



Your Chemistry For Life

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With its core competence for the chemical assembly of peptides, **Peptisyntha** is eager to stay at the leading edge of the latest innovation and development opportunities in the medical world. Hence, beyond its cGMP API businesses, Peptisyntha conducts pioneering ventures based on the unique properties of peptides.

In tandem with its sister company **Girindus**, a leading company in the chemical assembly of nucleotides, Peptisyntha covers access to both key chemistries of life – those issued from genomics and proteomics.

Peptisyntha and Girindus are members of the Solvay group.

Peptisyntha, a company of the Solvay group, is a leading manufacturer of peptides (peptide APIs) and peptidomimetics.

Through more than 20 years of experience in peptide manufacturing Peptisyntha has developed and demonstrated a **unique set of expertise in the design of peptide manufacturing processes and in the cGMP production** of clinical and commercial peptide APIs.

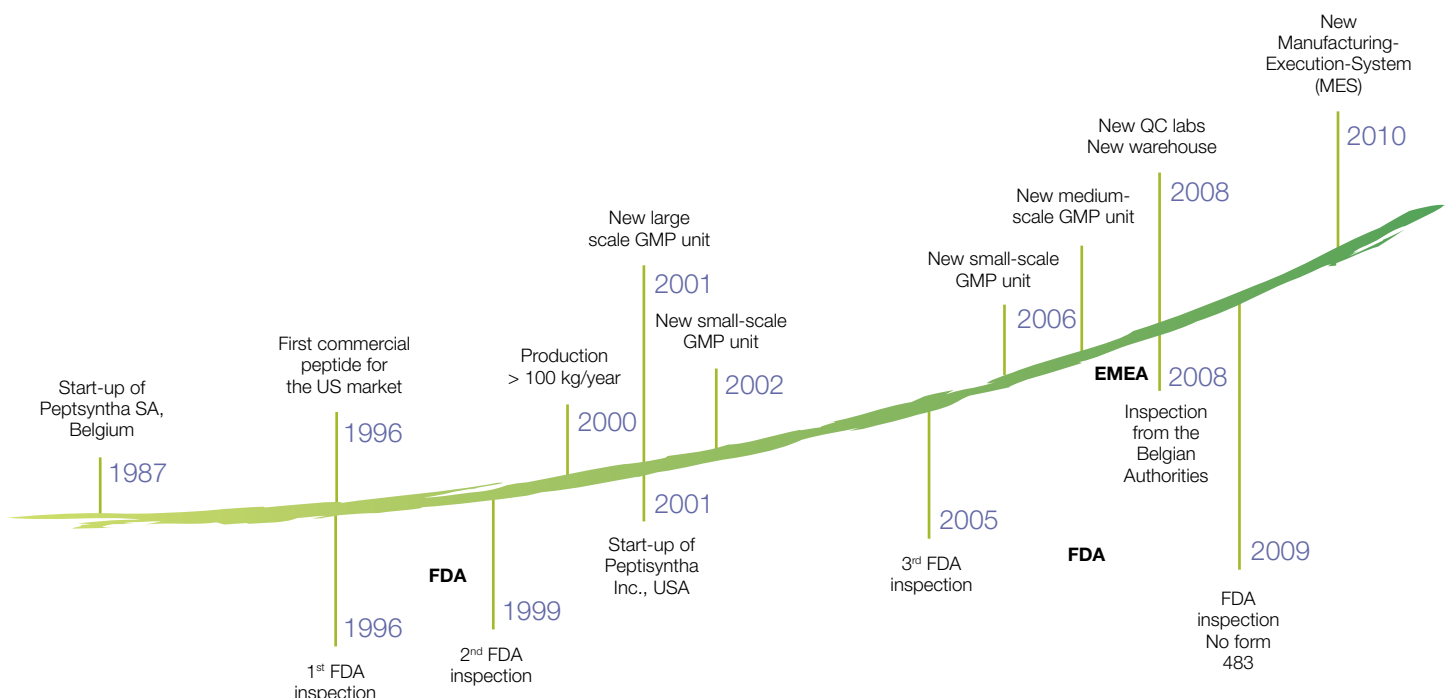
The Peptisyntha approach is to design the **most efficient process for your peptide API** project applying the best suited manufacturing strategy from

- Solid Phase Peptide Synthesis (SPPS)
- Liquid Phase Peptide Synthesis (LPPS)
- Hybrid Strategies (SPPS-LPPS)

Both of our sites in Europe and the USA are characterized by a strong and long-term commitment to the highest standards. These ambitions are reflected by a series of **successful FDA and EMEA inspections.**

Furthermore, outstanding quality assurance and regulatory support as well as effective project management underline our dedication to our customers. Our capabilities enable us to meet your project needs and to serve you with **innovation, performance, and dedication.**

Peptisyntha is a wholly owned company of SOLVAY, an international industrial group active in chemistry with 19,000 employees in 50 countries. It offers a broad range of products and solutions that contribute to improving quality of life.





