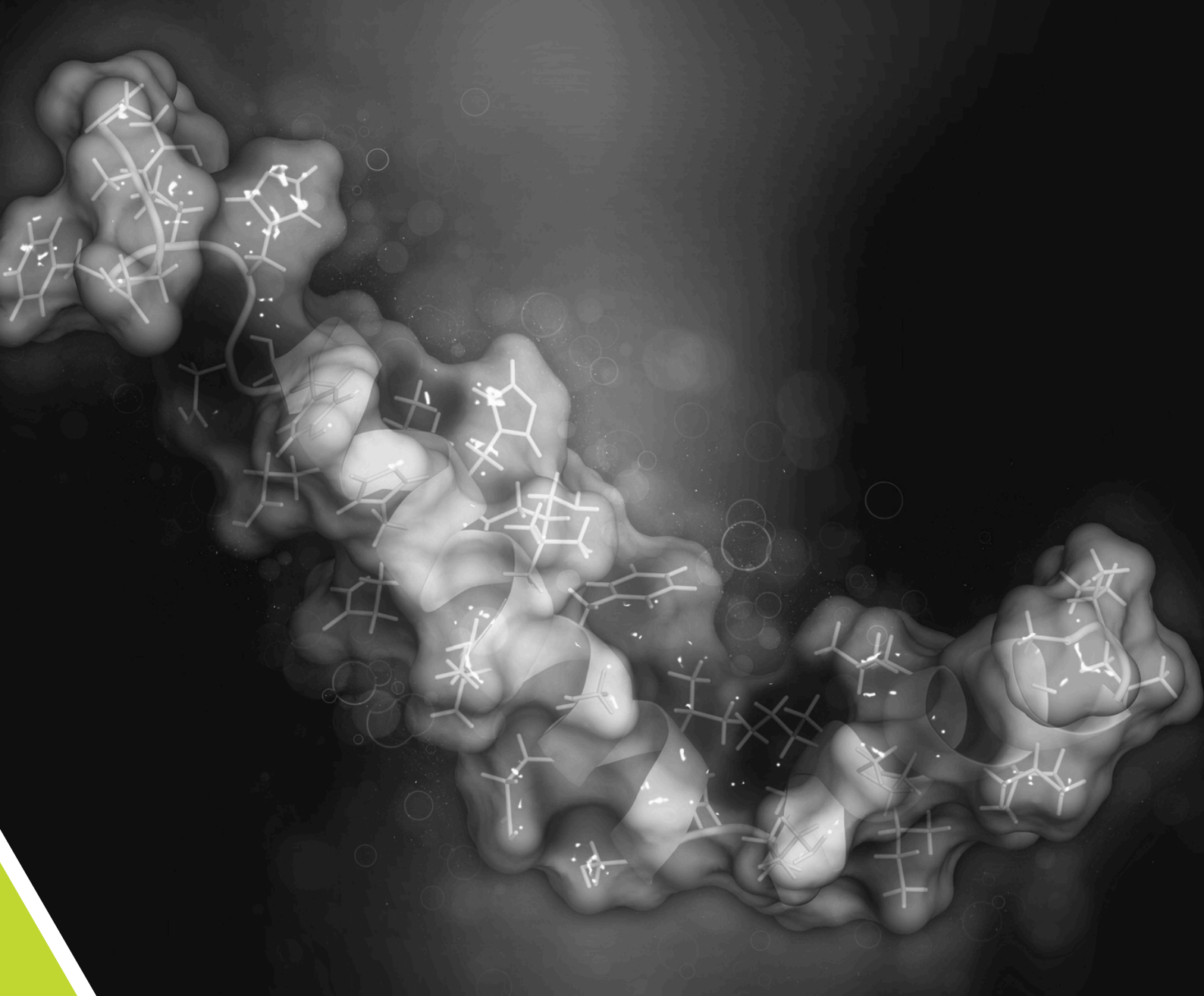




# Advancing Peptide Therapeutics

Challenges and Opportunities in a Booming Market

White Paper



# Executive Summary

Peptide drugs, once limited to naturally derived compounds, have undergone a transformative journey through advancements in synthetic chemistry and analytical techniques. Despite initial challenges in terms of stability, delivery, and competition from small molecule drugs, the field has witnessed a resurgence fueled by the success of GLP-1-based therapies.

