

ADVANCED
THERAPEUTIC
MODALITIES

Therapeutic Peptides

A STRATEGIC DRIVER
OF INNOVATION



Bluepharma is **strengthening its strategic positioning** in **Advanced Therapeutic Modalities**, with **therapeutic peptides** emerging as a key driver of innovation, technological differentiation, and sustainable growth.

Peptides

High Specificity. High Technological Value.

Therapeutic peptides, composed of short chains of amino acids, bridge the gap between conventional small molecules and large biologics. Their unique physicochemical and pharmacological properties provide several important advantages:

- High pharmacological specificity;
- Improved safety profile;
- Lower systemic toxicity;
- Reduced risk of drug–drug interactions.

These characteristics make peptides particularly valuable in challenging therapeutic areas such as oncology, immunology, metabolic disorders, and rare diseases, where targeted intervention is essential to maximize clinical efficacy while minimizing adverse effects.



Advanced Technical Capabilities and Specialized Infrastructure

Many peptides fall within the category of highly potent molecules, requiring handling in high-containment environments similar to those used for HPAPIs.

Bluepharma's specialized infrastructure and advanced technical expertise ensure the highest standards of quality, safety, and regulatory compliance, supporting the development and manufacturing of complex peptide-based medicines.

Applied Innovation: **Targeted Drug Delivery**

Beyond their direct therapeutic action, peptides can also function as cellular targeting agents, enabling selective drug delivery to specific tissues or cell types.

A concrete example is the patented FBL-MTX technology, developed by Solfarcos and manufactured under GMP conditions by the Bluepharma team for clinical studies. This program illustrates Bluepharma's ability to support the translation of innovative peptide-based technologies from concept to GMP manufacturing, using peptide-mediated targeting to deliver methotrexate selectively for the treatment of rheumatoid arthritis while reducing systemic side effects.

The Innovation Frontier: **Oral Peptides**

Historically, most peptide-based medicines have been developed for parenteral administration (injectables and lyophilized products) due to the intrinsic limitations of oral delivery.

Today, however, the development of oral peptide therapeutics represents one of the most promising frontiers in pharmaceutical innovation, with significant clinical and commercial potential.

Although strongly preferred by patients due to their convenience and reduced invasiveness, oral administration faces major challenges:

- Enzymatic degradation in the gastrointestinal tract;
- Instability in acidic environments;
- Low intestinal permeability.

To overcome these barriers, Bluepharma is investing in advanced formulation strategies that combine:

- Proteolytic enzyme inhibitors;
- Permeation enhancers;
- Advanced encapsulation systems for controlled and targeted release.

A High-Value and Growing Market

By the end of 2025, 88 peptide-based medicines had been approved globally, and the global peptide therapeutics market size was estimated at approximately €121 billion and projected to reach €255 billion by 2033.

The market is expanding steadily, supported by rising demand for targeted and high efficacy treatment options across major disease areas (metabolic disorders (diabetes/obesity), cancer and infectious diseases).

The majority of peptide therapeutics are injectables (solution or lyophilized formulations), while only a limited number are currently available as oral products - highlighting significant opportunities for innovation to address specific therapeutic indications that require oral administration.

Moreover, the development of new peptide formulations enables:

- Extension of the lifecycle of established molecules;
- Optimization of pharmacokinetic profiles;
- Creation of differentiated therapeutic combinations;
- Strengthening of industrial portfolio value.

HIGHLY
QUALIFIED AND
EXPERIENCED
R&D TEAM





Bluepharma

Precision. Innovation. Value.

With this strategic focus on Advanced Therapeutic Modalities, Bluepharma is positioning itself as a technology-driven partner in the development and manufacturing of high-complexity peptide therapeutics, combining scientific innovation, industrial excellence, and a forward-looking market vision.

To support this strategic vision, Bluepharma will expand in 2026 its industrial infrastructure with a new state-of-the-art sterile manufacturing unit dedicated to complex injectable medicines. The unit, is designed to meet the highest regulatory standards, including the revised.

EU GMP Annex 1, this facility will enable the production of complex sterile products across multiple development stages – from pilot and clinical batches to small-scale commercial manufacturing.

This new facility will play a key role in supporting the manufacturing of next-generation therapeutic Peptides requiring complex sterile processing.

Together, these capabilities position Bluepharma as a strategic partner for the translation of therapeutic peptides from concept to industrial-scale production.



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