



Adeno-Associated Virus
(AAV) Adherent Platform
AcceleratorSM Integrated Solutions

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Illustrations and recommendations are based upon a typical process and may be subject to change based upon your individual process requirements.

AAV Drug Products

An Introduction to Today's AAV Manufacture

Over the past years we've witnessed the approval of several gene therapy products, and these much-anticipated therapies are beginning to deliver on their promise and to have a radical impact on patient health. Gene therapies represent a new medical paradigm and their progress is the result of decades of research, acquired best practices, and hard lessons learned. Despite an increasing number of gene therapy drugs in development and clinical trials every year, this industry is still in its early stages. While this evolving industry is able to benefit from the experience already gained in the field of recombinant antibodies, manufacturers today are facing new issues and challenges throughout the drug commercialization journey - from development and manufacture, right through to the regulatory approval of AAV based therapies.

Plan for Speed in AAV Development

In process development, speed to market and costs are critical considerations. Selecting the most suitable production system that results in fast production, high yields, and a high ratio of full-to-empty AAV is key. Several producers are currently entering the market using transfection and adherent cells because it presents a fast route to market. There are however, limitations to transfection-based manufacture as typical AAV titers currently reach plateau at around 10^3 - 10^5 viral genomes per cell. For products that require high yield and low costs but have a longer time window for introduction to market, developing suspension cells or stable producer lines delivers long-term benefits regarding yields and scalability.

Increase Capacity and Quality in AAV Manufacture

The viral vector manufacturing capacity is estimated to be 1 - 2 orders of magnitude lower than what is needed to support commercial supply requirements both today, and in the future. All parts of the industry are therefore focused on what is needed to achieve sustainable increases in capacity. In addition to scaling out manufacturing capacity through existing and new manufacturing centers, the development of manufacturing practices that can increase productivity are ongoing. This includes optimizing cell lines and refining plasmid constructs, as well as enhancing process recovery in downstream processing. If we explore opportunities for improved yield, current downstream recovery is typically only 20% and maximizing yield while meeting both product and impurity specifications provides an immediate opportunity to improve downstream processing. Recently elaborated practices in the empty-full separation using scalable chromatographic methods, paired with an increasing understanding of purification conditions for different AAV serotypes, are fostering AAV recoveries and thus capacity of high-quality AAV drug product. These advances see chromatographic methods displacing older methods such as ultracentrifugation as the industry increasingly adopts scalable methods which are better suited to the industrialization of these processes.

Gain Regulatory Approval for AAV Drug Products

Moving AAV products into the highly regulated goods manufacturing practice (GMP) production environment puts a spotlight on the rising expectations in drug reviews as the understanding in industry and regulatory bodies is building. The much-needed regulatory framework is rapidly developing and supported through multiple guidance documents that have been published recently. Part of the challenge to obtain regulatory approval is paired with analytical constraints: viral titer, quality and impurity assays require lengthy offline processes and come with limited sensitivity. A series of next generation analytical tools are being developed at rapid pace and promise real-time monitoring and process analytical technology (PAT) implementation.

With several approved gene therapies and hundreds of products in the pipeline, the industry knowledge is building at pace. At the same time, the regulatory framework is rapidly developing which is increasing confidence in interpreting guidelines and builds regulatory maturity in both industry and regulators. The continued connection of academia research, industry investment and regulatory commitment comes with great potential for streamlining AAV manufacturing and allows new, high-quality AAV therapeutics to reach patients.

1. Cell Seeding

Early in therapeutic development, viral vectors are typically manufactured from adherent cells using two-dimensional stacked flatware or roller bottles. As processes scale-up and more virus is needed, the footprint and manual operations required to grow cells in this fashion quickly become problematic. Improving upon traditional flatware seed trains, the seeding process can be adapted to allow growth directly in the bioreactor. The result is a higher titer compared to seeding and performing induction at a low cell density.

Equipment

Xpansion® Multiplate Bioreactor System

The Xpansion multiplate bioreactor system is a closed, single-use system that has been specifically designed for the scale-up of shear-sensitive, adherent mammalian cells under controlled conditions. Its 2D multiplate design allows easy scale-up from traditional multitray systems.

Part Number (PN): XPNBRS

[Discover more](#)



Input

Allegro™ Bioprocessing Workstations
PN: LGRTBDC, LGRTSDC, LGRTPE20L,
LGRTLPE20L, LGRTRDC

Nunc♦ Cell Factory♦ System

T-Flasks

Transfer Sets

PN: 7292-1398X, 7292-1397E

Xpansion Seeding Manifold

PN: 7414-0972X

Allegro 2D Standard Systems

PN: 7190-1397U

Use of the Xpansion bioreactor to seed the iCELLis® bioreactor is process dependent. Please contact your Pall bioreactor applications scientist for assessment.

Output

Allegro 2D Standard Systems
PN: 7190-1397U



Supporting

mPath™ Benchtop Bioreactor
Control Tower
PN: MPATHLINK

Xpansion Lift
PN: XPNLIFT

Xpansion Bioreactor
PN: XPN100

Xpansion Harvest Station
PN: XPNHVST

2. Cell Culture – Growth

As the therapies progress into clinical development, there is a requirement to increase the quantity of the virus produced while maintaining or improving the quality. Manufacturing virus from adherent cells using fixed-bed bioreactor technology allows for direct transfer of the 2D reference process, which minimizes risk and reduces development time. The equipment footprint can be kept small whilst allowing for a large surface area for cell growth with the iCELLis bioreactor system.

