

**PolyPeptide Group** — a Contract Development & Manufacturing Organization. Your flexible, transparent and technically innovative partner from the simplest to the most **complex peptides** 



## COMPANY PROFILE

PolyPeptide is a Contract Development & Manufacturing Organization (CDMO) focusing on proprietary and generic GMP-grade peptides used by pharmaceutical and biotech companies in approved pharmaceutical products, drugs in clinical development as well as in generic products.

Dating back to 1952, PolyPeptide today manufactures around one half of all currently approved peptide drug substances with a global footprint of six GMP-certified facilities in Europe, the U.S. and India. As a multinational company with more than 1000 employees, its diversity brings breadth, depth of knowledge and experience to the group. PolyPeptide has grown organically and by selective acquisition of existing expertise, culminating in its position today as a leader in outsourced peptide manufacturing. PolyPeptide's shares (SIX: PPGN) are listed on SIX Swiss Exchange.



**Our mission** is to create customer satisfaction and foster long-term customer loyalty through excellence in peptide technology, quality, value, service and customer support.

Our goal is to assist our clients at every step of product development; from early stage development to commercial GMP grade manufacturing.

Our customers are our focus. We strive to be your preferred partner from simple to complex peptide manufacturing by consistently providing you with the highest quality products and services.

Manufacturing Facilities

More than 1000 Employees

From the Simplest to the Most Complex Peptides

Total Commitment to

# Quality

Over / O years' experience of manufacturing API's

30 approved peptide-based API's

## SOLUTIONS

## From Conception to Commercialization

from initial gram quantities to commercial per batch.



#### R&D

- \_ Small Scale
- \_ Research Grade
- \_ Custom Peptides
- \_ Radiolabeled Peptide

#### Pre-Clinical Manufacturing

- Preclinical and Toxicology Batches
- Process Development
- Analytical Method Development

#### GMP Phase I to Phase III

- \_ Drug Substance Supply
- Process Scale Up & Optimization
- Process Qualification and Validation
- \_ Analytical Method Qualification and Validation
- CMC Documentation

#### Approval

- \_ Regulatory Support
- \_ DMF, ASMF, COSs, ...
- Pre-Approval Inspection

### Commercial Manufacturing

- \_ Small to Large Scale
- Commercial Batches
- Peptides for Diagnostic Applications
- Peptides for Cosmetic Use

#### Generic Peptides

- For Human and Veterinary Markets
- \_ Available for your needs
- \_ Regulatory Documentation (DMF, ASMF, COSs,...)



## PRODUCT PORTFOLIO



## **GMP** services

The Manufacture of GMP grade peptides is the core business at PolyPeptide Group. With over 1000 peptides manufactured under GMP conditions within the Group, we offer the expertise to develop the most efficient processes to design, cost-effective and sustainable production.

# Custom Peptides for R&D & Lead Optimization

The PolyPeptide product line includes manufacture of custom research grade peptides, stable and radioactive isotope labelled peptides and peptidomimetic molecules.



# Individualized Peptide Therapeutics

The PolyPeptide Group is a major player in Individualized Peptide Therapeutics. The NeoAntigen PolyPeptide (NAPP™) operation is located within the GMP manufacturing area and follows GMP standards.



## Generic API Portfolio

The PolyPeptide Group manufactures a large range of generic peptide APIs at commercial scale for the human and veterinary markets.

Our Generic APIs are used for many different Therapeutic areas, such as:

- \_ Endocrinology, musculoskeletal
- \_ Obstetrics, gynecology
- \_ Cardiovascular diseases
- \_ Veterinary

- \_ Pediatrics
- \_ Anesthetics
- \_ Nephrology
- \_ And more...

# Cosmetics

Peptides are important ingredients in global cosmetic products and international brands, primarily for anti-aging applications. Peptides have various cosmetic benefits and each peptide used in products has a specific activity; irming, anti-wrinkle, anti-irritation and reduction in pigmentation. Our long standing experience of clinical grade peptide manufacture applies equally to cosmetic peptides. PolyPeptide adapts the quality standards to the cosmetic market needs.



The PolyPeptide Group produces one third of the commercially approved peptides in the world. Our experience in process development, manufacturing scale up, and regulatory filing makes us a trusted and reliable partner, a key benefit to our clients.







## Oligonucleotides

We aim to become the partner of choice for the development of Oligonucleotide API. With customer R&D activities at elevated level, we support early-stage projects with GMP capabilities, process and analytical development as well as regulatory support, building on our vast experience in Peptide API development and GMP manufacturing.



## Quality

Our goal is to design and develop manufacturing processes able to reproducibly generate product of consistent quality. Quality is also part of every step of our development process; from preliminary interactions with customers prior to the start of a project through to later phase discussions and ongoing communication and support after product delivery.

Quality continues after product release, with supporting stability studies, and assisting clients with regulatory filings.

# Technology & Innovation

Continuous improvement of Peptide Manufacturing: the optimization of existing techniques, introduction of new technologies, implementation of greener processes, in line monitoring and automation are integral to the group's growth and sustainability.

With our industry leading position, we have created a strong international network to identify, develop and promote new concepts on disruptive technologies that will significantly impact the way we develop and produce peptides in the near future.

# Regulatory Support

Regulatory requirements for peptide drug substances are unique and continually evolving. The PolyPeptide Group has the experience and the knowledge to assist and advise its customers through every step and change in the regulatory approval cycle. PolyPeptide Group's regulatory support includes preparation of all documents related to the drug substance required by the regulatory authorities. Regulatory support also includes assistance in meetings with regulatory agencies and, preparation of responses to questions from regulatory authorities in connection with the review of regulatory submissions.

To learn more about our experiences and the PolyPeptide Group, please visit www.polypeptide.com







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