This review provides an overview of the evolution of peptide drugs, emphasizing the complexities of their development, manufacturing, authorization and commercialization. It highlights the critical role of analytical services in addressing these challenges and ensuring the successful translation of peptide-based innovations into life-changing medicines.

# From Synthesis to Success: The Booming Market of Peptides

Historically, the only peptide drugs available were derived directly from natural sources and marketed in their native, unmodified form. While exhibiting excellent tolerability and specificity, native peptides possess significant limitations. Their short plasma half-life, poor permeability, and negligible oral bioavailability usually preclude oral administration and necessitate frequent subcutaneous injections at high doses. Consequently, these inherent drawbacks limit their suitability for direct pharmacological development.

Since the 1990s, advancements in bottom-up synthetic methods, especially solid-phase peptide synthesis (SPPS), and improved analytical techniques have enabled the production of modified peptides. These modifications can enhance the pharmaceutical properties of a peptide, improving half-life and specificity, and enhancing potency, leading to reduced drug dosages, mitigated side effects, and even the potential to target novel therapeutic targets.

These advances have propelled the growth of peptide-based therapeutics, with Glucagon-like peptide-1 (GLP-1) therapies emerging as a standout success. GLP-1 analogs help regulate blood sugar and appetite, making them highly promising for treating both diabetes and obesity —conditions that impact over a billion people worldwide.

Exenatide (Byetta®), the first GLP-1 analog approved by the FDA in 2005, required twice-daily administration, limiting its appeal and affordability. In contrast, semaglutide (Ozempic®, Wegovi®, Rybelsus®), approved in 2017, offers once-weekly dosing due to structural modifications that enhance its half-life. Despite a monthly cost of approximately \$1,000, semaglutide has achieved unprecedented market success due to its efficacy in treating obesity. Tirzepatide (Mounjaro®), another GLP-1 analog marketed by Eli Lilly, has also demonstrated significant commercial success and may become a market leader.<sup>3</sup>

Peptides make up 9% (31/370) of the new drugs approved by the FDA between 2016–2023<sup>1</sup>

The global peptide therapeutics market was estimated at \$43.45 billion in 2023<sup>2</sup>



1) Shaer, D. A., Musaimi, O. A., Albericio, F., & De La Torre, B. G. (2024). 2023 FDA TIDES (Peptides and oligonucleotides) harvest. *Pharmaceuticals*, 17(2), 243. <https://doi.org/10.3390/ph17020243>  
 2) Peptide Therapeutics Market Size, Share & Trends Analysis Report By Application , 2024 - 2030. (n.d.). <https://www.grandviewresearch.com/industry-analysis/peptide-therapeutics-market>  
 3) Dunleavy, K. (2023, June 19). Eli Lilly's Mounjaro is primed to overtake Novo Nordisk's popular diabetes and obesity duo: Report. *Fierce Pharma*. <https://shorturl.at/eWj8z>

# Outsourcing and Decentralization Challenges

## Peptide Startups and the CRO Bottleneck

The commercial success of GLP-1-based anti-obesity drugs has reignited interest in peptide therapeutics, leading to increased investment and a surge in peptide drug candidates. A wave of startups focusing on innovative peptide therapeutics has emerged, prioritizing speed to market — or more practically, speed to promising clinical data — due to the high costs of drug development and investor expectations. To attract funding or acquisition offers, these startups must demonstrate rapid progress.

