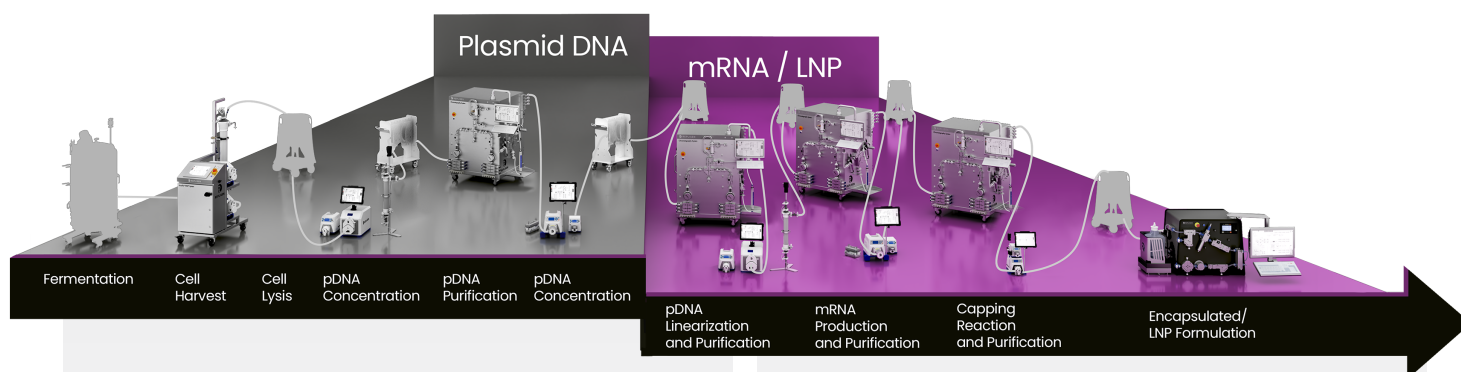


Accelerating pDNA / mRNA Manufacturing

End-to-end manufacturing solutions

With the proven success of mRNA-based vaccines in addressing the Covid-19 pandemic, mRNA technology is at the forefront of transforming the world of medicine, and the biopharma industry has ongoing clinical trials to develop both vaccines and therapies to treat infectious diseases and even cancer. pDNA is a critical raw material and acts as a template for mRNA manufacturing. Although cell-free, the IVT mRNA process workflow is impacted by low process yields and scalability challenges. Repligen technologies are uniquely suited to help overcome these challenges in process development and manufacturing at the commercial scale for pDNA and mRNA.



Challenges

Global high demand

- Scalability and cost effectiveness
- Accelerate speed to market
- Shear sensitivity
- Low productivity and purification yield

Product quality

Product quality and purity

- pDNA: open circular pDNA removal
- mRNA: removal of rDNA, dsRNA, RNA fragments, non-encapsulated LNPs

Limited process knowledge

- Limited scale-up process and implementation experience
- Lack of in-line process monitoring for cell and cell-free platforms

Solutions

Increased pDNA and mRNA yield

Optimized vector production

- pDNA: Intensify microbial growth for pDNA production with perfusion-based technology
- Simplify manufacturing process by replacing centrifugation with microfiltration TFF
- On-line pDNA product purity monitoring (Process Analytical Technology)

Fully scalable Chromatography and TFF equipment designed for low shear and low hold-up volume performance, maximizing product purity and recovery

Increased pDNA and mRNA quality

- Fully sterile and closed automated systems with single-use flow paths
- Pre-packed columns enable purification and process consistency
- Analytical in-line technology

Expert consultation

Hands-on process and implementation approach from recognized Gene Therapy, oncolytic and vaccines industry experts



pDNA/mRNA Manufacturing Technologies



XCell ATF® Systems

- Scalable, single-use cell retention
- Higher viable cell density and total pDNA titer



Hollow Fiber Filters

- Wide range of membrane formats, chemistries and pore sizes
- Recommended MWCO for TFF1: 10-300 kDa



SIUS® Gamma Flat Sheet Cassettes

- Fully assembled, irradiated cassettes for high flux performance and reduced process time
- Recommended MWCO: 10-300 kDa



KrosFlo® TFF Systems

- Automated hollow fiber or flat sheet TFF
- Ideal for shear-sensitive vectors with low hold-up volume



OPUS® Pre-packed Columns

- Broad range covering process development and commercial manufacturing requirements
- Pack any resin for plasmid and mRNA purification

KRM™ Chromatography Systems

- Superior gradient control, higher peak resolution, high yield
- Ready-to-operate single-use flow path



FlowVPX® Device

- In-line PAT monitoring in downstream
- Applications in pDNA, mRNA and LNP manufacturing



Fluid Management Solutions

- State-of-the-art valve and tubing technology
- Designed-for-purpose transfer and containment assemblies



ProConnex® Flow Paths

- Single-use, sterile, configurable flow paths
- Plug and play fluid management

Meet our experts



Rachel Legmann

Sr. Director of Technology,
Gene Therapy

Rachel Legmann is a subject matter expert focusing on gene therapy processes in upstream, downstream, analytics and scalability areas. She has over 20 years' experience in scalable biologics and gene therapy manufacturing of therapeutic products, viral vectors and proteins for gene therapy.



René Gantier

Sr. R&D Director, Advanced
Bioprocess Applications

René Gantier has 20 years of experience developing production and purification processes for biotherapies. He leads the development of advanced bioprocess applications and technologies with a focus on next-generation cell and gene therapy manufacturing processes.

[Learn more or
contact our team](#)

