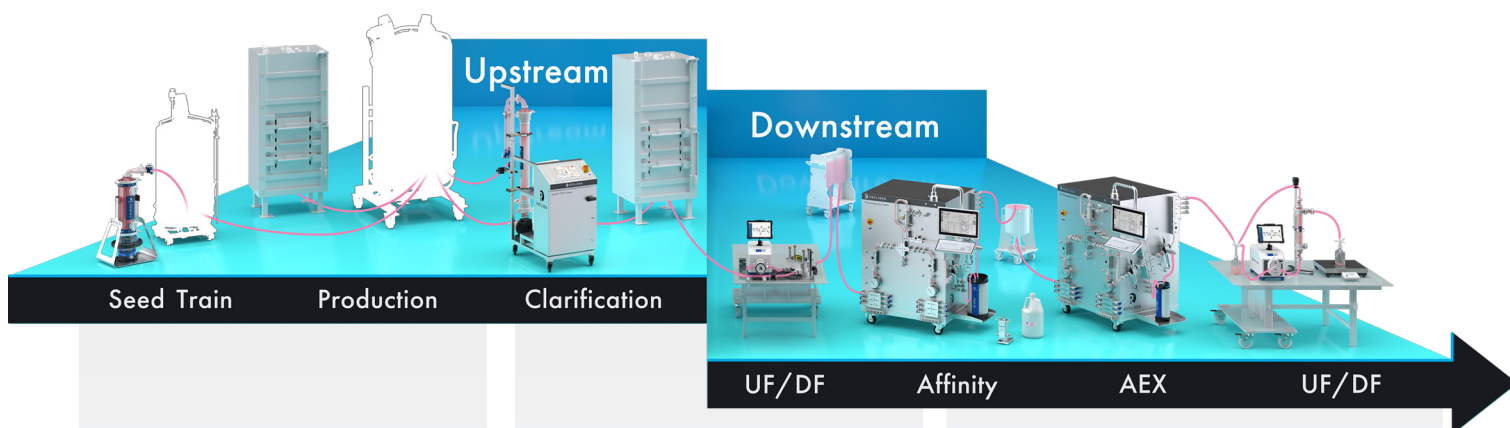


Gene Therapy Manufacturing 2.0

End-to-end process-intensified solutions for Gene Therapy manufacturing

Repligen offers unique and innovative technologies with in-depth process expertise to help intensify your gene therapy manufacturing processes at every step of the workflow.



Challenges

Low yields

- Low viable cell density in production bioreactor during transfection
- Multiple harvests
- Low purification recovery

Complex workflows

- Triple plasmids transfection and viral vector production
- High seed train volume
- Lysate clarification
- Inefficient downstream purification

Limited process knowledge

- Lack of standard platform for various modalities: AAV, Lentivirus, pDNA, exosomes
- Limited scale-up and/or implementation experience

Solutions

Increased yield

- Optimized vector production
 - Increased viable cell density with process intensification
 - Continuous harvest and clarification
- Optimized purification
 - High-throughput process development for resin optimization
 - Gene Therapy-specific affinity resins
 - Low shear/hold-up volume downstream equipment

Simplified workflow

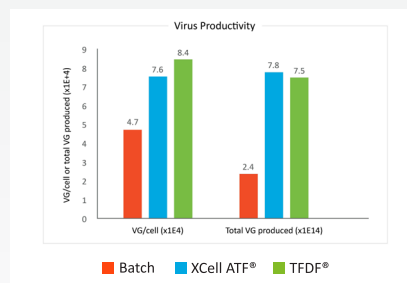
- Increased viable cell density in N-1 bioreactor
- Integrated perfusion and clarification steps
- Single-use fluid management

Expert consultation

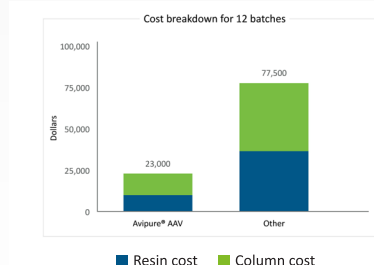
Hands-on process and implementation support from recognized Gene Therapy industry experts

Results

2X increased upstream productivity with process intensification



Significant cost reduction with caustic stable resins



Increased throughput, reduced filtration surface area, fewer steps

Post-lysis recovery of AAV8 particles

5 µm depth filter 23 L/m ² throughput 9 m ² surface area	2-5 µm TFDF® filter 300 L/m ² throughput 0.6 m ² surface area
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FROM GENE TO THERAPY



XCell ATF® Devices

- Scalable, single-use cell retention
- Higher pre-transfection viable cell density and total capsid titer



KrosFlo® TFD® System

- Perfusion and clarification in one step
- Enables multiple harvests and continuous clarification, low shear and hold-up volume



Hollow Fiber Filters

- Wide range of membrane formats, chemistries and pore sizes
- Ideal for Lentivirus large, shear-sensitive molecules



SIUS® Gamma Flat Sheet Cassettes

- Fully assembled, irradiated cassettes for high flux performance and reduced process time
- Ideal for concentrating AAV 20-60X prior to chromatography



KrosFlo® TFF Systems

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



AviPure® Resins

- First and only AAV-specific caustic stable Affinity resins
- Right-first-time custom affinity resins



OPUS® Pre-packed Columns

- Broad range covering process development and commercial manufacturing requirements
- Pack any resin for AAV, Lentivirus, or plasmid purification

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 viral vector and oligonucleotide purification



Fluid Management Solutions

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



ProConnex® Flow Paths

- Complete, 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.



Lauren Jarvis
Director of Business
Development,
Gene Therapy

Lauren has 20 years of business development and key account management experience in the global biopharmaceutical and cell and gene therapy markets. She believes in a customer-focused approach attuned to the needs of closed system processing and single-use solutions for process development to commercial scale.

