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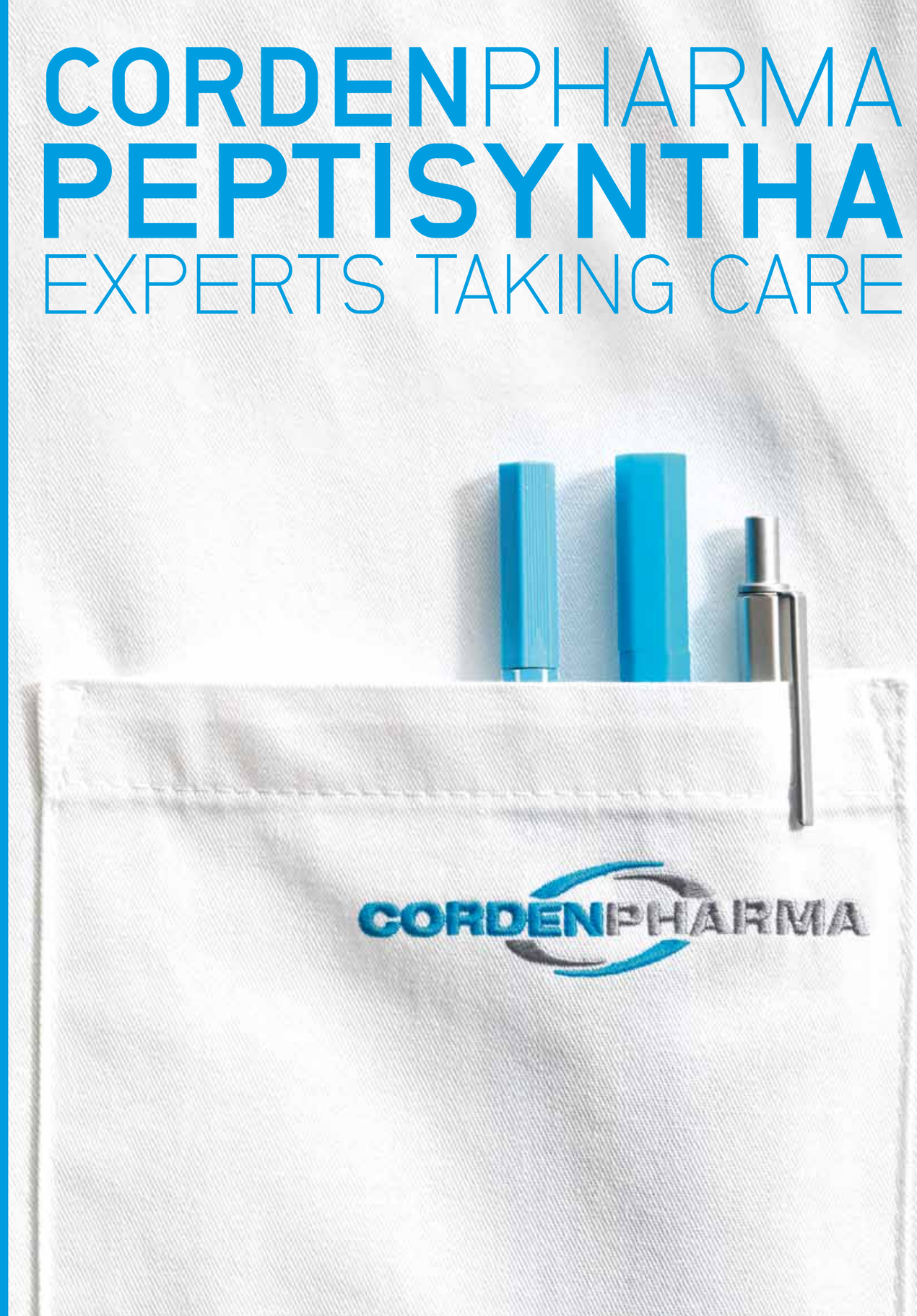
CORDENPHARMA