Equipment

iCELLis 500+ Bioreactor

The iCELLis bioreactor was the world's first fully integrated high-cell density bioreactor designed to simplify processes by combining the advantages of both single-use technology and a fixed-bed system to simplify cell culture and reduce operational costs. The system delivers a scalable platform to support cell culture from R&D to industrial scale GMP manufacturing.

PN: ICL500CSSSIPH

[Discover more](#)



Input

Magnetic Mixer
PN: MMG403, LM200JC-MA-B4N,
7404-1401R

LevMixer® System
PN: 7403-1356W, LM1000JCMA-B4N,
LM200JCMA-B4N, LMG403

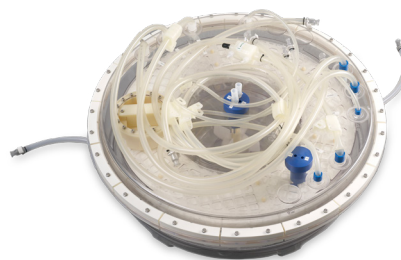
Allegro Bioprocessing Workstations
PN: LGRTBDC, LGRTSDC, LGRTDCPE,
LGRTPE20L, LGRTLPE20L

Allegro Plastic Totes
PN: LGRPTTE200L

Transfer Sets
PN: 7292-1381X, 7292-1381Q,
7292-1381U, 7292-1382M

Emflon® II Membrane in Kleenpak™
Capsules
PN: 7090-1388M

Allegro 2D Standard Systems
PN: 7190-1397P, 6415-0615S, 7190-1397S



Supporting

iCELLis 500+ Bioreactor Manifolds
PN: 6415-0464G, 6415-0615S, 6415-0615U

iCELLis 500+ Bioreactor Vessel
PN: 4415-1500H333

Output

Allegro 3D Standard Systems
PN: 7190-1376R

3. Cell Culture – Production

Applying carefully chosen process conditions identified as part of technology transfer, the bioreactor can produce high yields. However, such scale-up and tech transfer activities pose several challenges, including defining operating conditions, such as agitation rate and gas sparge rate. Non-scalable parameters like these may result in different physical and chemical growth environments leading to a different performance than predicted at small-scale. Therefore, it is imperative to determine the critical environmental parameters that impact the biological attributes, such as product yield, cell growth and quality.

Equipment

iCELLis 500+ Bioreactor

The fixed-bed design of the iCELLis bioreactor, coupled with the unique waterfall system for oxygenation and CO₂ stripping, provides a the perfect environment for virus production. This delivers increased productivity versus stirred tank systems in a small footprint with significantly reduced media volumes when compared to traditional flatware solutions.

PN: ICL500CSSSIPH

[Discover more](#)



Input

LevMixer System
PN: 7403-1352U, LM650JCMA-B4N, LMG403

Magnetic Mixer
PN: MMG403, 7404-1401R, LM200JC-MA-B4N

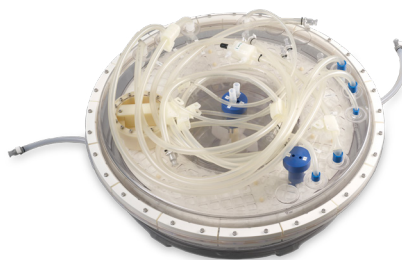
Allegro Bioprocessing Workstations
PN: LGRTPE20L, LGRTLPE20L, LGRTBDC, LGRTSDC, LGRTDCPE

Allegro Plastic Totes
PN: LGRPTTE200L, LGRPTRL200L

Transfer Sets
PN: 7292-1381X, 7292-1381Q

Allegro 2D Standard Systems
PN: 7190-1397P

Emflon II Membrane in Kleenpak Capsules
PN: 7090-1388M



Supporting

iCELLis 500+ Bioreactor Manifolds
PN: 6415-0464G

iCELLis 500+ Bioreactor Vessel
PN: 4415-1500H333

Output

LevMixer System
PN: 7403-1352U, LM650JCMA-B4N, LMG403

Transfer Sets
PN: 7292-1381X, 7292-1381Q

Allegro 3D Standard System
PN: 7190-1376R

4. Clarification

Additional resources 

The removal of cells, cell debris, and other insoluble impurities reduces the particulate burden on downstream operations. The simplest and most economical technology used to clarify the cell culture is filtration. Low yield is a common challenge in this step, especially as cell densities increase and for larger viral particles. Finding the right combination of depth filter sheets and membrane sheets is the key to optimizing both yield and performance. Our experienced technical team can help you achieve both by optimizing test protocols and process parameters, aiding selection of the best filter materials and size.

Equipment

Stax™ Depth Filters

Placed into a chassis, Pall's single-use Stax capsules eliminate the use of stainless steel housings which require costly cleaning and cleaning validation.

