Simplifying Progress

Setting the Standard in Cell and Gene Therapy

Perspectives on Performance, Scalability, and Regulatory Compliance

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Keywords or Phrases:
Cell therapies, gene therapies, stem cell, adeno-associated virus, viral vector processes

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Introduction

"Many of our customers working in cell and gene therapies are encountering novel challenges, different from the kinds of issues they faced when working on protein-based therapeutics. I think that's one of the major stumbling blocks."

Ian Ransome
Head of Product Management,
Process Development,
Bioreactor Technologies,
Sartorius

Cell and gene therapies (see next page) are next-generation biologics offering treatment and cures for diseases previously thought to be incurable. As such, they are addressing critical, unmet clinical needs.

For example, in 2023, the U.S. Food and Drug Administration (FDA) accelerated the approval of Elevidys, a new gene therapy that treats specific cases of Duchenne muscular dystrophy.[1] This life-threatening disease causes progressive and severe muscle weakness, leading to serious cardiac and respiratory symptoms and, ultimately, premature death.

Even more recently, in 2024, the FDA granted accelerated approval for Amtagvi, the first individualized T-cell therapy for solid tumors.[2] Amtagvi is a tumor-infiltrating lymphocyte (TIL) therapy for certain cases of advanced melanoma, which accounts for only ~1% of skin cancers but causes a large majority of skin cancer deaths.[3] These approvals represent an important example of how cell and gene therapies can meet the urgent need for advanced therapeutic options.

The recent surge in approvals underscores the rapid progress in the cell and gene therapy field.[4] Among the most exciting developments of 2023 was the approval of Casgevy, which is a treatment for sickle cell disease and is the first FDA-approved therapy that uses CRISPR-Cas9 gene editing technology.[5] This milestone highlights the fast pace of innovation and the growing opportunity for new treatments.

The demand for these innovations is on the rise, with the potential of cell and gene therapies now extending far beyond the treatment of rare and ultra-rare diseases. The increased attention has also highlighted the need for manufacturers to develop tools that expedite the commercialization of their products, thereby increasing patient access to effective therapies. However, the rapid evolution of the field brings challenges, including navigating regulatory hurdles, developing and scaling complex manufacturing processes, and overcoming logistical challenges related to specialized handling. These are associated with long timelines and high costs, but neglecting to take the appropriate measures increases the risk of trial failures.

Sartorius shares your mission to bring life-changing cell and gene therapies to patients. In this white paper, we examine the challenges associated with process development and manufacturing of cell and gene therapies. We then detail how you can accelerate commercialization with end-to-end solutions that prioritize performance and scalability with a simplified path to regulatory approvals. Together, we're setting the standard in cell and gene therapy.

