

# BCN

PEPTIDES



Quality, Experience And Flexibility  
in GMP Bulk Peptides



## BCN Peptides, your R&D Partner, your **Industrial Supplier**







## Quality, Experience and Flexibility in **GMP Bulk Peptides**

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**BCN Peptides** is completely focused on the Industrial cGMP manufacture of Bioactive Peptides for Pharmaceutical and Veterinary applications.

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We concentrate our efforts in the following activities:

- **Generic Peptides**
- **Custom Synthesis** of proprietary API Peptides

**BCN Peptides** complies with the highest Quality Standards; we have been audited and approved by the US FDA and the EDQM for the GMP manufacture of Peptides.

Since 2008, we are operating in a brand new custom-design facility, which allows **BCN Peptides** to be one of the leading companies into the GMP manufacture of bioactive peptides.

This facility is located in the surrounds of Barcelona (Spain).

**BCN Peptides** is dedicated to the manufacture of Peptides since 1990.

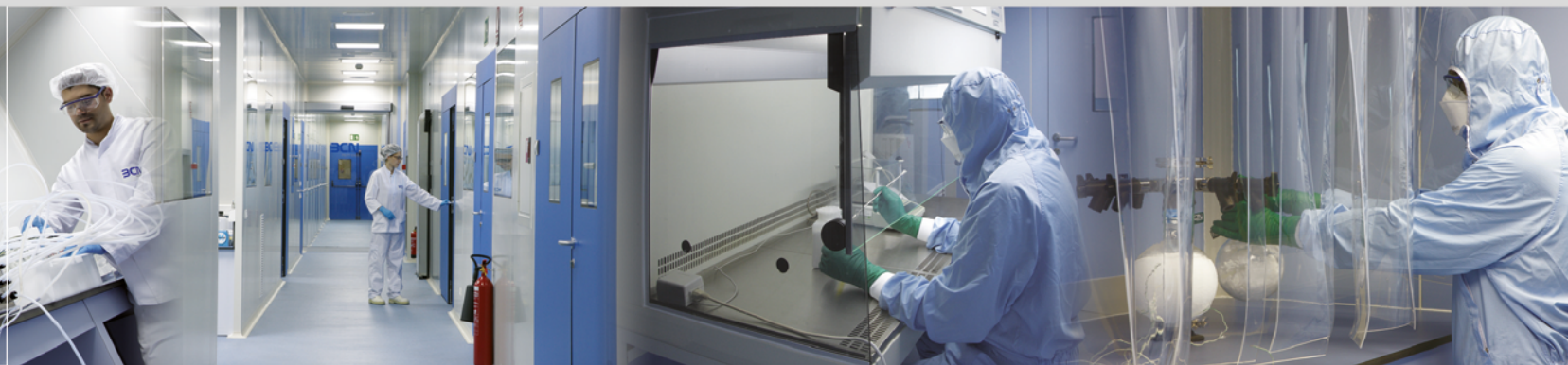




We are the **Experts** in the Solid Phase  
Synthesis of **Bioactive API**







# Peptides

- Key Technologies:
- Solid Phase Synthesis
  - **HPLC** Purification
  - Lyophilization under **GMP** conditions
  - Sterile Peptides

**Our facility** located in Sant Quintí de Mediona offers almost 2.500 sqm of production area and laboratories dedicated to the GMP manufacture and control of Peptides. This facility has been specially designed by **BCN Peptides** applying all our know-how in Solid Phase Synthesis and has been equipped with the most advanced technology.

**BCN Peptides** manufactures multi kilo batches of GMP Peptide using SPPS technology. We are specialists in long sequences and cyclic peptides.

**Classified Area** with 7 independent rooms for preparative **HPLC**, with columns between 10 and 20 cm diameter. (and analytical in process control laboratory).

**Classified Area** with 13 independent rooms for the Lyophilisation of the final API Peptide.

**Dedicated Classified Area** with different rooms from grade **D** to grade **A**, for the manufacture of Sterile API Peptides, including Lyophilization and packaging under sterile conditions.



# BCN Peptides

## Quality Guaranteed



**BCN Peptides** works under the highest Quality Standards for strongly regulated markets. Our activities always follow a Strict GMP Compliance. From R&D up to production all the processes are monitored by our Quality Assurance Unit.

BCN Peptides has been inspected and approved by:

- US FDA
- EDQM
- Different National Authorities Worldwide
- Some of the Top Ten Major Pharmaceutical Companies

### Pharmaceutical Laboratory for Quality Control of Drug Products

BCN Peptides is an authorized Laboratory for the analysis of Final Pharmaceutical Product. We are offering to our customers the possibility of performing the *Analytical development*, *Validations* and *Testing* both for the release and for the *Stability Studies* of Final Pharmaceutical Product containing API Peptides.





# BCA



**Regulatory Affairs Department**, with more than 25 years experience filing DMF/CTD documents to different National Authorities Worldwide.



We have been granted with six CEP's from the European Pharmacopoeia for the following products:

- Buserelin
- Desmopressin
- Goserelin
- Leuprolide (Sterile grade)
- Salmon Calcitonin (Sterile grade)
- Somatostatin

In our facility we have to highlight two aspects directly related with the quality of the product:

**Water System:**

Highly Purified Water produced by Osmosis. The Water loop is made in PVDF and is kept at low temperature.