PN: 7008444, 7008225

[Discover more](#)



Input

LevMixer System

PN: 7403-1352U, LM650JCMS-B4N, LMG403

Allegro Plastic Totes

PN: LGRPTE200L, LGRPTL200L, LGRPTTEL200L

Allegro Bioprocessing Workstations

PN: LGRKPCBKHD, LGRUFBK

Allegro 3D Standard Systems

PN: 7190-1376V

Transfer Sets

PN: 7292-1381A



Supporting

Allegro MVP Single-Use System

PN: 9430-1413Q, LGRMVPAPPE, CBG401A, 9430-1413S

Stax Depth Filters Chassis

PN: SXPSC10W

Supor® EAV Membrane Kleenpak Capsules

PN: 7090-1562Q

Output

LevMixer System

PN: 7403-1352U, LM650JCMS-B4N, LMG403

Allegro 3D Standard Systems

PN: 7190-1376T

Transfer Sets

PN: 7292-1381X

Allegro Plastic Totes

PN: LGRPTTEL500L, LGRPTE500L, LGRPTL500L

Stax Depth Filter Vent Bottle

PN: 7090-0936X

Transfer Sets

PN: 7292-1381A, 7291-1381B

5. Concentration 1

Additional resources 

Ultrafiltration (UF)/diafiltration (DF) using tangential flow filtration (TFF) membranes concentrates the target molecule and exchanges buffers to support downstream chromatographic purification. Achieving high yield is a common challenge with TFF, but our technical experts can work with you to optimize your UF/DF unit operation based on experience and thorough testing.

Equipment

ÄKTA readyflux[†] XL Single-Use Filtration System

ÄKTA readyflux XL system supports a broad flow-rate range and combines a single-use flowpath with a low hold-up volume to minimize cross-contamination and maximize yields. Multiple filtration-control features provide versatility for use in all ultrafiltration operations.

PN: 29593434



Input

LevMixer System

PN: 7403-1356W, LM1000JCMA-B4N, LMG403, LM50JCMA-B4N

Allegro Bioprocessing Workstations

PN: LGRTBDC, LGRTPE20L, LGRTLPE20L, LGRTRDC

Allegro Plastic Totes

PN: LGRPTTEL200L, LGRPTTE200L, LGRPTRL200L, LGRPTTEL200L

Allegro 2D Standard Systems

PN: 7190-1397U

Allegro 3D Standard Systems

PN: 7190-1374Y, 7190-1376R

Transfer Sets

PN: 7292-1381A

Supporting

LevMixer System

PN: 7403-1350S, LMG403, LM50JCMA-B4N

Allegro MVP Single-Use System

PN: CBG401A

Cadence[®] Single-Use Tangential Flow Filtration (TFF) Modules

PN: CSUM100T250, 7443-1437P

Transfer Sets

PN: 7292-1381A

ÄKTA readyflux XL Flow Kit TriClamp

C10 Manifold with TriClamp Ready for ÄKTA readyflux XL

UNICORN[†] Workstation License

Output

LevMixer System

PN: 7403-1350S

Allegro 3D Standard Systems

PN: 7190-1376V

Transfer Sets

PN: 7292-1381A

Allegro Plastic Totes

PN: LGRPTTE1000L, LGRPTTEL1000L, LGRPTTEL1000L

6. Prefiltration

Additional resources 

Reducing bioburden through a suitable grade 0.2 µm or 0.45 µm filter is usually the next step in this process and is essential for maintaining stability and quality of the drug intermediate. The optimal filter used here can vary based on the titer and volume of material, fouling properties of the fluid, and processing time requirements. Excessive bioburden and propagation of contaminants can be easily controlled in the downstream process through strategic positioning of a well-selected filter.

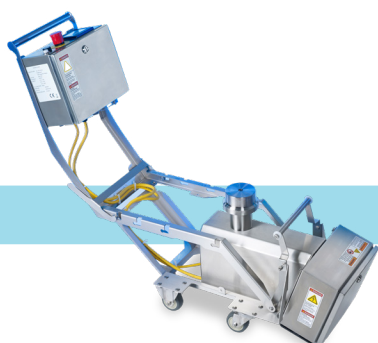
Equipment

Fluorodyne® EX EDF Membrane in Kleenpak Capsules

Fluorodyne EX grade EDF membrane in Kleenpak capsules are built for biopharmaceutical use with their durable and compact design. Using Fluorodyne EX grade EDF filters promotes higher protein transmission and a sterile cell harvest. Its prefiltration layers and bacterial retention performance combine to deliver efficient purification in intermediate and final biological process solutions.