Innovation

Lead optimization to commercial cGMP

Peptisyntha offers a strong track record in providing **scale up under full cGMP conditions** and is proud of having successfully developed numerous peptide manufacturing processes and supplied several hundreds of kg of peptides with **challenging sequences**.

Our scale up equipment is especially designed for consistent and robust transitions from small scale to large scale manufacture. We provide particular expertise in:

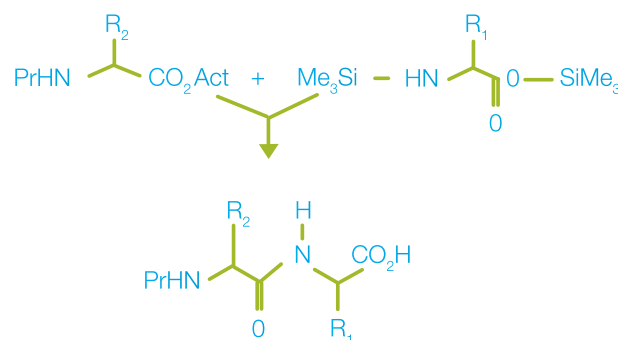
- Complex peptides and peptidomimetics
- Peptide-conjugations (PEGs, proteins, lipids, carbohydrates)
- Cyclic peptides and peptides with multiple disulfide bridges
- Peptides <12 AA without HPLC purification
- Arginine-rich peptides



Excellence in cost effective processes

Over the last 20 years Peptisyntha has developed **a wide range of solutions** in order to respond swiftly and cost effectively to the most challenging peptide projects – with unique technologies that make the difference.

- Silylation Technology
- Arginine-rich peptides
- Phoc-AA (Phenyl-oxy-carbonyl) in peptide synthesis
- Coupling UNCAs (Unrethan-N-Carboxy-Anhydrides) with free amino acid powder
- Peptide-Resin transesterification instead of acidic cleavage
- Synthesis of short peptides without HPLC purification
- Peptide isolation and purification
- Synthesis of long peptides





SPPS, LPPS or Hybrid?

The best approach for your project.

Solid phase or liquid phase peptide synthesis or hybrid strategy -
The most efficient process will be designed for your API project.

One of the key advantages Peptisyntha offers is its capability and proven experience to manufacture large volumes of peptide APIs by solid phase synthesis, liquid phase synthesis and hybrid solid-liquid strategies.

SPPS requires careful sequence analysis to determine critical coupling steps.

We possess extensive experience both in Fmoc and Boc strategies and have successfully produced peptides having more than 100 amino acids.

LPPS. With our unique expertise in liquid phase synthesis we develop the best fragment condensation strategy for your peptide. Our innovative synthesis technologies allow for cost effective processes by reducing the number of chemical steps and increasing the yields.

Hybrid strategies are more suitable for long sequences and high volumes.

Our experts will design the best fragment strategy. The segments are coupled either in liquid or on solid support to achieve the highest crude purity and avoid extensive HPLC purification.



Performance

FDA and EMEA inspected

The **state-of-the-art facilities** of Peptisyntha, located in **Europe and the USA**, cover all possible scales and technologies (SPPS, LPPS or SPPS-LPPS) including purification and lyophilisation. Peptisyntha's GMP units allow for the production of peptides for clinical trials and peptides for commercial drugs.

EMA and FDA inspected facilities in Brussels with no FDA form 483 observation reflect our commitment to the highest standards.

- Large scale GMP units (5 kg – 100s of kg)
- Medium scale GMP units (1 kg – 5 kg)
- Small scale GMP units (1 g – 1 kg)
- HPLC purification units
- Lyophilisation units
- Clean rooms (class 100,000; class 10,000; class 100)

Complementing one another, the facilities are available as a set of well adjusted equipment to perfectly fit your peptide and peptidomimetic needs.



Dedication

In-house Analytical Capabilities

As an integrated part of its services Peptisyntha offers access to an extensive range of in-house **analytical capabilities and expertise for analytical development, analytical methods validation and routine analysis.**

cGMP Specifications: Peptisyntha provides you with all standard GMP specifications for your project.

Our in-house capabilities include most analytical methods traditionally used for peptide APIs, such as:

- HPLC
- LC-MS
- Ionic Chromatography
- Karl Fischer
- NMR
- GC Headspace
- ICP-MS
- Microbial Limit Testing (Bioburden)
- LAL Assay (Endotoxins)

In addition, we offer analytical expertise for solid state characterization. This can be of high relevance for peptides which are isolated by methods other than the usual freeze drying.

In-house capabilities for solid state characterization include Scanning Electronic Microscopy, X-Ray Diffraction, DSC, Infra-Red and Raman Spectrometry.



Quality Assurance and Regulatory Affairs

The **strong quality assurance system** in place at Peptisyntha guarantees the fulfillment of the most stringent and latest quality requirements.

