ANASPEC

Leading provider of integrated proteomic solutions worldwide

GMP PEPTIDE MANUFACTURING

Experience the quality

Applications

- **API drug substance**
- **Pharmaceutical excipients & precursors**
- **Neoantigens for *ex vivo* cell therapy**
- ***In vitro* Diagnostics**

Our Expertise

With over 30 years of expertise, AnaSpec offers a continuum of peptide grades from **R&D to GMP** drug substance (API) for early clinical phase studies. Our GMP grade peptides are manufactured in our highly controlled **ISO 7 classified (10,000) cleanrooms**, under a comprehensive quality management system, compliant with 21 CFR 210 and 211 and ICH Q7 guidelines. We offer **feasibility and engineering** runs to identify critical in-process controls (IPCs) that ensures successful GMP campaign with high quality product.

Discuss **your project** with us **to get your free quotation**

› **Contact us**
gmppeptides@anaspec.com

Peptide Grades Comparison

	SMALL & LARGE SCALES	
	CLASSICAL & COMPLEX Peptide chemistry (cyclic, stapled, phosphorylated, biotinylated, fluorescent dye or quencher labeled or both for FRET/TR-FRET)	
Attributes	**GMP API**	**Research Grade**
Product Applications	API Biopharmaceutical	Research & Discovery
Quality Systems Controls	21 CFR parts 210 & 211	ISO 9001
Service Agreement / Audits	Standard	
Analytical Methods	v	v
Certificate of Analysis	v	v
Change Control Notification	v	v
Product Specification	v	v
Incoming Raw Material Specification & Testing	v	
Expiry or Retest Date	v	v
Supplier Qualification	v	
Identification of Critical Process Parameters	v	
Batch Manufacturing Record & Review	v	
Lot Sample Retained	v	
Dedicated Project Management	v	
Classified clean room ISO7 (10.000)	v	
Validation	v	

Services

Trusted Quality

Production in classified cleanrooms (ISO7). Solid Quality Management System.

Analytical Services

Large panel of QC analytical methods. Method Validation & Stability studies.

Short Lead-times

Streamlined Process and cleanrooms for efficiency.

Simple to Complex

Incorporate unnatural amino acids, dyes or structural modifications.

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