PN: 7090-1437X

[Discover more](#)



Input

LevMixer System
PN: 7403-1350S, LM50JCMA-B4AN, LMG403

Allegro 2D Standard Systems
PN: 7190-1397S

Allegro Bioprocessing Workstations
PN: LGRTBDC, LGRTBDC, LGRTLPE20L, LGRTLPE20L, LGRTLPE20L, LGRTTRDC, LGRUFBK, LGRKPCBKHD

Transfer Sets
PN: 7292-1381X



Supporting

Allegro MVP Single-Use System
PN: LGRMVPAPE, 9430-1413G, 9430-1413Q

Output

LevMixer System
PN: 7403-1350S, LM50JCMA-B4A, LMG403

Allegro 2D Standard Systems
PN: 7190-1397S

Transfer Sets
PN: 7292-1381X

7. Affinity Chromatography

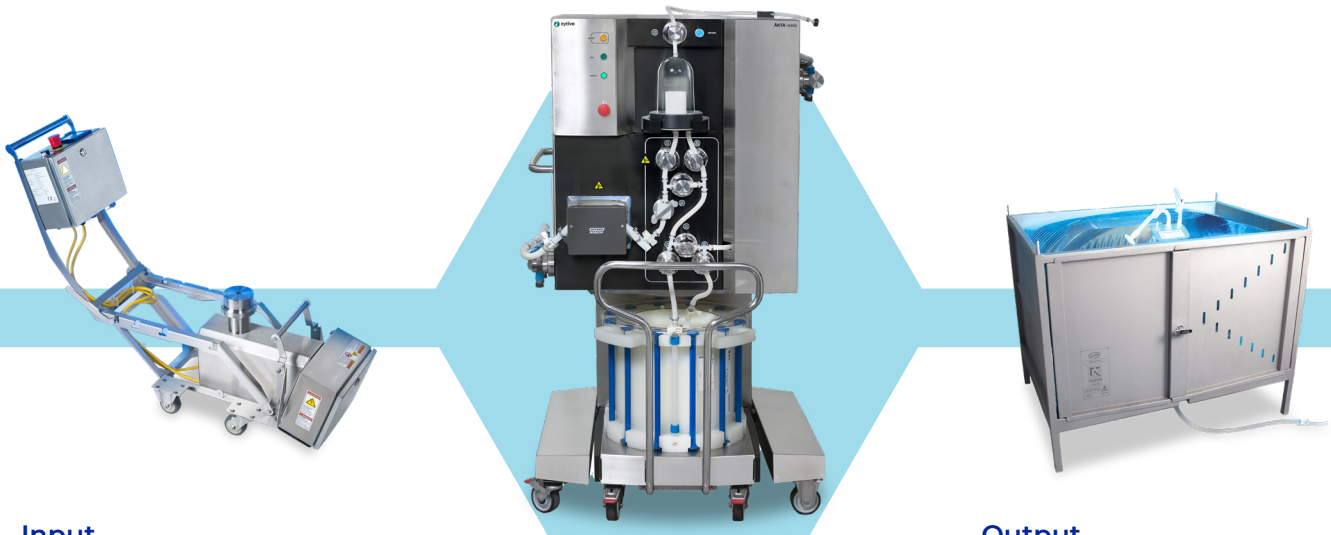
Relying on the unimpeded interaction between the viral particles and an immobilized ligand, affinity chromatography can be an effective purification step and can achieve high specificity and high binding capacity to deliver an economic and scalable purification step. Often the challenge is the ability of affinity chromatography to capture the viral particles. When there are many serotypes and a lack of a universal structural element to bind to, this can be overcome by structuring ligands, to target specific viral serotypes.

Equipment

ÄKTA ready† Single-Use System

ÄKTA ready is a single-use liquid chromatography system built for process scale-up and manufacturing. The systems use disposable flow paths and prepacked columns that enable flexibility and speed in bioprocessing.

PN: 29032038



Input

LevMixer System

PN: 7403-1350S, LM50JCMA-B4N,
LMG403

Allegro Bioprocessing Workstations

PN: LGRTBDC, LGRTPE20L,
LGRTBDC, LGRTTRDC

Allegro Plastic Totes

PN: LGRPTE200L, LGRPTRL200L,
LGRPTE50L, LGRPTE500L,
LGRPTRL500L, LGRPTEEL200L,
LGRITBSC, LGRPTEEL500L

Allegro 2D Standard Systems

PN: 7190-1397S

Allegro 3D Standard Systems

PN: 7190-1376R, 7190-1374W,
7190-1374Y

Transfer Sets

PN: 7292-1381L



Supporting

Transfer Sets

PN: 7291-1399Y

Resin (Suggested Capto† AVB)

ÄKTA ready Low Flow Kit

UNICORN Workstation License

Output

LevMixer System

PN: 7403-1350S, LM50JCMA-B4N,
LMG403

Transfer Sets

PN: 7292-1381L

Allegro 3D Standard Systems

PN: 7190-1374Y, 7190-1376T

Allegro Plastic Totes

PN: LGRPTE200L, LGRPTRL200L,
LGRPTE500L, LGRPTRL500L,
LGRPTEEL200L, LGRPTEEL500L

8. Neutralization

Additional resources 

The neutralization and dilution step in AAV manufacture will often occur in single-use mixers. Viral cell constructs can be very fragile with special buffer solutions needed to keep them stable. Carefully selected mixing technology also enables sensitive mixing at lower speeds.

Equipment

Supor EKV Sterilizing-Grade Filter Cartridges

Validated sterilizing grade membranes for the most cost-effective filtration of a wide range of liquids such as buffers, tissue culture media, and others.