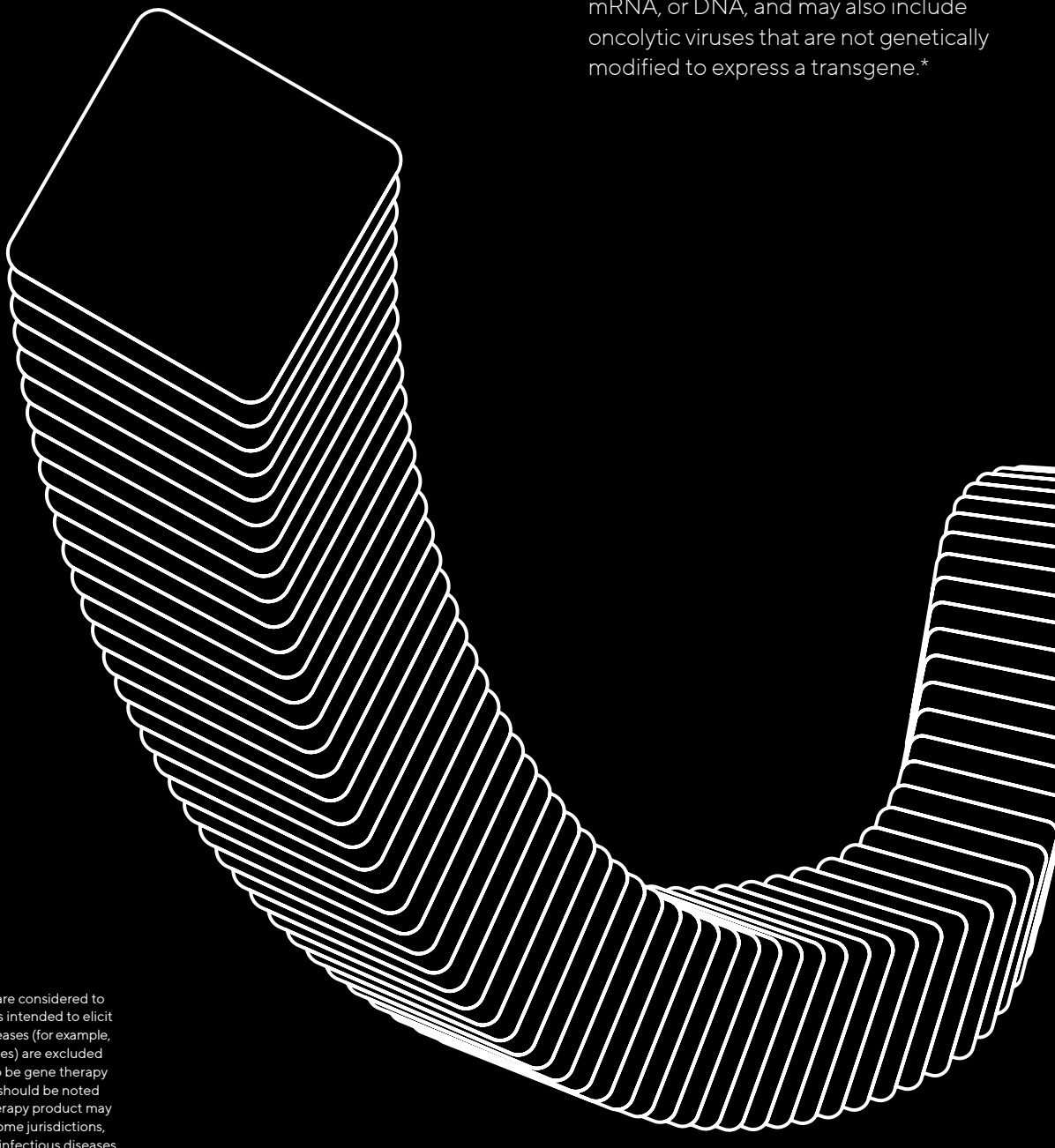
Cell and Gene Therapies at a Glance

Cell and gene therapies refer to a diverse range of drug products that work by directly modifying human cells and tissues or altering genetic material to treat disease at the molecular level. While they sometimes overlap, their features and therapeutic applications are often distinct.

The World Health Organization (WHO) defines them as follows:[8]

Cell therapy product: a product composed of human nucleated cells intended for replacement or reconstitution, and | or for the treatment or prevention of human diseases or physiological conditions, through the pharmacological, immunological, or metabolic action of its cells or tissues.

Gene therapy product: a medicinal product containing nucleic acids (for example, plasmids, messenger RNA (mRNA) or DNA) that are intended to regulate, repair, replace, add or delete a genetic sequence. The intended therapeutic effect is dependent upon the encoded gene used. Gene therapy products include those containing non-viral vectors (for example, lipid nanoparticles) or viral vectors that are used *in vivo*, as well as cells that have been modified by these types of vectors *ex vivo*. They may contain plasmids, mRNA, or DNA, and may also include oncolytic viruses that are not genetically modified to express a transgene.*

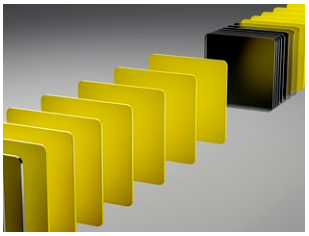


*Within this definition, gene edited products are considered to be gene therapy products. However, vaccines intended to elicit an immune response to prevent infectious diseases (for example, mRNA, plasmid DNA or viral-vectored vaccines) are excluded from this definition and are not considered to be gene therapy products within the definition of an ATMP. It should be noted that the scope of what constitutes a gene therapy product may vary between regulatory authorities and, in some jurisdictions, might include prophylactic vaccines against infectious diseases.

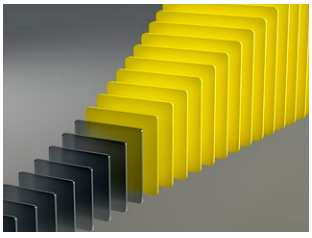
Development and Manufacturing Challenges

Cell and gene therapies are a unique class of treatments that present some new manufacturing challenges. Often, existing equipment and consumables used in the production of traditional biotherapeutics are not optimal for cell and gene therapy processes. The relative nascency of the field means deep process understanding is lacking. Combined with the complexity and diversity of these therapies, there is an absence of standardized production platforms.