**Classified Area (HVAC System):**

After the Chemical Synthesis all steps including Purification and Lyophilization are performed in Classified Areas, from grade D to A. The packaging is always performed under laminar flow hood grade A into a Classified Area.



# Optimal size

BCN Peptides is a reliable, fast and reactive supplier for your custom synthesis project

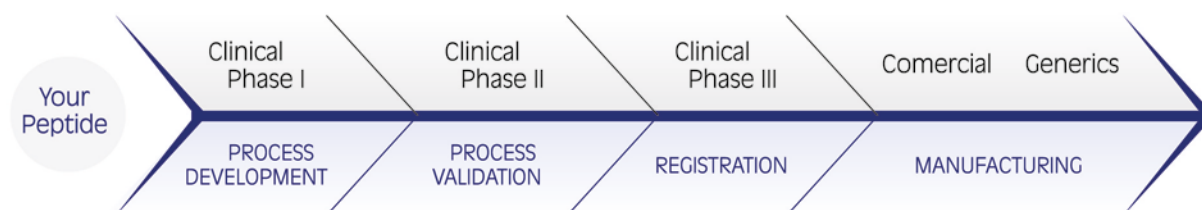
**Our company size,** our technology and our customer oriented organization allow us to help you reducing time to Market





# to maximize Flexibility for your **Peptide Projects**

Where can **BCN Peptides** assist your peptide project?



## BCN Peptides' API Peptide development, what's in?

- **Analytical Development**
  - Characterization
  - Working Standard Preparation
  - Establishment of Specifications
  - Analytical Methods Validation
- **Synthetic Development**
  - R&D (Route development)
  - Three validation batches
  - Process validation
- **ICH Stability Study**
- **IMPD/IND and CTD/DMF Preparation**
- **Regulatory Support in front of US FDA/EMEA**
- **Quality Control of Final Drug Product**
- **Industrial Manufacturing**

All the activities are performed under cGMP procedures.

If you are looking for a partner to develop your peptide, the combination of our Experience, our commitment and our state of the art facility makes **BCN Peptides** the best choice.



# Looking for an API Peptide?



BCN Peptides is offering a broad range of Generic Peptides for Pharmaceutical and Veterinary applications

## Product List • BCN Peptides

### • Growth Hormone Regulators

Lanreotide  
Octreotide  
Pasireotide  
Somatostatin

### • Calcium Regulating Hormones

Elcatonin (Carcinocalcitonin)  
Salmon Calcitonin  
Teriparatide (PTH 1-34)

### • LHRH Analogue Agonists

Alarelin  
Buserelin  
Fertirelin  
Gonadorelin  
Goserelin  
Lecirelin  
Leuprolide  
Triptorelin

### • Vasopressin Analogues

Arginine Vasopressin  
Desmopressin  
Lysine Vasopressin  
Terlipressin

### • Secretins

Synthetic Human Secretin  
Synthetic Porcine Secretin

### • Thymus Hormones

Thymosin alpha 1  
Thymosin beta 4  
Thymosin beta 15

### • Glucagon-Like Peptides

GLP-I (7-37)  
Pramlintide

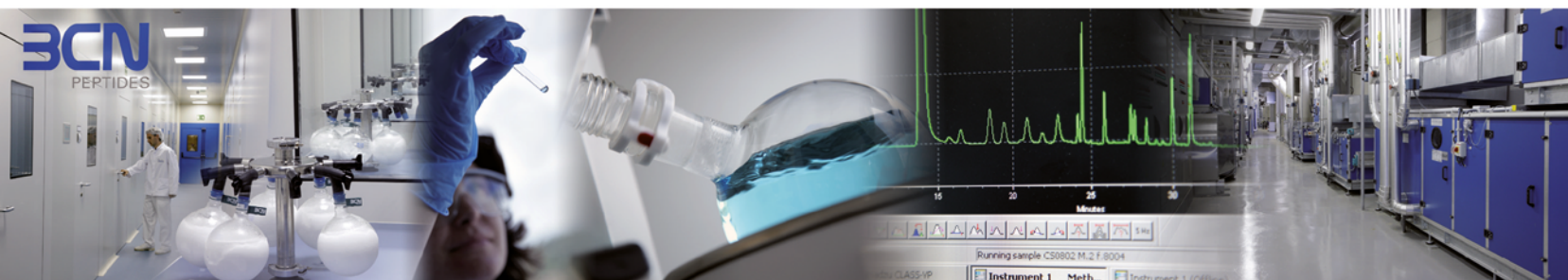
### • Miscellaneous

ACTH  
Abaloparatide  
Angiotensin I/II (1-7)  
Angiotensin II  
Atosiban  
Carbetocin  
Carperitide  
Eledoisin  
Etelcalcetide  
Ganirelix  
GHRP-6  
Nesiritide  
Icatibant  
Protirelin  
PYY (3-36)  
Tetracosactide  
Vasoactive Intestinal Peptide



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