PN: 7090-1437Z

[Discover more](#)



Input

LevMixer System
PN: 7403-1350S, LM50JCMA-B4N, LMG403

Allegro Bioprocessing Workstations
PN: LGRKPCBKHD, LGRUFBK, LGRTBDC

Allegro Plastic Totes
PN: LGRPTTE50L, LGRTBSC

Allegro 3D Standard Systems
PN: 7190-1374W

Transfer Sets
PN: 7292-1381X



Supporting

Allegro MVP Single-Use System
PN: LGRMVAPE

Transfer Sets
PN: 9430-1413G, 9430-1413Q

Output

LevMixer System
PN: 7403-1351N, LM100JCMA-B4N, LMG403

Transfer Sets
PN: 7292-1381X

9. IEX Chromatography

Additional resources 

Purity has a direct impact upon the potency, efficacy and the safety of the therapy. Reliably reducing DNA and host cell proteins (HCP) increases product safety and the removal of empty capsids increases potency to reduce the risk of undesirable dose related side effects. The challenge of large-scale manufacture is to ensure the percentage of empty capsids is minimized, and the empty/full ratio is always controlled. Adsorptive membrane chromatography provides an effective option for polishing of gene therapy products.

Equipment

ÄKTA ready Single-Use System

ÄKTA ready is a single-use liquid chromatography system built for process scale-up and manufacturing. The systems use disposable flow paths and prepacked columns that enable both flexibility and speed in bioprocessing.



Input

LevMixer System
PN: 7403-1351N, LM100JCMA-B4N,
LMG403

Allegro Plastic Totes
PN: LGRPTE200L, LGRPTL200L,
LGRPTEL200L

Allegro 3D Standard Systems
PN: 7190-1376R, 7190-1374Y

Transfer Sets
PN: 7292-1381L



Supporting

Mustang® Q XT Ion Exchange
Chromatography Capsules
PN: XT5000MSTGQP1V, XT5000B100,
XT5000H100, XT5000T100

Transfer Sets
PN: 7291-1399Y

ÄKTA ready Low Flow Kit

UNICORN Workstation License

Output

Transfer Sets
PN: 7292-1381L

LevMixer System
PN: 7403-1350S, LMG403,
LM50JCMA-B4N

Allegro 3D Standard Systems
PN: 7190-1376R, 7190-1374Y

Allegro Plastic Totes
PN: LGRPTE200L, LGRPTL200L,
LGRPTEL200L

10. Concentration 2

A second phase of concentrating the target molecule into the final concentration buffer is an optional step using TFF membranes.

Equipment

ÄKTA readyflux Filtration System

The automated system uses gamma irradiated single-use flow kits including single-use flow path, pumps and sensors for pressure, conductivity, temperature, flow and pH. These allow a wide variety of control modes and help users to tailor the filtration controls to different processing requirements.



Input

LevMixer System
PN: 7403-1350S, LM50JCMA-B4N,
LMG403

Allegro Bioprocessing Workstations
PN: LGRTBDC, LGRTSDC, LGRTPE20L,
LGRTLPE20L, LGRTRDC

Allegro Plastic Totes
PN: LGRPTE200L, LGRPTL200L,
LGRPTEL200L

Allegro 2D Standard Systems
PN: 7190-1397P, 7190-1397U

Transfer Sets
PN: 7292-1381L



Supporting

Cadence Single-Use Tangential
Flow Filtration (TFF) Modules
PN: CSUM100T010

Transfer Sets
PN: 7292-1381L

Allegro 2D Standard Systems
PN: 7190-1397P

Output

Allegro 2D Standard Systems
PN: 7190-1397P

Allegro 3D Standard Systems
PN: 7190-1374Y

Transfer Sets
PN: 7292-1381L

11. Bulk Filtration

Manufacturing for clinical purposes requires the production of highly purified and biologically active vectors that meet regulatory requirements. A final sterilizing grade (0.2 µm) filtration step ensures the removal of any potential bacterial contamination before the product is stored, frozen and sent for final filling. The knowledge that a filter is integral post-processing, contributes to confirmation that a final drug product is sterile and gives assurance for patient safety prior to bulk filling. Ensuring data integrity when conducting filter integrity testing is essential to comply with the latest regulations for electronic audit trails.

Equipment

Palltronic® Flowstar V Filter Integrity Test Instrument

The Palltronic Flowstar V integrity test instrument ensures accurate filter integrity testing with a further reduction in test time, full compliance with 21 CFR Part 11, advanced automation capabilities, and simplified network integration; saving the user time while improving process efficiency.

PN: FFS05

[Discover more](#)



Input

Bulk Filtration Assembly with Supor Membrane in Mini Kleenpak Capsules
PN: 7090-1388G

