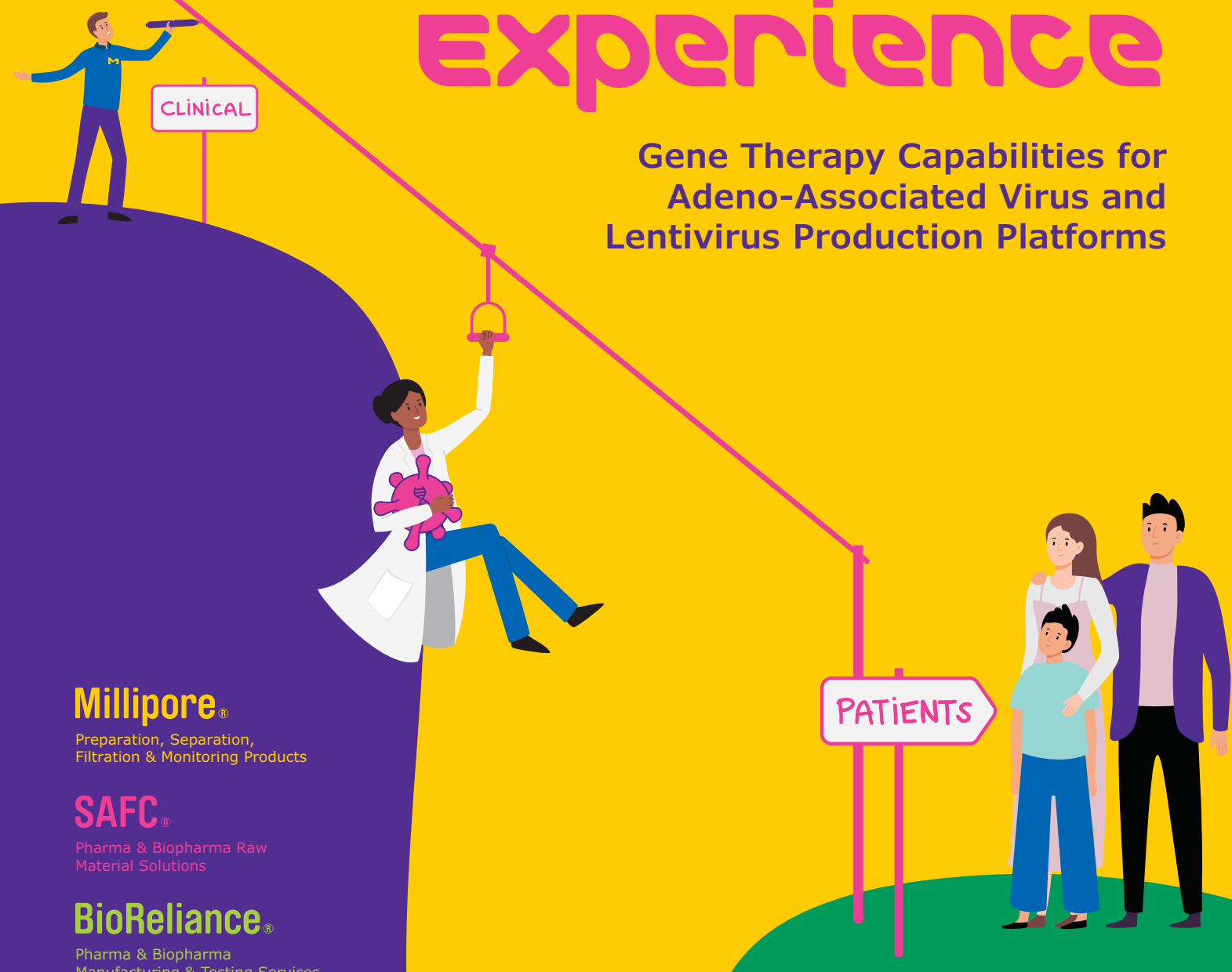
Draw on our experience

Gene Therapy Capabilities for Adeno-Associated Virus and Lentivirus Production Platforms



Millipore®
Preparation, Separation, Filtration & Monitoring Products

SAFC®
Pharma & Biopharma Raw Material Solutions

BioReliance®
Pharma & Biopharma Manufacturing & Testing Services

MilliporeSigma is the U.S. and Canada Life Science business of Merck KGaA, Darmstadt, Germany.