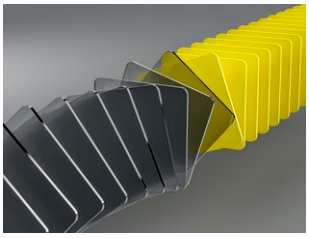
We consider the challenges of cell and gene therapies to fall under three key needs: achieving reproducible performance, streamlining scale-up, and simplifying the path to regulatory compliance.



Reproducible Performance
Cell and gene therapy process development is often slow and expensive owing to a lack of deep process understanding, time-consuming manual operations, and batch-to-batch variability. Overlooking quality and reproducibility until the end of the development process can significantly increase costs and extend development timelines.



Streamlined Scalability
Without scalable tools and methods, transferring cell and gene therapy processes from development- to large-scale production can create inconsistent results, including reduced yields. This can lead to costly changes in process procedures and a prolonged time to market.



Regulatory Compliance
Cell and gene therapy manufacturers must be prepared to adhere to the latest regulatory guidance in a rapidly changing landscape. This includes developing and managing efficient, high-quality Chemistry, Manufacturing, and Controls (CMC) to demonstrate a well-characterized and controlled process.

In the following sections, we navigate cell therapies and gene therapies independently to address their unique challenges. Recognizing the distinct hurdles within each area, we concentrate on two representative examples: stem cells for cell therapies and adeno-associated viruses (AAV) for gene therapies.

Cell Therapy

Cell therapy involves introducing cells into the patient to replace, modulate the function of, or remove diseased cells. A range of cells can be used in cell therapy; typically, stem or immune cells are employed due to their regenerative and therapeutic properties. Depending on the treatment required, these cells may be administered in their natural state or after undergoing modification to alter their function or enhance their efficacy. The cells can be sourced from the patient (autologous), ensuring compatibility and reducing the risk of rejection, or from a donor (allogeneic), broadening the scope for treatment options and accessibility.

Clearly, cell therapies are diverse, and a one-size-fits-all production approach is inappropriate. They are also distinct from traditional biotherapeutics, in which cells are typically used as 'hosts' during production. In cell therapies, the cells themselves are the therapeutic product. As such, they require tailored manufacturing strategies and tools to support their successful production.

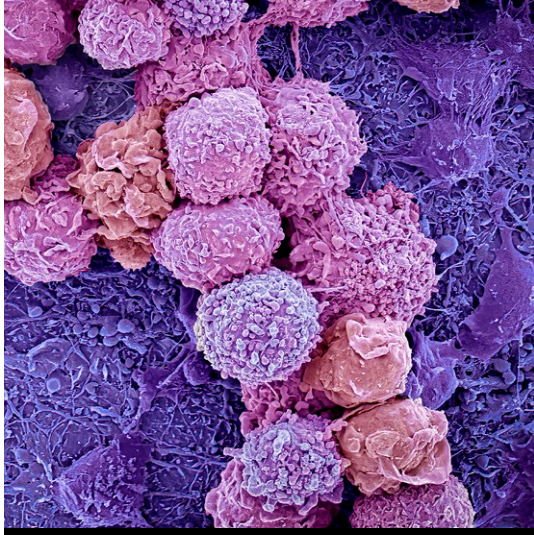
Modality in Focus — Stem Cells

Stem cell therapies include pluripotent stem cells (PSCs), induced pluripotent stem cells (iPSCs), mesenchymal stem cells (MSCs), and hematopoietic stem cells (HSCs), among other types. They work by generating new tissue, encouraging the body to repair damaged tissue, modulating the immune system, and potentially delivering gene therapy.

Here, we help you navigate the challenges of stem cell therapy manufacturing to achieve reproducible performance, streamlined scale-up, and a simplified journey to regulatory compliance.

Setting the Standard in Reproducible Performance

Stem cell therapy production processes are diverse, making process standardization a challenge. Ensuring high yield and viability is particularly challenging because the cells themselves are the therapeutic product and must be safeguarded throughout the workflow. This requires more gentle solutions than those typically used for other modalities. Combined with tedious, manual processes and the challenge of maintaining sterility, avoiding process variability and batch losses is challenging.



FDA-Approved Stem Cell Therapies

Casgevy (2023) — an autologous cell-based gene therapy that uses CRISPR | Cas9 genome editing technology to boost the production of fetal hemoglobin in the HSCs of patients with sickle cell disease.

Omisirge (2023) — an allogenic cell therapy to reduce the risk of infection in blood cancer patients scheduled for umbilical cord transplantation following myeloablative conditioning.

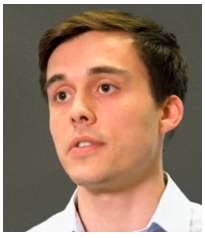
Lyfgenia (2023) — an autologous cell-based gene therapy in which the patient's HSCs are modified to produce a functional hemoglobin A protein to treat sickle cell disease.