Allegro 2D Standard Systems
PN: 7190-1397P



Supporting

Supor EKV Sterilizing-Grade Filter Cartridge

Emflon II Membrane in Kleenpak Capsules

Additional Resources

Process Description	Format	Title	Link
Cell Seeding	Poster	Scaling-Up and Industrializing the Production of Viral Vectors and Cells for Therapeutic Use	▶
Cell Seeding	Poster	Overcoming Adherent Seed Train Biomass Limitations: Xpansion® Bioreactor	▶
Cell Culture	Video	iCELLis Single-Use Fixed-Bed Bioreactors	▶
Cell Culture	Poster	Development of a Scalable Viral Vector Upstream Process for Gene Therapy: rAAV-8 Production by Transient Transfection of HEK-293 Cells in iCELLis Bioreactor	▶
Cell Culture	Poster	Transient Transfection at Large Scale for Clinical AAV9 Vector Manufacturing	▶
Cell Culture	Webinar	Transient Transfection at Large Scale for Clinical AAV9 Vector Manufacturing	▶
Clarification	Poster	Optimizing the Clarification of Viral Vector Culture for Gene Therapy	▶
Chromatography	White Paper	Scalable Purification of High Yield Adeno-Associated Virus and Lentivirus Gene Therapy Vectors Using Membrane Chromatography	▶
Overall Process	Webinar	Scalable, Single-Use Solutions for Purification of Viral Vectors	▶

Equipment List

Step No.	Process Description	Product	Part Number	Link
1	Cell Seeding	Allegro 2D Standard Systems	7190-1397U	▶
1	Cell Seeding	Allegro Bioprocessing Workstations	LGRTBDC, LGRTSDC, LGRTPE20L, LGRTLPE20L, LGRTRDC	▶
1	Cell Seeding	Transfer Sets	7292-1398X, 7292-1397E	
1	Cell Seeding	mPath Benchtop Bioreactor Control Tower	MPATHLINK	▶
1	Cell Seeding	Nunc Cell Factory System	N/A	
1	Cell Seeding	T-Flasks	N/A	
1	Cell Seeding	Xpansion Bioreactor	XPN100	▶
1	Cell Seeding	Xpansion Harvest Station	XPNHVST	▶
1	Cell Seeding	Xpansion Lift	XPNLIFT	▶
1	Cell Seeding	Xpansion Multiplate Bioreactor System	XPNBRS	▶
1	Cell Seeding	Xpansion Seeding Manifold	7414-0972X	▶
2	Cell Culture – Growth	Allegro 2D Standard Systems	7190-1397P, 6415-0615S, 7190-1397S	▶
2	Cell Culture – Growth	Allegro 3D Standard Systems	7190-1376R	▶
2	Cell Culture – Growth	Allegro Bioprocessing Workstations	LGRTBDC, LGRTSDC, LGRDCEPE, LGRTPE20L, LGRTLPE20L	▶
2	Cell Culture – Growth	Allegro Plastic Totes	LGRPTTE200L	▶
2	Cell Culture – Growth	Supor EAV Membrane Kleenpak Capsules	7090-1388M	▶
2	Cell Culture – Growth	iCELLis 500+ Bioreactor	ICL500CSSSIPH	▶
2	Cell Culture – Growth	iCELLis 500+ Bioreactor Manifolds	6415-0464G, 6415-0615S, 6415-0615U	▶
2	Cell Culture – Growth	iCELLis 500+ Bioreactor Vessel	4415-I500H333	▶
2	Cell Culture – Growth	Transfer Sets	7292-1381X, 7292-1381Q, 7292-1381U, 7292-1382M	
2	Cell Culture – Growth	LevMixer System	7403-1356W, LM1000JCMA-B4N (EU), LM1000JCMA-B4A (US), LM200JCMA-B4N (EU), LM200JCMA-B4A (US), LMG403	▶
2	Cell Culture – Growth	Magnetic Mixer	MMG403, LM200JCMA-B4N (EU), LM200JCMA-B4A (US), 7404-1401R	▶
3	Cell Culture – Production	Allegro 2D Standard Systems	7190-1397P	▶
3	Cell Culture – Production	Allegro 3D Standard Systems	7190-1376R	▶
3	Cell Culture – Production	Allegro Bioprocessing Workstations	LGRTPE20L, LGRTLPE20L, LGRTBDC, LGRTSDC, LGRDCEPE	▶
3	Cell Culture – Production	Allegro Plastic Totes	LGRPTTE200L, LGRPTRL200L	▶
3	Cell Culture – Production	Supor EAV Membrane Kleenpak Capsules	7090-1388M	▶
3	Cell Culture – Production	iCELLis 500+ Bioreactor Vessel	ICL500CSSSIPH	▶