Adeno-associated Virus and Lentivirus Manufacturing

PROCESS FLOW

Viral & Gene Therapy Manufacturing and Testing Services From Development Through Commercialization

Thaw and Expand Cells and Seeds

AAV Production
- Sf-RVN® Insect Cell Line*
- HEK293 VirusExpress® Cells†
- Early PD Services
- Raw Materials Testing
- Validation Services
- Cell Banking Services

Lentivirus Production
- HEK293T VirusExpress® Cells◇
- Early PD Services
- Raw Materials Testing
- Validation Services
- Cell Banking Services

* Sf-RVN® Platform
† VirusExpress® AAV Platform
◇ VirusExpress® Lentiviral Platform

Media and Inoculum Prep

AAV Production
- EX-CELL® CD Insect Cell Media*
- EX-CELL® CD HEK293 Viral Vector Media†◇
- Cellvento® 4HEK Media
- Mobius® Power MIX
- Millipore Express® SHR Filters
- Early PD Services
- Raw Materials Testing
- Validation Services

Lentivirus Production
- EX-CELL® CD HEK293 Viral Vector Media†◇
- Mobius® Power MIX
- Millipore Express® SHR Filters
- Early PD Services
- Raw Materials Testing
- Validation Services

* Sf-RVN® Platform
† VirusExpress® AAV Platform
◇ VirusExpress® Lentiviral Platform

Cell Growth and Virus Production

AAV Production
- Upstream Chemicals and Media Supplements
- Poloxamer-188 Cell Culture Optimized
- Mobius® Bioreactors
- NovaSeptum® GO Sterile Sampling Systems
- Cell and Virus Bank Production, Characterization and Storage

Lentivirus Production
- Upstream Chemicals and Media Supplements
- Mobius® Bioreactors
- NovaSeptum® GO Sterile Sampling Systems
- Cell and Virus Bank Production, Characterization and Storage

Cell Lysis

AAV Production
- Emprove® Chemicals: Surfactants e.g. High Pure PS-80 and PS-20, Deviron® C-16 Detergent Deviron® 13-S9 Detergent
- Mobius® Power MIX
- Adventitious Virus Testing
- Mycoplasma Testing
- Sterility Testing

DNA Digestion

AAV Production
- Benzonase® endonuclease Safety Plus Emprove® Expert
- Benzonase® Salt Tolerant endonuclease Emprove® Expert
- Mobius® Power MIX

Lentivirus Production
- Benzonase® endonuclease Safety Plus Emprove® Expert
- Mobius® Power MIX

Primary Clarification

AAV Production
- IPEC-PQG Emprove® Expert Chemicals and Cleaning-in-Place Solutions
- Clarisolve® 20MS Filters
- Millistak+® HC Pro Filters
- Validation Services

Lentivirus Production
- IPEC-PQG Emprove® Expert Chemicals and Cleaning-in-Place Solutions
- Clarisolve® 60HX Filters
- Millistak+® CE Filters
- Validation Services

Secondary Clarification

AAV Production
- IPEC-PQG Emprove® Expert Chemicals and Cleaning-in-Place Solutions
- Milligard® PES Filters 1.2/0.22
- Millistak® F0HC X0HC Filters
- Millistak® D0SP Filters
- Validation Services

Lentivirus Production
- IPEC-PQG Emprove® Expert Chemicals and Cleaning-in-Place Solutions
- Milligard PES Filters
- Millistak+® CE50 Filters
- Validation Services

UF/DF

AAV Production
- IPEC-PQG Emprove® Expert Chemicals and Cleaning-in-Place Solutions
- Pellicon® Capsules
- Pellicon® Cassettes
- Validation Services

Lentivirus Production
- IPEC-PQG Emprove® Expert Chemicals and Cleaning-in-Place Solutions
- Pellicon® Capsules
- Pellicon® Cassettes
- Validation Services

Chromatography (1–2 Steps)

AAV Production
- IPEC-PQG Emprove® Expert Chemicals and Cleaning-in-Place Solutions
- Fractogel® Family
- Viral Clearance Services
- Eshmuno family