Skysona (2022) — an autologous cell-based gene therapy in which the patient's HSCs are modified to produce a functional adrenoleuko-dystrophy protein to treat patients with early cerebral adrenoleuko-dystrophy (CALD).

Zynteglo (2022) — an autologous cell-based gene therapy that treats beta-thalassemia by adding a modified beta-globin gene to the patient's HSCs *ex vivo*, allowing them to produce near-normal levels of hemoglobin.

"We have tools that are 21 CFR Part 11 compliant, as well as audit trails and everything needed to be prepared if and when you have interactions with the authorities."

Johan Hultman
Manager of Technical Sales
and After Sales Support,
Digital Solutions,
Sartorius



"The situation we're facing is we've got truly life-saving therapies, but we're not able to produce enough to get them into the hands of patients. We need scalable processes with high-throughput process development tools, which will ease and facilitate the progression into clinical and eventually commercial phase production and hopefully provide these therapies to a much wider base of patients."

Pierre-Springuel
PBioChemEng PhD Candidate,
University College London

Building robust, reproducible stem cell therapy processes requires replacing slow, complex, and risky manual processes with high-throughput automated platforms supported by data analytics to reveal valuable process insights.
These tools might include microbioreactor systems that support consistent performance from process development to commercial-scale production, as well as solutions to simplify the small-volume liquid handling required for cell therapies.

Maintaining the attributes necessary for therapeutic efficacy requires high-quality input materials optimized to maintain and expand the cells of the correct phenotype. This includes cell culture media, cytokines, and biopreservation solutions, all of which contribute to the functionality and performance of the cells. Critical factors to consider include maintaining pluripotency or multipotency, differentiation capacity, genetic stability, cell viability, and the expression of cell type-specific phenotype markers. Additionally, during processing, low-shear solutions specifically designed for cell therapy harvest and purification are necessary to maximize yields and preserve the viability of these sensitive modalities.

Setting the Standard in Streamlined Scale-Up

Obtaining a clinically relevant number of stem cells with traditional culture methods is poorly sustainable and cost-prohibitive. The expansion of cells in 2D cultures is limited by surface area, making it difficult to achieve the large cell numbers required for clinical applications. This requires large volumes of expensive raw materials, increases the facility footprint, and ties up precious labor resources.

Compounding these logistical challenges are potential issues with yield and quality. The critical quality attributes achieved with the tools used during process development may not be replicated with the tools appropriate for larger volumes, leading to costly revalidation efforts. Possible changes in the culture environment during scale-up can also impact performance: cells grown in 2D culture may not accurately represent the 3D, *in vivo* state . This can lead to changes in cells' morphology, behavior, and differentiation potential, which can affect the clinical efficacy of the final product.

Scalable manufacturing platforms are required to quickly and seamlessly move from research and development to late-stage clinical or commercial manufacturing. Single-use, geometrically-conserved bioprocessing solutions are an ideal solution for achieving consistent performance across scales. These include culture systems from benchtop to commercial-scale bioreactors that support high-density 3D cultures, and single-use bags for scalable freeze | thaw.

Transitioning from small- to large-volume stem cell culture requires a partner that can provide a secure supply of sufficient volumes of high-quality, consistent cell culture reagents to avoid stalling production or introducing variability.

Setting the Standard in a Simplified Journey to Regulatory Compliance

Cell and gene therapies are novel, complex, and diverse, making navigating regulatory approvals challenging. Of critical importance is the CMC, which must be properly designed and implemented to demonstrate process robustness and patient safety throughout the lifecycle.[6]

Challenges include demonstrating that contamination risk is minimized by limiting open handling steps, avoiding batch-to-batch variabilities, and utilizing GMP-compliant reagents to consistently achieve the required quality throughout the drug lifecycle.

A simplified journey to regulatory compliance requires solutions that support tightly controlled, aseptic processing and high-quality media and reagents, as well as the expertise required to navigate the complex regulatory landscape.

These might include single-use, pre-assembled consumables and systems designed to support closed processing, ensuring the maintenance of sterility throughout your process. Sourcing media and reagents backed by stringent quality assurance protocols, produced in accordance with relevant GMP guidelines, and supported by the relevant documentation will also aid in regulatory approvals.

"You need to collaborate with a partner who understands the regulatory landscape. You should also have early discussions with the regulatory authorities to understand whether you are taking the right path. This avoids being surprised by CMC stumbling blocks that will impact development timelines and cost."