Equipment List

Step No.	Process Description	Product	Part Number	Link
3	Cell Culture – Production	iCELLis 500+ Bioreactor Manifolds	6415-0464G	▶
3	Cell Culture – Production	iCELLis 500+ Bioreactor Vessel	4415-I500H333	▶
3	Cell Culture – Production	Transfer Sets	7292-1381X, 7292-1381Q, 7292-1381U, 7292-1382M	
3	Cell Culture – Production	LevMixer System	7403-1352U, LM650JCMA-B4N, LMG403	▶
3	Cell Culture – Production	Magnetic Mixer	MMG403, 7404-1401R, LM200JC-MA-B4N	▶
4	Clarification	Allegro 3D Standard Systems	7190-1374Y, 7190-1376R	▶
4	Clarification	Allegro Bioprocessing Workstations	LGRKPCBKHD, LGRUFBK	▶
4	Clarification	Allegro MVP Single-Use System	9430-1413Q, LGRMVPAPE, CBG401A, 9430-1413S	▶
4	Clarification	Allegro Plastic Totes	LGRPTTE200L, LGRPTRL200L, LGRPTTEL200L, LGRPTTEL500L, LGRPTTE500L, LGRPTRL500L	▶
4	Clarification	Transfer Sets	7292-1381X	
4	Clarification	LevMixer System	7403-1352U, LM650JCMA-B4N (EU), LM650JCMA-B4A (US), LMG403, 7403-1356W, LM1000JCMA-B4N (EU), LM1000JCMA-B4A (US)	▶
4	Clarification	Stax Depth Filters	7008444, 7008225	▶
4	Clarification	Stax Depth Filter Vent Bottle	7090-0936X	▶
4	Clarification	Stax Depth Filters Chassis	SXPSC10W	▶
4	Clarification	Supor EAV Membrane in Kleenpak Capsules	7090-1437W	▶
5	Concentration 1	ÄKTA readyflux XL Flow Kit TriClamp	29403627	
5	Concentration 1	ÄKTA readyflux XL Single-Use Filtration System	29609298	
5	Concentration 1	Allegro 2D Standard Systems	7190-1397U	▶
5	Concentration 1	Allegro 3D Standard Systems	7190-1374Y, 7190-1376R, 7190-1376V	▶
5	Concentration 1	Allegro Bioprocessing Workstations	LGRTBDC, LGRTPE20L, LGRTLPE20L, LGRTRDC	▶
5	Concentration 1	Allegro MVP Single-Use System	CBG401A (EU), CBG402A (US), LGRMVPAPE (EU), LGRMVPAPA (US)	▶

Equipment List

Step No.	Process Description	Product	Part Number	Link
5	Concentration 1	Allegro Plastic Totes	LGRPTTE200L, LGRPTRL200L, LGRPTEL200L, LGRPTTE200L, LGRPTRL200L, LGRPTEL200L, LGRPTTE1000L, LGRTRLPT1000L, LGRPTEL1000L	▶
5	Concentration 1	C10 Manifold with TriClamp Ready for ÄKTA readyflux XL	CSUM100T250, 7443-1437P	
5	Concentration 1	Cadence Single-Use Tangential Flow Filtration (TFF) Modules	CSUM100T250, 7443-1437P	▶
5	Concentration 1	Transfer Sets	7292-1381A	
5	Concentration 1	LevMixer System	7403-1356W, 7403-1350S, LM1000JCMA-B4N (EU), LM1000JCMA-B4A (US), LM50JCMA-B4N (EU), LM50JCMA-B4A (US), LMG403	▶
5	Concentration 1	UNICORN Workstation License	29128116	
6	Prefiltration	Allegro 2D Standard Systems	7190-1397S	▶
6	Prefiltration	Allegro Bioprocessing Workstations	LGRTBDC, LGRTBDC, LGRTLPE20L, LGRTPE20L, LGRTLPE20L, LGRTRDC, LGRUFBK, LGRKPCBKHD	▶
6	Prefiltration	Allegro MVP Single-Use System	LGRMVPAPE (EU), LGRMVPAPA (US), 9430-1413G, 9430-1413Q	▶
6	Prefiltration	Fluorodyne EX EDF Membrane in Kleenpak Capsules	7090-1437X	▶
6	Prefiltration	Transfer Sets	7292-1381X	
6	Prefiltration	LevMixer System	7403-1350S, LM50JCMA-BAN (EU), LM50JCMA-B4A (US), LMG403	▶
7	Affinity Chromatography	ÄKTA ready Low Flow Kit	28930182	
7	Affinity Chromatography	ÄKTA ready Single-Use System	29032038 (gradient system) 28906261	
7	Affinity Chromatography	Allegro 2D Standard Systems	7190-1397S	▶
7	Affinity Chromatography	Allegro 3D Standard Systems	7190-1374Y, 7190-1376T, 7190-1376R, 7190-1374W	▶
7	Affinity Chromatography	Allegro Bioprocessing Workstations	LGRTBDC, LGRTPE20L, LGRTBDC, LGRTRDC	▶