The fact that we had no form 483 observations following the most recent FDA inspections in Brussels provides evidence of this commitment.

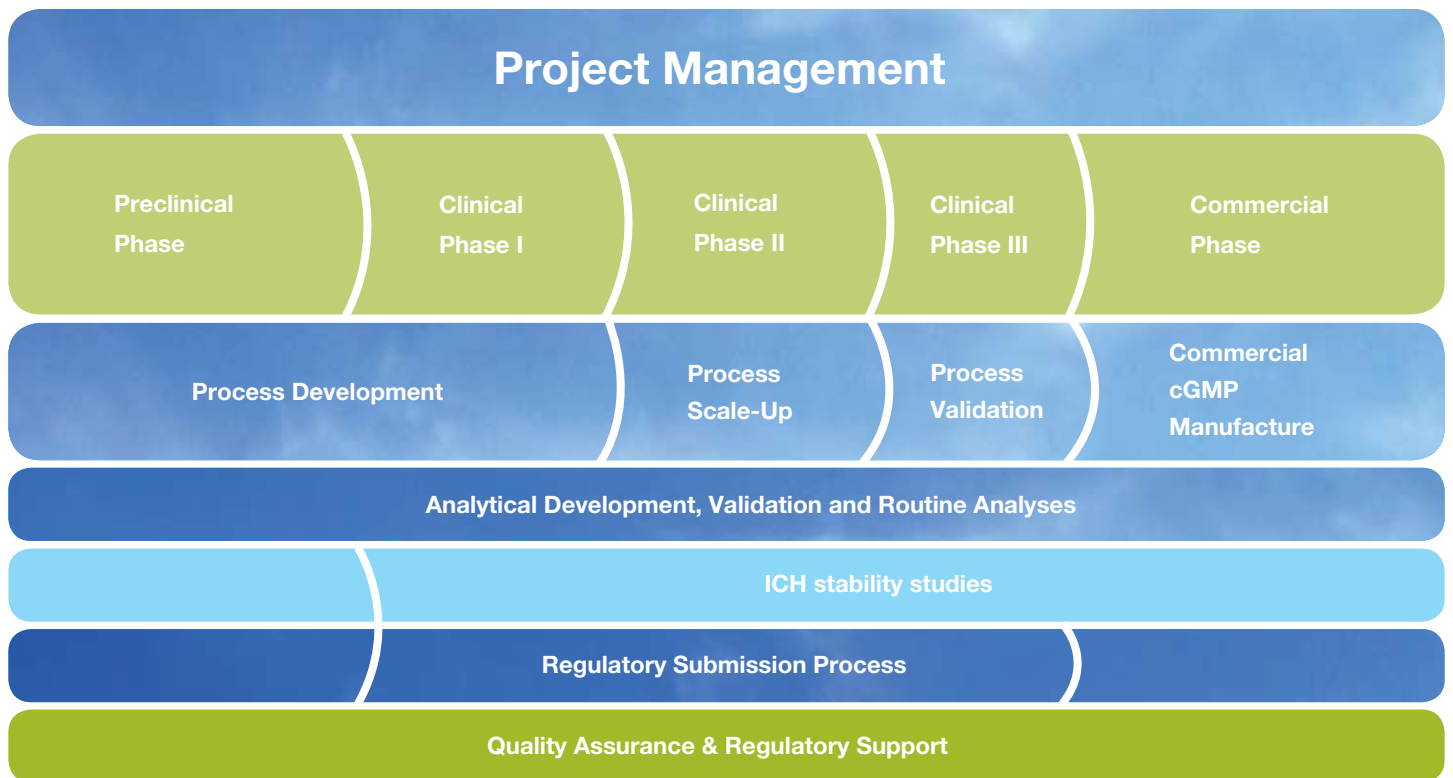
At the same time, our well-designed quality assurance system allows the organization to breathe and benefit from efficient processes.

Our customers benefit from this **synergy of quality and efficiency.**

From clinical to commercial stage, Peptisyntha provides you with all required **regulatory support for your API.**

- Process validation
- Development and validation of testing methods
- Reference standard qualification
- Impurity characterization
- ICH stability studies
- All documentation required for your IND/IMPd or NDA/MAA filings
- CMC and DMF compilation will be provided and maintained by continuous updates
- Annual product reviews

Project Management



Peptisyntha is known and much-lauded for its open-mindedness, the joy it takes in entertaining pleasant and effective relations with customers and for the expertise and passion of its employees. This is our foundation for **successful and long lasting collaborations.**

At Peptisyntha we believe that reliable project management is the key to every successful collaboration and project realization. We implement this using a dynamic project management model:

At the beginning of the development, the chemistry is the driver in the communication between Peptisyntha and the customer. After process scale up, the quality and regulatory aspects become a priority, along with the filing. At all stages a management team including technical, quality, regulatory and business development experts will accompany your project.

This team of experts will be dedicated to your API and lead you through the highly regulated development and manufacturing process.

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