A recent success story is VectivBio, a Swiss startup founded in 2019 and acquired by Ironwood Pharmaceuticals for around \$1 billion in 2023. Their lead candidate, Apraglutide, a next-generation GLP-2 analog, recently achieved positive top-line results from a global Phase III trial for short bowel syndrome<sup>3</sup>.

Peptide drug development is complex, often leading startups to rely on Contract Manufacturing Organizations (CMOs). However, extensive consolidation within the CMO landscape since the early 2000s has resulted in a limited number of experienced peptide-focused service providers, creating capacity constraints and placing additional pressure on development timelines and analytical control.

## Decentralized Production and Quality

Meanwhile, pharmaceutical giants like Novo Nordisk and Eli Lilly<sup>4</sup> face significant challenges in meeting surging demand due to production capacity constraints. Solid Phase Peptide Synthesis (SPPS) remains the leading method for manufacturing synthetically modified peptide drugs, which provides flexibility for testing but is resource-intensive, requiring excess reagents, multiple protection steps, and extensive purification, all of which contribute to yield losses. As a result, large-scale batches are needed, requiring a reliable supply of high-quality raw materials to meet demand.

Therefore, pharmaceutical companies are expanding manufacturing across multiple sites, introducing operational complexities. These capacity constraints, decentralized production, and the intricacies of peptide development create challenges in ensuring consistent product quality, highlighting the crucial role of robust, centralized analytical quality control throughout the product lifecycle.



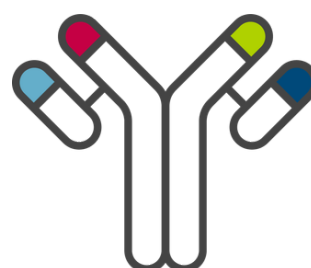
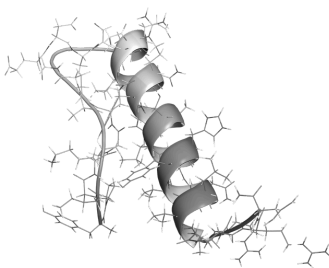
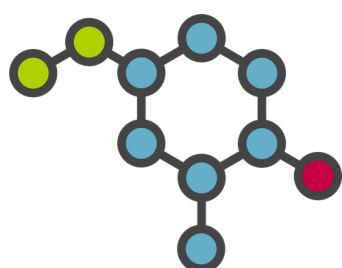
<sup>3</sup>) Ironwood announces the completion of Squeeze-Out merger with VectivBio. (n.d.). <https://investor.ironwoodpharma.com/press-releases/press-release-details/2023/Ironwood-Announces-the-Completion-of-Squeeze-Out-Merger-With-VectivBio/default.aspx>

<sup>4</sup>) GlobalData Healthcare & GlobalData Healthcare. (2024, August 27). Shortages improve for Lilly's GLP-1 weight loss drugs, bumping sales forecast by \$3bn. Pharmaceutical Technology. <https://www.pharmaceutical-technology.com/analyst-comment/shortages-improve-lilly-glp-1-weight-loss/?cf-view>

# The Critical Role of Analytics in Peptide Quality Control

Peptides drugs are a unique modality that falls between small molecules and large molecular biologics, bringing unique regulatory and analytical challenges. With the increasing popularity of synthetic peptide drugs, regulatory questions have been recently addressed by new guidelines from the FDA and EMA.

A comprehensive multidisciplinary understanding, supported by sophisticated analytical techniques, is fundamental for the successful development and commercialization of peptide drugs.



molecular weight <500 Da

PEPTIDES

molecular weight >5000 Da

Critical quality attribute (CQAs) to be considered during peptide drug development include:

