Thank you for your continued support and for the confidence you have placed in the PolyPeptide Group. Our goal is to be your preferred partner for peptide manufacturing by consistently providing you with the highest quality products and services. Whether you require peptides for early development, or GMP-grade peptides for clinical trials or commercial manufacturing, our total commitment to customer satisfaction is what sets PolyPeptide apart from the competition.

With six sites across three continents we continue to build on our global knowledge base to solidify our position as a global leader in peptide manufacturing and technology. The recent addition of the Belgian manufacturing site to our team further enhances our capacity to provide you with an unparalleled level of support, regardless of the scale of the project or the complexity of the peptide.

We strive to ensure your satisfaction with every project, every time. We constantly look for new and innovative technologies to achieve improvements in product quality, process efficiency and greener technologies. Our quality and regulatory groups continue to upgrade our systems to be as efficient as possible without compromising our excellent regulatory inspection and API approval track record. And our project management and support teams continue to look for ways to improve the customer experience with PolyPeptide by providing open, transparent communication through the entire project.

The combination of technical excellence, quality and regulatory experience and total commitment to customer satisfaction that exists within the PolyPeptide Group is second to none and represents your guarantee of success for any peptide manufacturing project undertaken. We hope you will make PolyPeptide your preferred peptide manufacturing partner.

Jane SALIK
CEO, PolyPeptide Group

Dear Customer,

[Image of a person]

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Jane SALIK
CEO, PolyPeptide Group

[Timeline]

1952
START OF COMMERCIAL THERAPEUTIC PEPTIDE MANUFACTURE AT MALMÖ IN SWEDEN

1996
FOUNDING OF THE POLYPEPTIDE GROUP IN HILLERØD, DENMARK AND TORRANCE, USA

1997
OPERATIONS START IN TORRANCE, USA

1998
ACQUISITION OF WHERL GMBH AND PRAGUE POLYPEPTIDE LABORATORIES SRO

2006
START OF CONSTRUCTION OF INDIAN FACILITY NEAR MUMBAI
The PolyPeptide Group, which employs about 800 staff at sites in Belgium, France, India, Sweden and the USA, is one of the world’s largest independent contract manufacturers of therapeutic peptides.

The privately-held organization manufactures over one third of all approved peptide drug substances and accounts for ~30% of the sales of outsourced peptide therapeutics worldwide. The Group offers its customers an unprecedented long-term security of supply with six GMP facilities worldwide and an exclusive focus on pharmaceutical peptide manufacture.

The PolyPeptide Group has identified critical roles and set up Global Directors who are responsible for coordinating those roles at the different sites. This ensures the use of technology and expertise across the globe and guarantees the same level of quality regardless of the site of manufacture.

**KEY FIGURES**

- **6** production sites worldwide
- **Over 1000 kg** of peptides per year
- **Over 1000** GMP peptides produced
- **Over 50** successful regulatory inspections

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**2007**
- **ACQUISITION OF THE NEOMPS GROUP**

**2008**
- **OPENING OF NEW MANUFACTURING PLANT IN STRASBOURG, FRANCE**

**2009**
- **ACQUISITION OF A NEW BUILDING IN TORRANCE, USA**
- **EXPANSION IN MALMÖ, SWEDEN**
- **INAUGURATION OF THE FACILITY IN INDIA**

**2012**
- **22 COMMERCIAL PRODUCTS MANUFACTURED AT POLYPEPTIDE**

**2017**
- **POLYPEPTIDE GROUP ACQUIRED THE NEW BUSINESS AND OPERATIONS OF LONZA IN BRAINE-L’ALLEUD, BELGIUM**
We encourage our clients to discuss and sign a Quality Agreement with PolyPeptide before the start of any clinical grade peptide project.
Quality is part of every step of the development process; from initial discussions with the client before the start of a project to discussions and support after product delivery.

This includes recognition of Quality when generating a quote, confirming an order, designing the most suitable manufacturing process, controlling product quality at each production step, informing clients in a timely fashion, conducting finished product testing, generating the Certificate of Analysis (CoA) and releasing the final product.

Quality still continues after product release, when conducting stability, and assisting clients with regulatory filings.
PRE-GMP DEVELOPMENT
The designed manufacturing scheme is applied to the production of the initial pilot lots and pre-GMP animal toxicology lots.

GMP COMPLIANCE & REGULATORY SUPPORT
At the PolyPeptide Group, peptide active pharmaceutical ingredients (APIs) are manufactured in compliance with ICH guidelines including Q7 and other related and applicable sections. Manufacturing is performed in facilities which have been inspected by the US FDA and several other regulatory authorities, either for routine site inspections or for approval of specific products.

Our regulatory support includes assistance in the preparation of all documents required by the regulatory authorities. This includes generation of a pre-IND meeting dossier or package, a CMC section for an IND filing, assistance with responses to questions by the reviewing agencies, visiting the regulatory authorities at the request of the client, if necessary, and NDA filing.

PRODUCTION
The PolyPeptide Group specializes in developing small-scale to large-scale production processes for proprietary peptides. Whether you require gram or multi-kilogram quantities, we can support your custom or generic project at every development step and every quantity requirement, even with the most complex peptides.

