PRECISION POLYMERS FOR DRUG DELIVERY

Custom Manufacturing Capacities (CDMO)

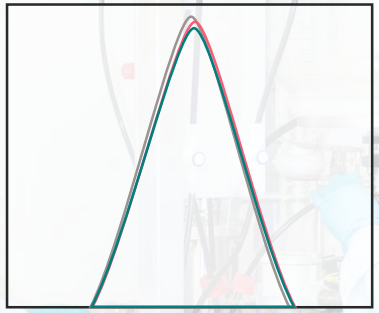
CDMO - Services

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

Expertise

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.



Save Cost & Time

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

Average project timeline

80 Days I Preclinical GLP TOX BATCH

45 Days I Feasibility

120 Days I IND Enabling GMP Batch

Flexible Schedule

Our team will integrate within your company workflow with full transparency, performance, diligence and flexibility.

CDMO - Capacities

Drug Substance

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 equiped to manufacture any type of polyamino acid-based therapeutics.

Drug Product

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.

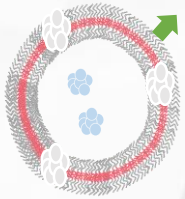
Analytical Development & QC

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.

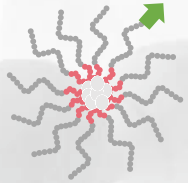
Bioanalytical Development

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

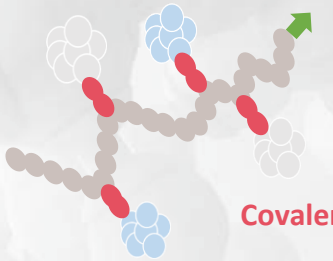
POLYAMINO ACID BASED THERAPEUTICS



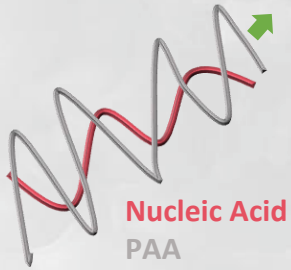
Polymersomes (Vesicles)



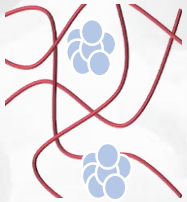
Micellar structures



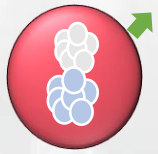
Polymer Drug Conjugates (PDCs), Polymer Biomolecule Conjugates (PBCs), *New Chemical Entities.*



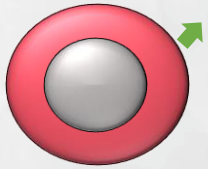
Polyplexes (Non-Viral Vectors)



Hydrogels



PAA nanoparticle Nanoparticles (NPs)



PAA coated Nanoparticle

Lipophilic/Hydrophilic/Targeting Actives /Drugs/Directing groups

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Biodegradability **Higher Molecular Weigth** **High water solubility** **Reduced immunogenicity** **Multivalency** **Enhanced Cargo Loading**

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[1]Conejos-Sanchez, I. et a., Polymer Chemistry, **2013**, 4, 3182; [2]Deming T. J., Chem. Rev., **2016**, 116, 786; [3]González-Henríquez C.M. et al., Polymers, **2017**, 9, 551; [4]Byrne M. et al., Macromol. Rapid Commun. **2015**, 36, 1862; [5]Duro-Castaño A., Biomater. Sci., **2015**, 3, 1321; [6]Habraken G. J. M. et al., Macromol. Rapid Commun. **2011**, 33, 272−286; [7] Heise A., Chem. Soc. Rev., **2013**, 42, 7373; O. Zagorodko, *Macromolecular Bioscience,* **2017,** 17 , 1600316.

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

Please contact Dr. Vicent Nebot at
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914-8063188

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