Equipment List

Step No.	Process Description	Product	Part Number	Link
7	Affinity Chromatography	Allegro Plastic Totes	LGRPTTE200L, LGRPTRL200L, LGRPTTE50L, LGRPTTE500L, LGRPTRL500L, LGRPTTEL200L, LGRTTBSC, LGRPTTEL500L	▶
7	Affinity Chromatography	Transfer Sets	7292-1381L	
7	Affinity Chromatography	LevMixer System	7403-1350S, LM50JCMA-B4N (EU), LM50JCMA-B4A (US), LMG403	▶
7	Affinity Chromatography	UNICORN Workstation License	29128116	
8	Neutralization	Allegro 3D Standard Systems	7190-1374W	▶
8	Neutralization	Allegro Bioprocessing Workstations	LGRKPCBKHD, LGRUFBK, LGRTBDC	▶
8	Neutralization	Allegro MVP Single-Use System	LGRMVPAPE (EU), LGRMVPAPA (US)	▶
8	Neutralization	Allegro Plastic Totes	LGRPTTE50L, LGRTTBSC	▶
8	Neutralization	Transfer Sets	9430-1413G, 9430-1413Q	
8	Neutralization	LevMixer System	7403-1350S, LM50JCMA-B4N (EU), LM50JCMA-B4A (US), 7403-1351N	▶
8	Neutralization	Supor EKV Sterilizing-Grade Filter Cartridges	7090-1437Z	▶
9	IEX Chromatography	ÄKTA ready Low Flow Kit	28930182	
9	IEX Chromatography	ÄKTA ready Single-Use System	29032038 (gradient system) 28906261	
9	IEX Chromatography	Allegro 3D Standard Systems	7190-1376R, 7190-1374Y	▶
9	IEX Chromatography	Allegro Plastic Totes	LGRPTTE200L, LGRPTRL200L, LGRPTTEL200L	▶
9	IEX Chromatography	Transfer Sets	7292-1381L	
9	IEX Chromatography	LevMixer System	7403-1351N, LM100JCMA-B4N (EU), LM100JCMA-B4A (US), LM50JCMA-B4N (EU), LM50JCMA-B4A (US), LMG403	▶
9	IEX Chromatography	Mustang Q XT Ion Exchange Chromatography Capsules	XT5000MSTGQP1V, XT5000B100, XT5000H100, XT5000T100	▶
9	IEX Chromatography	UNICORN Workstation License	29128116	
10	Concentration 2	ÄKTA readyflux Filtration System	29151000	
10	Concentration 2	ÄKTA readyflux Flow Kit Plus TriClamp	29151600	

Equipment List

Step No.	Process Description	Product	Part Number	Link
10	Concentration 2	Allegro 2D Standard Systems	7190-1397P	▶
10	Concentration 2	Allegro 3D Standard Systems	7190-1374Y	▶
10	Concentration 2	Allegro Bioprocessing Workstations	LGRTBDC, LGRTSDC, LGRTPE20L, LGRTLPE20L, LGRTRDC	▶
10	Concentration 2	Allegro Plastic Totes	LGRPTTE200L, LGRPTRL200L, LGRPTTEL200L	▶
10	Concentration 2	Bagkart Bag Trolley	29151500	
10	Concentration 2	Cadence Single-Use Tangential Flow Filtration (TFF) Modules	CSUM100T010	▶
10	Concentration 2	Transfer Sets	7292-1381L	
10	Concentration 2	LevMixer System	7403-1350S, LM50JCMA-B4N (EU), LM50JCMA-B4A (US)	▶
10	Concentration 2	UNICORN Workstation License	29128116	
11	Bulk Filtration	Allegro 2D Standard Systems	7190-1397P	▶
11	Bulk Filtration	Bulk Filtration Assembly with Supor Membrane in Mini Kleenpak Capsules	7090-1388G	
11	Bulk Filtration	Supor EAV Membrane Kleenpak Capsules		▶
11	Bulk Filtration	Palltronic Flowstar V Filter Integrity Test Instrument	FFS05	▶
11	Bulk Filtration	Supor EKV Sterilizing-Grade Filter Cartridges		▶

Scientific and Laboratory Services

The scientific and regulatory knowledge that supports the selection, adoption and ongoing use of critical process technology, coupled with analytical, imaging and measurement capabilities, creates a versatile and practical resource ready to respond to an ever-changing industry. Pall duplicates these laboratories across the globe and leverages their cumulative knowledge to deliver practical scientific and regulatory support to all process technologies to keep you moving forward.

Technical Services

The accessibility of local technical support networks minimize delays in your journey at all points. From the early stage of process development to on-site support for mature processes, Pall's technical support groups are there to help remove barriers to progress and to make your journey as rapid and stress-free as possible. Our knowledge of the technology and the process can be applied to everything from training to troubleshooting and consultancy. Our global team of technology experts are on hand to respond to your changing needs.

Advanced Separation Systems

Operating within the defined design space demands the monitoring and control of critical process parameters to assure product quality. Systems that control critical unit operations and that communicate with your existing process components can control process risks and maximize productivity by reducing operator involvement for many processes, Pall applies strong engineering and regulatory understanding to deliver compliant and qualified systems that safeguard and simplify your journey.

Process Development Services

Prior knowledge is a rare and valuable commodity, especially when preparing to take a new direction or when under pressure to deliver to a tight deadline. Take advantage of Pall's experience, process knowledge and technical know-how to help you achieve your goals. From the optimization of an end-to-end continuous process to establishing the right parameters for a single unit operation, our teams of scientists are ready to work with you and to generate the data you need to make the critical decisions necessary for success.

Validation Services

Arriving at your destination counts for nothing without the necessary paperwork to proceed to the next stage. Pall's Validation Services are committed to delivering the supporting data packages and analysis required to quantify process risk and to support regulatory submission. Our strengths include critical filtration technologies such as the performance validation of sterilizing grade filtration, and we are at the forefront of the evolving needs in the area of extractables and leachables for all product contact components. We combine the generation of data with interpretation and consultancy to deliver data packages that are ready for regulatory scrutiny and to ensure there are no barriers to progress.

Servicing and Maintenance

Our range of service packages keeps your equipment protected and well maintained, and includes itemized pay-as-you-go services, start-up care and training packages and a variety of post-warranty service plans that include priority response times, discounts for emergency repairs and flexible payment options. Pall service plans provide total peace of mind and worry-free support throughout the coverage period.



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