With our proprietary technologies, established global network of scientists and state-of-the-art production facilities, the PolyPeptide Group has the capabilities and capacity to deliver your peptide products in an efficient and timely manner. From IND to NDA, our regulatory team will provide all documentation to ensure product approval success and commercial production. The PolyPeptide Group manufactures a third of the peptide API’s approved in the world.
Using a full range of synthetic technologies and methodologies, we manufacture peptides up to 80 amino acids in length, or more, and in quantities ranging from milligram/gram to multi-10 kg, and even to multi-100 kg quantities. Our robust, carefully designed, and cost effective manufacturing processes will help optimize the value of development and production of your product from pre-clinical to commercial scale.

SOLID PHASE PEPTIDE SYNTHESIS (SPPS)
SPPS is the technology of choice for the manufacturing of most peptides in multi-10 kg quantities or more, especially those with longer, more complex sequences. We offer both Fmoc- and tBoc-based solid-phase manufacturing.

LIQUID (SOLUTION) PHASE PEPTIDE SYNTHESIS (LPPS)
LPPS is in general the technology of choice for the large scale manufacturing of short peptides or structures that are not easily prepared on a solid support. This approach ultimately provides cost-effective processes for the large-scale manufacture of multi-10 kg to multi-100 kg lots.

HYBRID FRAGMENT SYNTHESIS
This technology involves coupling shorter, SPPS generated sequences together in solution. It is particularly suitable for some longer peptide structures, offering higher yields than sequential SPPS.

CYCLIZATION
Our experience includes the manufacturing of commercial peptides containing a single or multiple disulfide bridges. It also includes the manufacturing of lactam peptides cyclized through the formation of an amide bond. Some projects may require both forms of cyclization within the same molecule.

PURIFICATION
Using our modern preparative high-pressure liquid chromatography (HPLC) technology, the PolyPeptide Group is capable of achieving or exceeding the required purity of products at almost any scale, from a few grams or less to a 100 kilograms or more.

Purification techniques include the following:
- automated reverse-phase HPLC with columns up to 60 cm in diameter;
- ion exchange chromatography with columns up to 1 meter in diameter;
- size exclusion chromatography up to 1 meter in diameter.

ISOLATION
Final isolation of peptides is typically achieved using bottle and tray lyophilizers (up to 260 kg ice capacity) permitting the isolation of single lots of up to 10 kg for highly soluble peptides.

Depending on the nature of your API, alternative isolation procedures such as precipitation, crystallization, and spray drying, are also available and can be scaled to process significantly larger single lots than lyophilization could permit.
CAPACITY AND CAPABILITIES
When custom products are considered, assessing the capacity is always product dependent; the higher the overall production yield, the higher the output with the facilities and existing equipment and therefore the larger the capacity.
The PolyPeptide Group offers the flexible capability of Liquid Phase, Solid Phase, or Hybrid approaches for peptide synthesis. Not all commercial peptides require large quantities, however, for those projects that require high output, PolyPeptide offers a manufacturing capacity of over 250 kg of peptide using Liquid Phase Peptide Synthesis, and over 500 kg using the Solid Phase Peptide Synthesis approach.

PROCESS DEVELOPMENT AND OPTIMIZATION
Process development starts at an early stage, when all possible routes of synthesis are reviewed by the global development team in order to implement the most suitable type of chemistry. The developed manufacturing process is optimized over the course of the product life cycle, particularly when advancing to be used in Phase II or III clinical trials. To avoid potentially discovering new impurities at a later stage of product manufacturing, an analytical method for purity determination and product stability indication is typically developed at an early stage. Validation of analytical methods is always performed for releasing material to be used in Phase III trials and beyond.

COMMERCIAL MANUFACTURING
GENERIC PEPTIDES
The PolyPeptide Group manufactures a range of peptide-based generic APIs at commercial scale for the human and veterinary market.
One of the world's top leading manufacturers of Generic Peptides.
Over 50 years' experience of manufacturing API's (Active Pharmaceutical Ingredients).

LATE STAGE DEVELOPMENT
The data gathered from the manufacturing of the early phase lots is summarized in a report. This report serves as the basis for the product's late stage development activities also referred to as pre-Process Validation activities.

These pre-Process Validation activities can be divided into three general parts:
1/ Risk Assessment, where the critical parameters are identified and rated using an internal system in order to determine if further process evaluation and experiments are required.
2/ Hold Time Studies, typically performed on a lot before starting Process Validation in order to determine the shelf life of key intermediates.
3/ Operational Range finding studies and Design of Experiments (DOE's), are performed as part of the late stage development and before the process validation activities.

The activities above are performed in order to reach the necessary operational parameters that will minimize the risk of failure during process validation and commercial manufacturing.

Full GMP documentation and support with required regulatory documentation such as European and US Drug Master Files and Certificates of Suitability.
A global presence with six US FDA approved GMP manufacturing sites throughout the world.
OUR GENERIC API PORTFOLIO:

ACTH (Corticotropin)
Atosiban
Bivalirudin
Calcitonin
Carbetocin
Deslorelin
Desmopressin
Eptifibatide
Exenatide
Felypressin
Glucagon, HCl
Gonadorelin Acetate / HCl
GRF (1-29) Amide
Lanreotide
Leuprolide
Liraglutide
Octreotide
PTH (1-34) / Teriperatide
Somatostatin
Triptorelin
Vasopressin, 8-L-Arginine

The range of generic products is continuously expanding—please scan or visit our website for the latest version.
Your Peptide needs, from R&D to GMP Manufacturing, PolyPeptide provides **Global Support** for a **Quality Solution**
PolyPeptide Group

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