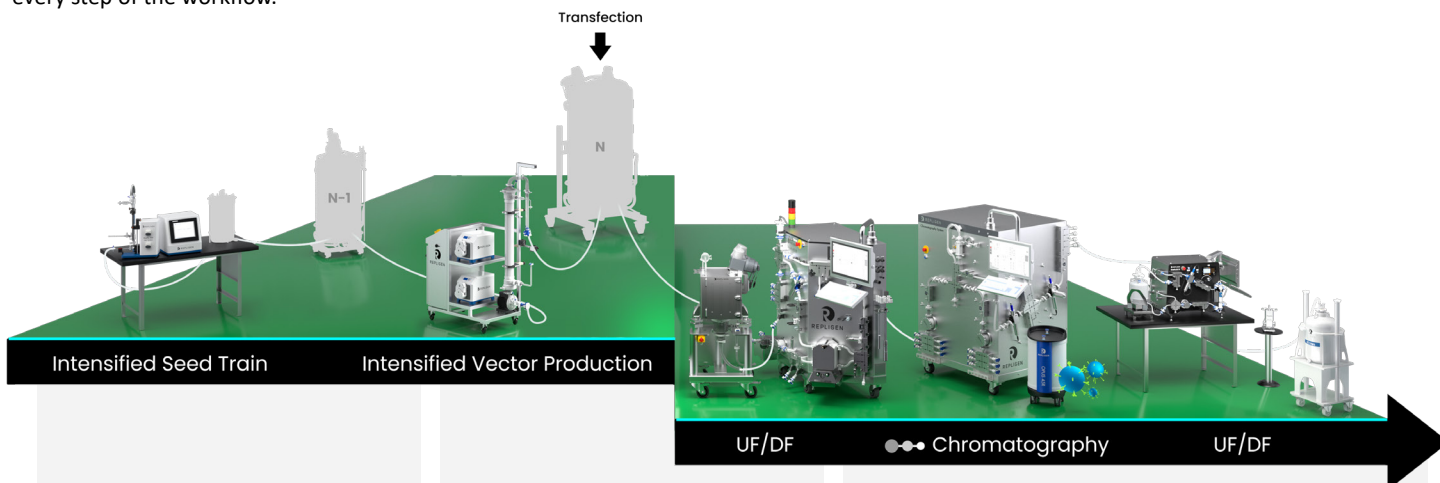


# Gene Therapy Manufacturing: Advanced Platform-Based Bioprocessing

Data Sheet

## 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

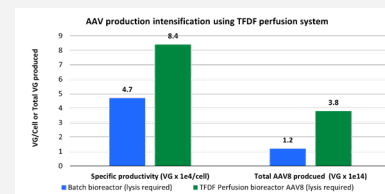
#### Expert consultation

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

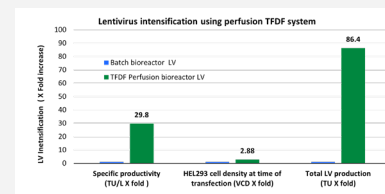
### Intensification Data

#### Upstream viral vector production intensification

3X AAV8 production using KrosFlo® TFDF® System



> 80X Potent Lentivirus production using KrosFlo® TFDF® System

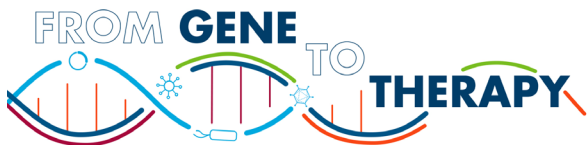


#### Scaling rAAV9 Purification with KRM™ Chromatography System

167X load volume into capture column

240X total AAV recovery (VG)

## REPLIGEN SOLUTIONS

**KrosFlo® TDFD® System**

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

**ProConnex® Flow Paths**

- Complete, configurable flow paths
- Plug and play fluid management

**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® RS 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 (readily available in AAV 2, 5, 8 and 9)
- 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

**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 viral vector and oligonucleotide purification

**KrosFlo® RPM System**

- Combined benefits of KrosFlo® KR2i TFF system with FlowVPX® in-line PAT device
- Completely automated Real-time Process Management

**Fluid Management Solutions**

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

## 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