Polypeptide Therapeutic Solutions (PTS) specializes in Custom Manufacturing of polyaminoacid-based Drug Substances and Drug Products (DP). Our company provides a comprehensive CMC package, including Preclinical Development, Technology Transfer, GMP Manufacturing and Fill&Finish.

**PTS IS A LEADER IN GMP MANUFACTURING OF POLYAMINOACID-BASED THERAPEUTICS**

Excellent feedback from regulatory agencies on the CMC packages delivered to date from both EMA and FDA. Consistent reproducibility across the different project stages and scales. GMP certificate from Spanish authority based on part 2 2001/83/EC Directive.

We get there faster, with cost efficient and mitigated risk approach.

Our team will integrate within your company workflow with full transparency, performance, diligence and flexibility.
PTS provides complete support to transition from R&D, prototype optimisation, GLP TOX studies, clinical trials and market authorization through a comprehensive and step-wise process development and scale-up approach. 8 Clean Rooms (4 GMP suits) fully equipped to manufacture any type of polyamino acid-based therapeutics.

Our company can perform formulation screening for your drug product and provide GMP Fill & Finish of aseptic vials and other non aseptic formats in small batches (15,000 vials) to support your (pre)clinical development.

PTS´s QC scientists support the development of Drug Substances through the entire project life-cycle. Equipment and skills are specially suited but not limited to method development, validation and stability studies. All analytical work is performed using state-of-the-art, GMP & GLP qualified, equipment and facilities.

PTS runs cell-based, in vitro transfection, drug potency and immunogenicity evaluation. We offer biodistribution, PK and PD studies.
### POLYAMINO ACID BASED THERAPEUTICS

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<th>Biodegradability</th>
<th>Higher Molecular Weight</th>
<th>High water solubility</th>
<th>Reduced immunogenicity</th>
<th>Multivalency</th>
<th>Enhanced Cargo Loading</th>
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**WHAT’S NEXT**

**Design R&D**
- Polymer Design
- Endotoxin Controlled Material
- Complete QC
- 2-3 months

**Functional Proof of Concept**
- In vitro, In vivo models
- 1-3 months

**Lead Candidate Optimization**
- Optimized Polymer Performance
- 1-2 months

**GLP TOX Batch**
- Process and Analytical development
- CMC development: ICH compliant
- Full support: Documental and regulatory support for (pre) IND/IMPD submissions
- 3-6 months

**GMP Clinical Batches**
- GMP compliant: according to EU and US Guidelines.
- Validable: QCs: according to USP and European Pharmacopeia
- Fully Support: Quality-regulatory batch documentation
- 6-9 months

**Full commercial supply**

Please contact Dr. Vicent Nebot at vnebot@pts-polypeptides.com or Dr. Sergey Rakhilin at srakhilin@pts-polypeptides.com 914-8063188