- Provision of response documents
- Lifecycle management (dossier maintenance, PQRs, annual reports, post-approval changes and variations)



piCHEM



piCHEM

Peptides for Nuclear Medicine

piCHEM develops and provides a wide range of molecules which are utilised as precursors for radiopharmaceuticals.

Labeled precursors are used for:

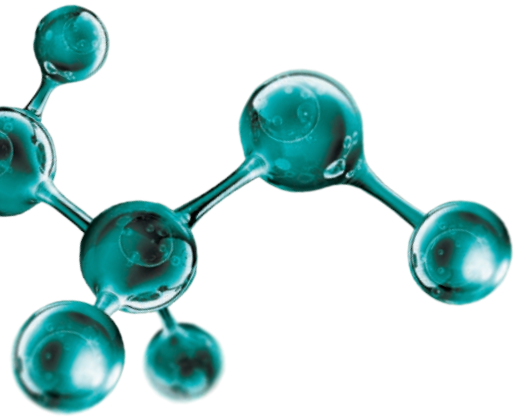
- Targeted tumor diagnosis and therapy
- Non invasive examinations in oncology
- Tumor tracers for receptor scintigraphy and therapy (PET)
- Development of "cold test kits"
- Development of new targeting molecules in close collaboration with radiopharmacy departments and nuclear medicine centers

piCHEM provides all products in R&D or GMP-quality!

Most products are available on stock as bulk or in different aliquotations. Individual peptides will be produced according to our customers´ requirements and needs.

Request for a quote at www.pichem.at!

piCHEM



piCHEM

Custom Peptide Synthesis

piCHEM provides peptides of any length and complexity. Our experienced peptide chemists and our well trained team provide you with full support in the design of your peptides and complex organic molecules.

Synthetic peptides are tailor-made to client´s needs. Our R&D department provides a broad range of different strategies from conventional synthesis in solution to solid phase synthesis methods using –tBOC or –FMOC strategies. Fully automatic peptide synthesizers or large scale batch reactors are available allowing flexibility in production scales for batch sizes from milligram to several hundred gram quantities.

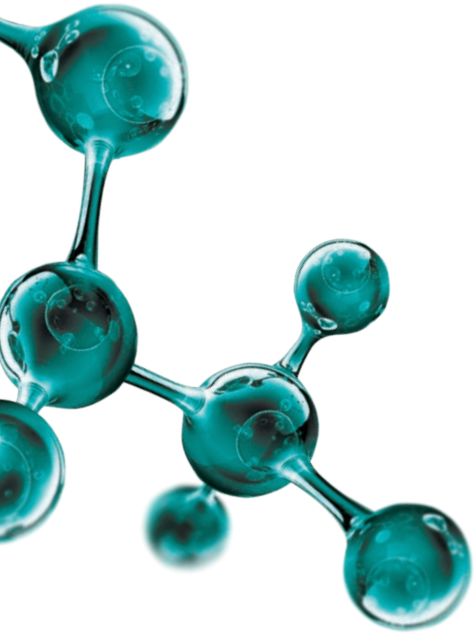
Selection of Modifications

- Incorporation of unnatural aminoacids
- Biotinylation
- Phosphorylation
- Fluorescent labeling
- Dye labeling
- Chelator labeling
- Carrier protein conjugation
- Stable isotope labeling
- C-N cyclisation
- Disulfide bridge formation
- Click chemistry
- Glycosylation

...and many more

Request for a quote for your peptide project at www.pichem.at.

piCHEM



piCHEM

Stability Studies

As a supportive service **piCHEM** offers stability studies according to ICH guidelines for APIs and drug products including long-term stability testing, accelerated stability testing and forced degradation testing/stress tests. The services are performed under GMP conditions. The design of the studies is based on individual needs and agreed by the customer prior to start. Analytical measurements are performed using appropriate, robust methods to detect new degradation products. Data are reported to the customer in interim and final reports and are implemented in regulatory affairs dossiers where required.
All incubation areas/ stability chambers (-20°C, 5°C and 25°C) are equipped with a 24/7 alarm system and an emergency backup generator.

Analytical Method Validation

The efficient development and validation of analytical methods are critical elements in the development of APIs and drug products. According to the stage of development of products a required analytical method validation is provided. **piCHEM** maintains an appropriate level of expertise to give step-by-step support. Analytical method validation is performed following ICH guidelines to guarantee analytical methods acceptable for their intended use. Reports are supplied to the customer and submitted to the authorities if applicable.

piCHEM

Analytical Support

piCHEM provides comprehensive analytical support of high quality throughout the whole lifecycle of your products:

- Development of analytical methods for new products
- Characterisation of new entities
- Quality control of incoming goods
- Routine release analytics
- Stability studies according to ICH
- Analytical method validation according to stage of development

Our modern laboratories are equipped with a broad set of state-of-the-art equipment, operate to GMP standards and offer a comprehensive range of testing capability:

