PolyPeptide Group

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Meeting the growing demand for peptide therapeutics

The PolyPeptide Group is a leading manufacturer of peptide-based drugs worldwide, providing 50 years of experience, GMP production on 3 continents and unsurpassed security of supply.

Although peptide-based drugs have been commercially available since the 1950s, interest in these pharmaceuticals has boomed in the last two decades. In 2012, global sales were close to or more than $1 billion each for the peptide pharmaceuticals copaxone, leuprolide, goserelin, octreotide and liraglutide, and sales of hPTH(1-34) and exenatide were close behind.

In addition, the average number of new peptides entering Phase I clinical studies has risen from 5 in the 1980s, to 10 in the 1990s, to an average of 17 in each of the last 2 decades. In 2012, eight peptide therapeutics were approved—the most ever in a single year. Today, several hundred peptides are in various stages of preclinical and clinical development.

This upswing is due to recent advances in genomics that have identified new targets for peptide pharmaceuticals, coupled with the fact that peptides can be safer and more selective than small molecule drugs.

The PolyPeptide Group is a world leader in peptide manufacture, from industrial-scale pharmaceuticals for human and veterinary use to small-scale custom peptides for academic and government researchers. The company is committed to excellence in peptide chemistry and understands the needs of each of its customers, which range from small biotech startups to major pharmaceutical corporations, and supports them with a complete range of services to move their projects from inception to commercialization.

The Group has had manufacturing sites in Denmark, Sweden, France and the U.S. for many years and recently added a site in India to address the growing capacity requirements of its customers. With ongoing expansion, the PolyPeptide Group can support multiple projects at a variety of scales. Altogether, the facilities worldwide total more than 17,500 square meters, with solution phase reactors from 160 to 1,000 liters and solid phase reactors from 2 to 280 liters, and the capability to manufacture peptides in quantities from milligrams to 100 kilograms.

Multiple sites worldwide also ensure security of supply for clients. “We can have backup manufacturing at any site,” explained Trishul Shah, business development key account manager for PolyPeptide Laboratories in Torrance, California. Security of supply is bolstered further by the facts that the Group is privately held and has a well-defined focus on peptides.

Shrinking the Group’s environmental footprint is another priority. Environmental initiatives include reducing waste, recycling waste solvents and eliminating the use of toxic chemicals by switching to safer alternatives. Notably, the Danish Environmental Protection Agency has classified PolyPeptide Laboratories A/S in Denmark as a top green company.

Comprehensive GMP services

The PolyPeptide Group meets the needs of clients at all stages of pharmaceutical peptide development, from preclinical studies through to commercialization. Regulatory agencies require GMP for pharmaceutical production, and the Group’s comprehensive GMP package includes GMP-conforming manufacture of peptides in quantities from milligrams to 100 kilograms as well as all services needed to obtain regulatory agency approval. These services include development, optimization and validation to obtain robust, scalable and economic processes. The Group is also leader in the ‘risk-based approach’ to pharmaceutical manufacturing that is now recommended by the FDA.

“There are a lot of companies making peptides worldwide, but we are one of the few that has FDA approval for commercial manufacture of peptide-based active pharmaceutical ingredients [APIs],” Shah said. The PolyPeptide Group manufactures more than 25 approved peptide APIs, which represent about one-third of all peptide APIs globally approved as therapeutics. These APIs are a mix of proprietary and generic drug substances. Major generics produced by the company include leuprolide, desmopressin, octreotide and salmon calcitonin. Moreover, the Group’s San Diego site is one of largest manufacturers of peptide vaccines in the U.S.

In addition to its experience with the FDA, the PolyPeptide Group has extensive experience with regulatory authorities globally. The company has filed Drug Master Files in Europe, Japan, Korea, Australia and other parts of the world.

Moreover, all manufacturing sites have process and analytical development teams that collaborate with each other to identify the best production processes for each API. The Group invests heavily in process development early in each project, which avoids potential delays later in the campaign, and consistently looks for improvements in its manufacturing processes. By achieving process excellence and minimizing variation, the company reduces lead times and boosts production capacity.

Custom research services

Research-grade custom peptide synthesis is another service offered by the PolyPeptide Group, which has contracted with the NIH for nearly two decades to provide research and clinical-grade peptides in milligram to multigram quantities. Modifications for custom research peptides include biotinylation, cyclization and phosphorylation, and labeling with fluorescent dyes, as well as stable and radioactive isotopes. Services for immunologists range from basic peptide conjugation to complete polyclonal antipeptide antibody production and affinity purification.

PEGylation and conjugation services

The PolyPeptide Group’s services also include bioconjugation, which can overcome some of the challenges peptide therapeutics face regarding short half-lives. Peptides containing only naturally occurring amino acids are typically degraded within minutes by enzymes *in vivo*. However, the half-life of circulating peptide drugs can be boosted as much as 100-fold by conjugating the peptides to molecules that are larger and less easily metabolized, such as polyethylene glycol (PEG). “We have a high level of expertise in PEGylation and conjugation of peptides to biological moeties,” said Shah.

In summary, the PolyPeptide Group is committed to the highest quality of peptide manufacturing, from the simple to the complex, as well as from small-scale custom peptides to GMP peptides in clinical trials to large-scale production of approved drug substances. Each client receives the same level of attention to optimizing process development, which minimizes impurities and maximizes efficiency when scaled up to commercial production. “We are known for quality,” Shah noted. “And we have some of the brightest peptide scientists in the industry.”

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