# CORDENPHARMA PEPTISYNTHA

## EXPERTS TAKING CARE



US

## Our History

- 1987: Peptisyntha founded by Solvay
- 1996: First pre-approval FDA inspection for a major peptide made by Peptisyntha for the worldwide market. Following FDA inspections: 1999, 2005, 2009 and 2013
- 2001 - 2009: Production facility extensions with additional small scale, medium scale and large scale GMP units: synthesis, HPLC purification, freeze-drying and packaging
- 2011: Solid-phase GMP peptide production units added
- 2013: FDA inspection, no 483 form. Total of 5 successful FDA inspections
- 2013: Peptisyntha acquired by ICIG (International Chemical Investors Group) to join CordenPharma

# CORDENPHARMA PEPTISYNTHA

## The Peptide CMO

## > 25 Years of Experience

**Peptisyntha Focus on Therapeutic Peptides -**
Founded in 1987 and dedicated to the manufacture of peptides, Peptisyntha has built a track record of success in supplying pharmaceutical and biotech companies with development and commercial scale cGMP peptide API manufacturing services using world-class cost-effective production processes. Through expertise and capabilities in all synthetic manufacturing technologies, Peptisyntha designs customized manufacturing approaches to achieve the most effective manufacturing process for the peptide APIs of its customers.
A world class facility, innovative peptide technologies, a skilled team of experts, constructive support and trust are some of the hard and soft assets that make Peptisyntha the peptide CMO of choice.

## Compliance Worldwide

- 5 FDA inspections: Most recently 2009 and 2013 with no 483 Form
- Belgian Health Authorities on behalf of EMEA: 2014
- DMF filing experience: USA, Europe, Japan, Australia, Canada, New Zealand


A220
R220/D


# WHAT WE DO

## Small to Large-Scale Peptide API Production

LPPS / SPPS / Hybrid

Peptisyntha masters all peptide synthesis technologies including solution-phase, solid-phase and the hybrid approach solid-solution phase peptide synthesis. Peptisyntha technically differentiates itself from competitors with a wide range of solutions which enable quick and cost-effective response to the most challenging peptide projects. Our unique technologies make the difference and add substantial value to the development and commercial programs of our customers.

## CORE CAPABILITIES

- Liquid-phase peptide synthesis (LPPS)
- Solid-phase peptide synthesis (SPPS)
- Hybrid strategies (SPPS-LPPS)
- Short peptides, often with no HPLC purification
- Complex peptides and peptidomimetics
- Cyclic peptides
- Peptide-conjugates (PEGs, proteins, lipids, carbohydrates)
- Arginine-rich peptides

## KEY TECHNOLOGIES

- Silylation technology
- Tetraphenyborate (TBP) technology for the synthesis of Arginine-containing peptides
- Non-natural amino acid building blocks
- Use of Phenyl-oxy-carbonyl-protection (Phoc-AA) of amino acids / peptides

**Peptisyntha's manufacturing technologies enable cost–effective production of peptide APIs by:**

- **Reducing the number of chemical steps and increasing yield, thereby improving productivity**
- **Avoiding racemization and increasing purity, thereby saving extensive preparative HPLC purification**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## GMP FACILITY

- Large-scale GMP units (10 kg – 100 kg)
- Medium-scale GMP units (1 kg – 10 kg)
- Small-scale GMP units (50 g – 1 kg)
- HPLC purification units (small, medium & large-scale)
- Lyophilisation units
- Clean rooms (class 100,000; class 10,000; class 100)

## ANALYTICAL CAPABILITIES

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

## PARTNER FROM CLINICAL TO COMMERCIAL STAGE

Peptisyntha is one among very few companies that can provide high quality, cGMP-compliant therapeutic peptide APIs and services at all scales and competitive prices to customers in the pharmaceutical and biotechnology industries. The state-of-the-art FDA inspected facilities of Peptisyntha cover all possible scales and peptide synthesis technologies (SPPS, LPPS and hybrid SPPS-LPPS) including HPLC purification and lyophilization, and allow Peptisyntha to accompany and support its customers in their journey from clinical to commercial stage.


Peptisyntha manufactures GMP peptide APIs via solid-phase, solution-phase and hybrid solid-solution phase synthesis from small-scale to large-scale (100s of kg).