- **Identity:** The correct amino acid sequence and molecular weight of the peptide is essential for its properties and biological activity.
- **Characteristics:** Physical properties such as appearance, solubility, solid form, and particle size.
- **Structure:** The correct primary structure, as well as higher-order structures, including disulfide bonds and other post-translational modifications.
- **Purity:** The percentage of the desired peptide in the final product. Impurities can be peptide-related, such as truncated peptides, or non-peptide small molecular or inorganic contaminants.
- **Aggregation:** Peptides can aggregate into larger particles, which can affect their solubility, stability, and bioactivity.
- **Degradation:** Peptides can degrade through various mechanisms, such as hydrolysis, oxidation, and deamidation.
- **Solubility:** The ability of the peptide to dissolve in a suitable solvent, which is important for formulation and administration.
- **Stability:** The ability of the peptide to maintain its quality over time under various storage conditions.
- **Bioactivity:** The ability of the peptide to exert its intended biological effect.
- **Immunogenicity:** The potential for the peptide to induce an immune response, which can affect its safety and efficacy.

# Breaking Down Boundaries in Peptide Analytics

With over 20 years of experience, Solvias supports companies of all sizes, from startups to pharmaceutical giants, across the entire peptide development lifecycle, from early-stage preclinical research to commercialization. We provide comprehensive analytical control and method development, backed by a broad range of in-house capabilities and deep expertise in both small and large molecule analysis. Our independence ensures objective quality assessment when collaborating with multiple manufacturing sites.

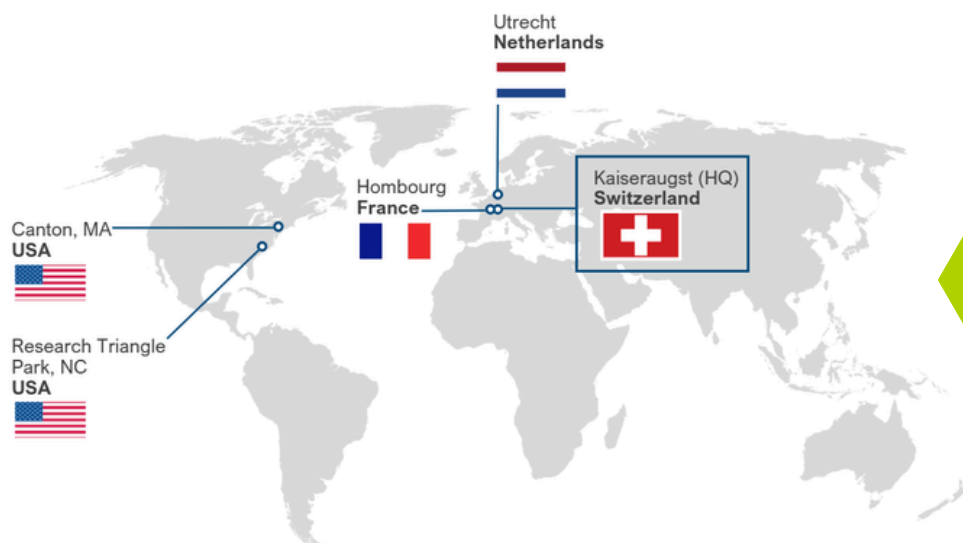
As peptide drug demand grows, multi-site development and manufacturing becomes essential to fulfill market expectations. Solvias offers a single-source solution for consistent analytical control, enabling scalability and mitigating risks from potential limitations with partners focusing on development or manufacturing. Unlike Contract Manufacturing Organizations (CMOs) often prioritizing production over analysis and lacking capabilities, we provide a full suite of analytical services, including long-term stability studies and reference management. This comprehensive approach supports global operations by connecting research, development, and manufacturing sites.



For further information and details about peptide analytical testing services, visit our [peptides page](#) and contact us at [info@solvias.com](mailto:info@solvias.com).

## Why partner with us?

- CRO
- Founded in 1999
- 800+ team members
- 175+ PhD-level scientists
- GMP, GLP, ISO9001 certified
- 23K m<sup>2</sup> of lab capacity
- 700+ customers worldwide
- 5 centers of excellence



**Contact us to speak with  
an expert:** [info@solvias.com](mailto:info@solvias.com)

