

The PolyPeptide Group is a privately held company focused primarily on the manufacture of GMP peptides for the human and veterinary pharmaceutical markets. The Group employs 450 trained staff at six separate manufacturing sites across three continents: Denmark (Hillerød), France (Strasbourg), India (Mumbai), Sweden (Malmö) and the USA (San Diego and Torrance). With more than 50 years of experience producing therapeutic peptides the Group is one of the world's leading peptide manufacturing organizations.

Peptide manufacturing services range from small-scale non-GMP custom synthesis for basic research and lead discovery, through support for pre-clinical studies and on to pre-GMP development of large-scale manufacturing processes. The range of peptide structures manufactured at the PolyPeptide Group according to GMP extends from dipeptides up to the most complex structures being developed in today's therapeutic market. These include conjugates with PEG, lipids, and non-peptidic components as well as peptides with multi-cyclic, branched, and substituted sequences. Exotic amino acids and other organic chemicals can be developed in-house. By rigorous integration of analytical development into all aspects of R&D, the Group ensures that all products are of the highest purity. GMP manufacturing scale ranges from gram lots through to multi-10 kg quantities. By careful and ongoing harmonization of procedures and technology across the individual sites, the Group can offer local development of manufacturing processes with the potential to transfer the identical process to a second site as requirements grow.

The Group has a long history of cGMP-compliant manufacture and has successfully undergone more than 15 FDA Pre-Approval and Site Inspections. Altogether, the Group has more than 20 approved drug substances worldwide. The generic portfolio of the PolyPeptide Group includes established drug substances such as Calcitonin, Desmopressin, Leuprolide and Octreotide, as well as a continually expanding range of new products including Eptifibatid, Bivalirudin, Exenatide and hPTH (1-34). GMP services include support for all regulatory and approval processes, and full documentation is provided for all products.

The PolyPeptide Group also offers a full spectrum of complementary services for peptide projects, including a comprehensive catalogue of more than 1,250 bioactive peptides; a dedicated catalogue section includes more than 750 special amino acids and derivatives, building blocks and turn mimics, all available from stock. Other services include manufacture of research grade peptides, stable and radio isotope-labeled peptides, and production of anti-peptide antibodies. Custom synthesis of non-peptidic molecules from grams to several hundreds of grams as well as cGMP manufacturing at the kilogram scale can also be provided.

With its exclusive focus on peptides, a solid financial base, multiple manufacturing sites and a proven and established track record with regulatory agencies, the PolyPeptide Group offers an almost unique security of supply to its customers.

CONTACT INFORMATION

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Large-capacity shelf freeze dryer for cGMP manufacturing



200-litre reactor for solid phase peptide synthesis