Lentivirus Production
- IPEC-PQG Emprove® Expert Chemicals and Cleaning-in-Place Solutions
- Fractogel® Family
- Viral Clearance Services
- Eshmuno family

Virus Filtration

AAV Production
- Viresolve® NFR Filters
- Viral Clearance Services

UF/DF

AAV Production
- IPEC-PQG Emprove® Expert Chemicals
- Pellicon® Capsules
- Pellicon® Cassettes
- Safety
- Content/Strength
- Identity
- Purity

Lentivirus Production
- IPEC-PQG Emprove® Expert Chemicals
- Pellicon® Capsules
- Pellicon® 3 Cassettes
- Safety
- Content/Strength
- Identity
- Purity

Sterile Filtration

AAV Production
- Durapore® 0.22 µm Filters
- Millipore® Express filters
- Millipak® Final Fill Filters
- Validation Services

Lentivirus Production
- Durapore® 0.22 µm Filters
- Millipak® Final Fill Filters
- Validation Services

Final Fill

AAV Production
- Mobius® Filling Assemblies
- NovaSeptum® GO Sterile Sampling Systems
- High Purity Stabilizers (e.g. Polysorbates and Sucrose with very low endotoxin)
- Safety
- Content/Strength
- Identity
- Purity

Lentivirus Production
- Mobius® Filling Assemblies
- NovaSeptum® GO Sterile Sampling Systems
- High Purity Stabilizers (e.g. Polysorbates and Sucrose with very low endotoxin)
- Safety
- Content/Strength
- Identity
- Purity

SAFC Products
Millipore Products
BioReliance Services

Bringing Your Therapy To Life

You've created a gene therapy with the possibility to help patients. But the development and manufacturing of your gene therapy, how it's developed, produced and approved, are still being outlined. No process template exists. You have to design one as you go, despite the uncertainty and unique challenges. We're here to help. With 30+ years of gene therapy experience, we bring expertise in viral vector manufacturing and testing as well as a global organization to integrate process development, scale-up, safety testing and regulatory guidance to meet your process needs.

Our products and services for Adeno-associated virus, Lentivirus and other viral vectors provide solutions to your most challenging pain points around process development, speed, manufacturing and regulatory guidelines. We are ready for you to draw on our experience to help bring your gene therapy to life.

MilliporeSigma has brought together the world's leading Life Science brands, so whatever your life science problem, you can benefit from our expert products and services.

Millipore®

The Millipore® portfolio of MilliporeSigma offers an ecosystem of industry-leading products and services, spanning preparation, separation, filtration and monitoring – all of which are deeply rooted in quality, reliability and time-tested processes. Our proven products, regulatory and application expertise are a strong foundation you can rely on to consistently perform at the highest level.

SAFC®

The SAFC® portfolio of MilliporeSigma offers customized and ready-to-use raw material solutions, backed by deep regulatory expertise. Our high-quality products and services are supported by an experienced and responsive team of raw material and regulatory experts who are committed to understand your requirements and provide tailored solutions.

BioReliance®

The BioReliance® portfolio of MilliporeSigma encompasses biopharmaceutical characterization, safety testing and process development, as well as clinical and commercial biomanufacturing. Our experienced teams and operational expertise make us the partner who supports you all the way and always has your vital goal in mind.

No guide will replace the need to conduct process development and optimization experiments. The unique nature of every process stream combined with application and regulatory requirements play a part in determining the optimum process solutions. Use this selection guide as a starting point for selecting and sizing the most appropriate MilliporeSigma's solutions.

We provide information and advice to our customers on application technologies and regulatory matters to the best of our knowledge and ability, but without obligation or liability. Existing laws and regulations are to be observed in all cases by our customers. This also applies in respect to any rights of third parties. Our information and advice do not relieve our customers of their own responsibility for checking the suitability of our products for the envisaged purpose.

The holder of the manufacturing authorization shall ensure that the excipients are suitable for use in medicinal products by ascertaining the appropriate good manufacturing practice.

This is particularly true if the material in a certain application is regarded as high risk excipient, for example in parenteral dosage forms.

SigmaAldrich.com/gene-therapy

54406
04/2024