AnaSpec's GMP Compliance Verification by PSC Biotech

AnaSpec meets cGMP for Phase 1 drug substance production, per PSC Biotech inspection.

FREMONT, CA, US, April 26, 2024 /EINPresswire.com/ -- PSC Biotech inspection results: AnaSpec meets the requirements to produce Active Pharmaceutical Ingredients (Drug Substance) according to current Good Manufacturing Practices (cGMP) for phase 1 clinical trials.

Ready to manufacture cGMP API (drug substance) peptides ：

AnaSpec was successfully audited by PSC Biotech on the following areas related to the manufacturing and testing of GMP grade materials:

- Quality Management System (QMS) and Regulatory Compliance
- Buildings, Facilities and Equipment
- Material and Sample Management
- QA Department
- QC Laboratory (In-house and external labs)
- GMP Manufacturing areas and processing areas
- GMP cleaning processes
- Validation and Data Integrity

It is the auditor's evaluation that AnaSpec has the systems, policies, and procedures in place to

produce cGMP API (Drug Substance) for phase 1 clinical trials that meet internal and external standards and industry guidelines.

Strengthening Anaspec's position as a global manufacturer of custom peptides :

Manufacturing GMP API peptides will complement our current production offering, expanding from research and discovery to Phase I clinical trials.

Dr. Veronique Mainfroid, AnaSpec's Deputy President said, "AnaSpec is one of the few companies manufacturing highly complex peptides.
This acknowledgment by regulatory experts underscores our quality standards, as it unambiguously sets our quality level at the top.
Embarking on a new chapter in our manufacturing capabilities, we are ready to seamlessly guide our clients through every stage, from initial discovery to the final release of their GMP API batches.
We are proud to offer a continuum in our expertise, customer support, and quality."
This move will allow us to respond to the needs of customers who prefer to work with one flexible provider for streamlined, uninterrupted peptide service, from small to large scales.

State-of-the-art highly controlled cGMP cleanroom areas :

Our cGMP facilities feature separate state-of-the-art restricted upstream and downstream areas for proper material segregation.

It includes our highly controlled cleanroom areas that are certified to meet ISO 14644 Class 7 standards. All areas are fitted with advanced synthesis and purification equipment for efficient manufacturing of peptides that meet the customers pre-determined specifications and requirements.

About AnaSpec, Inc :

Established in 1993, AnaSpec a subsidiary of Kaneka Eurogentec S.A., is a globally recognized biotechnology company that manufactures and sells quality catalog and custom R&D, cGLP, and cGMP proteomic related products and services for the biopharmaceutical industry, diagnostic companies, agro-food firms, academia and governmental agencies.

Headquartered in Fremont California, AnaSpec specializes in the manufacture of custom and catalog Peptides, Enzyme Assay Kits, Fluorescent Dyes, Recombinant Proteins, Amino Acids, and other related reagents. As a pioneer in custom peptide synthesis services, AnaSpec offers expertise in the production of unmodified to complex modified peptides including Macrocyclic peptides, Fluorescent peptides, Lipopeptides, Glycopeptides, Metal-chelator peptides, and many other modification types. Over the past 30 years, more than 1,835 customer-owned patents have been issued that reference AnaSpec products and services.

About PSC Biotech® :

PSC Biotech® based in Pomona California, has over 25 years of experience working with organizations to meet cGMP regulatory compliance requirements by providing oversight, investigations, gap assessments, and auditing services, to such industries as the biotech, pharmaceutical, medical device, chemical, cosmetic, food and beverage sectors. With offices across North America, Europe, and Asia, PSC operates in 52 countries globally and has served thousands of clients.

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