



# GMP Peptides

One-Stop Service  
Provider

We specialize in **GMP peptide manufacturing**, leveraging decades of expertise, a rigorous quality management system, and state-of-the-art facilities to deliver **complex-modified peptides** and **peptidomimetics** tailored to your unique requirements.



30 years  
of experience



mg to kg  
net quantity

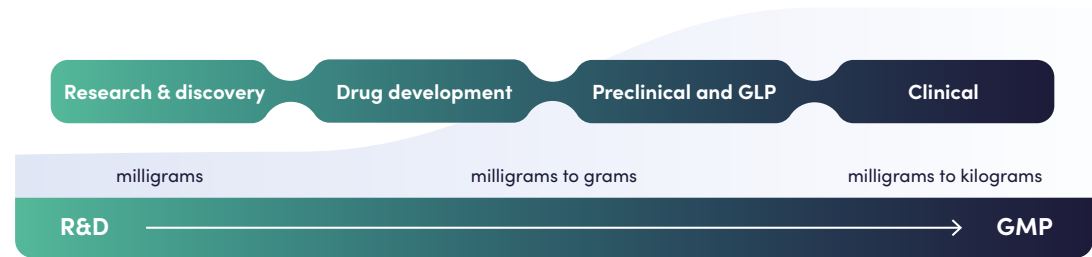


Fast  
lead-times



Made  
in the USA

Get the right quantity and quality, at the right time.



## Comprehensive GMP Peptide Manufacturing Services

Our fully customizable GMP peptide service is **designed to meet the diverse requirements of our clients, delivering high-quality peptides at the scale** that suites your specific needs.

We support each stage of your GMP peptide drug development, from early **R&D to clinical**, ensuring consistent quality and compliance throughout your project's lifecycle.

## From milligrams to kilograms

We produce peptides in quantities ranging **from milligrams to kilograms**, in our facilities equipped to handle both **small-scale** production and **large-scale** manufacturing.

We offer both **Gross and Net quantities** of peptides, packaged in the amount per vial as requested.

Our **flexible production capabilities** ensure you receive the **right peptide quantity and quality** according to your specifications.

### IN-VIVO & GLP STUDIES

We give you access to *in vivo* and *in vitro* preclinical studies prior to progress to clinical trials.

### PEPTIDE MODIFICATION EXPERTS

Our expert team brings decades of experience in peptide synthesis and purification of highly modified peptides including :

#### Labeled

- Fluorescent Dyes
- FRET
- TR-FRET
- Heavy isotope

#### Structural

- Lactam ring cyclic
- Disulfide-bridge
- Stapled
- Thioether-bridge
- Thiolactone cyclization

#### Conjugated

- Drug-Peptide (PDC)Chelation
- Peptide-Oligo Conjugates
- Carrier Proteins

#### Specialized

- Unusual Amino Acids
- Lipopeptides
- Phosphorylated
- Glycosylated
- Peptidomimetics

to  
**98%**  
purity by HPLC

Each peptide we produce undergoes rigorous testing to ensure it meets your pre-established acceptance criteria.

## State-of-the-Art Manufacturing Facilities

Our cutting-edge **44,000-square-foot** facility in California's Silicon Valley is designed to support high-quality GMP peptide production with state-of-the-art equipment and **ISO 7** cleanrooms.

We adhere to strict **GMP guidelines**, including secure **airlock** entry, rigorous environmental **monitoring**, and thorough **segregation** of processing areas.

## Solid Quality Assurance

Our comprehensive Quality Management System (QMS) adheres to 21 CFR 210 and 211 as well as ICH Q7 guidelines, applicable for products intended use.

### Key elements of our QMS include :

- | **Regulatory Compliance**: We follow GMP standards and undergo regular audits to ensure quality.
- | **Raw Material Control**: We verify the quality of starting materials and qualify suppliers.
- | **In-Process Control**: Robust controls during production ensure our products meet specifications.
- | **Quality Control**: We use qualified analytical methods to verify peptide quality.
- | **Stability Testing**: Stability samples are maintained and monitored in validated storage chambers, upon request.
- | **Documented Process**: Our GMP manufacturing process is meticulously documented and archived for five years, with redacted records available for transparency.

## Efficient Project Management

With our robust project management, we ensure **timely and efficient delivery** of your custom peptides. Our **dedicated project managers** work closely with you to understand your requirements, provide regular updates, and **ensure that all milestones are met**.

## The Benefits of Choosing AnaSpec

### One-Stop Provider

We offer a **5-in-1 solution**, including GMP **manufacturing**, Analytical Method **Validation**, **Stability** Programs, **CMC** assistance for IND filing, and **GLP study** packages.

### Small to Large Scale

Our end-to-end approach, provides a **single point of contact** for process development, manufacturing validation, and quality control—streamlining your workflow.

### Fast Lead-Times

**Quick delivery** of peptide API for clinical use, emergency IND use, API precursors and excipients, and other critical raw materials.

### Quality Management

Our comprehensive **QMS policy** ensures **top-quality products** from raw materials to manufacturing, QA, QC, shipping, and beyond.

### Transparent Communication

We provide **fast, responsive**, and **transparent communication**, with access to key team members. Client audits are always welcome.

### Made in the USA

Our state-of-the-art facility in **Silicon Valley** **houses all departments**, including manufacturing, QA, QC testing, EH&S, and materials management.



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