- Peptide purity by HPLC
- Assay determination (HPLC)
- Mass determination
- Amino acid and peptide content determination
- Determination of enantiomeric purity
- Determination of counter ions
- Determination of residual water
- Determination of residual solvents
- FTIR spectroscopy
- Photometry
- Determination of specific optical rotation
- Electrophoresis
- Protein content determination
- Elemental analysis
- Photometry
- Heavy metals determination
- MS-MS sequencing
- NMR analyses
- Determination of bacterial endotoxins
- Determination of microbial contamination/ bioburden
- Sterility testing
- Determination of osmolality
- Determination of subvisible particles

piCHEM The Peptide Company Parkring 3, 8074 Raaba-Grambach, Austria Phone +43 316 68 17 11-0 www.pichem.at

piCHEM

GMP Production

In 2017 **piCHEM** opened a brand new production facility providing 1.200m² edge-cutting laboratory and production space as well as adequate storage rooms. Peptides are manufactured in compliance with ICH guidelines and according to applicable laws and regulations. The production facilities are inspected and approved by the national authorities and the US FDA.

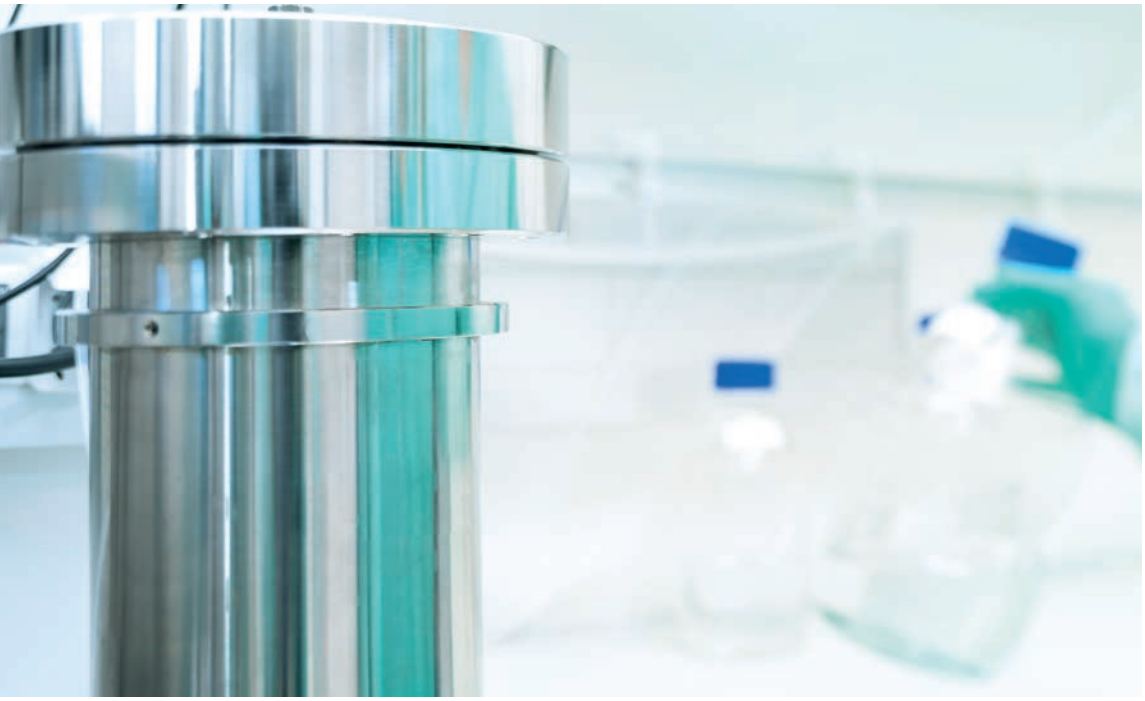
Our pharmaceutical contract manufacturing department supports your drug development project through all stages of clinical trials. **piCHEM** conducts GMP manufacturing of APIs from milligram to several hundred gram scale.

Peptides

piCHEM offers peptide synthesis according to GMP with applicable techniques in peptide chemistry. Depending on the structure, quantity or special client requirements, different strategies are available, from **conventional synthesis** in solution to **solid phase synthesis** methods (SPPS).

Reversed phase chromatography and ion exchange chromatography are applied as standard purification procedures for synthetic peptides.

Peptides are available as lyophilisate in bulk or in bulk aliquots. For final manufacturing steps, cleanrooms in class D/C are available.



piCHEM

Peptide-Protein Conjugates

piCHEM has broad expertise in conjugation of peptides to carrier proteins like KLH, CRM-197 or BSA under GMP conditions. Conjugation manufacturing and purification processes strongly depend on the characteristics of the employed peptide and are designed individually.
Peptide protein conjugates are manufactured in cleanrooms class D/C and are supplied as liquid or lyophilised bulk.

Fill & Finish Services

As a value-added service **piCHEM** provides aseptic fill & finish services in cooperation with qualified partners.

Supporting GMP Services

Supporting services include project management, process scale up and validation activities, analytical method development and validation, stability studies, generation of reference materials as well as regulatory services.

Products supplied are released by a qualified person (QP) in full compliance with the EU GMP requirements (Eudralex Vol. 4 – Guidelines for good manufacturing practices for medicinal products for human and veterinary use).

Request for a quote for your peptide project at www.pichem.at.

piCHEM The Peptide Company Parkring 3, 8074 Raaba-Grambach, Austria Phone +43 316 68 17 11-0 www.pichem.at