Ahmed Youssef
Senior Manager USP,
Ascend Therapies

Stem Cell Therapy Workflow

Sartorius' diverse portfolio for stem cell production processes includes upstream solutions like automated media aliquoting solutions and specialized media, and downstream solutions like low-shear centrifugation systems and reliable biopreservation media.

For a detailed process view, visit sartorius.com/en/applications/cell-and-gene-therapy/cell-therapy/stem-cell-therapy

1 Media and Buffer Preparation


Linkit® AX


Stem Cell Media


Biowelder® TC


Sartopore® 2


Sartocheck® 5 Plus


Confidence® Validation Services

2 Cell Isolation, Reprogramming, and Banking


Recombumin® rHA


NutriFreez® D5 & NutriFreez® D10

3 Expansion and Differentiation


Ambr®


Biostat STR®


Recombumin® rHA


Stem cell media


Preclinical- and GMP-grade cytokines.

4 Analytics


MODDE® DOE


SIMCA® MVDA

5 Harvest


Ksep®


Stem cell media


Recombumin® rHA

6 Formulation, Fill and Finish


Celsius®


Recombumin® rHA


NutriStor®


NutriFreez® D5 & NutriFreez® D10

Gene Therapy

In gene therapies, genetic material is introduced into patient cells or tissues to treat disease. They work by replacing a disease-causing gene with a healthy copy, inactivating a disease-causing gene, or introducing a new or modified gene.

Gene therapy products can include viral vectors, plasmid DNA, mRNA, and genome editing technologies such as CRISPR | Cas9-based therapies. Currently, the most established and leading platform for gene therapies are viral vectors. However, even within this category, there are various types, such as adenoviruses, AAVs, and lentiviruses, each with its own diversity. Here, we focus on the leading viral vector technology, AAV.

Modality in Focus—AAV

A 2022 market report on the gene therapy landscape reported that 32% of the gene therapies in the clinical and commercial pipeline use AAV vectors,[7] with five currently approved by the FDA. AAV-based gene therapy is popular because of the broad cell tropism of the many AAV serotypes, which allows them to specifically target a variety of cell types, and their low immunogenicity in humans, minimizing adverse events in patients. These valuable properties are increasing the demand for reliable platforms for the reproducible, scalable, and regulatory-compliant production of AAVs.

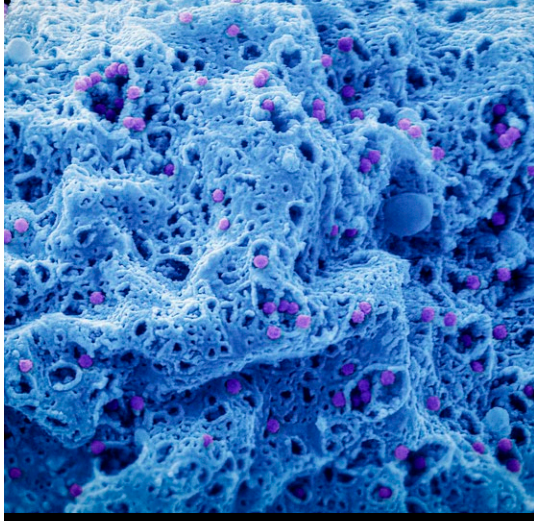
However, AAV production processes are complex. Unlike mature modalities, like monoclonal antibodies (mAbs), AAV processes are not well-established, creating a lack of process understanding that delays development timelines.

Below, we discuss how you can overcome gene therapy manufacturing hurdles through reproducible performance, streamlined scale-up, and a simplified journey to regulatory compliance.

Setting the Standard in Reproducible Performance

Gene therapy manufacturers require a robust and high-performing process, which lays the foundation for reproducible results. However, the diversity of different serotypes makes designing a platform approach challenging. This forces manufacturers to rely on largely manual, disjointed processes and long development times to establish a high-performing process.

Upstream processes are hampered by difficult transfection steps, which can generate lower titers and AAVs lacking the necessary critical quality attributes (CQAs), such as empty and partial capsids. Downstream processes must overcome the technical challenge of isolating full capsids, which requires individual optimization for each process and serotype.



FDA-Approved AAV Therapies

Elevidys (2023)—Recombinant AAVrh74 delivers a micro-dystrophin gene to muscle cells to treat children with certain types of Duchenne muscular dystrophy.

Roctavian (2023)—Recombinant AAV5 targets liver cells to deliver a modified form of factor VIII to treat patients with certain types of hemophilia A.

Hemgenix (2022)—Recombinant AAV5 targets liver cells to deliver an active factor IX protein to treat patients with certain kinds of hemophilia B.

Zolgensma (2019)—Recombinant AAV9 delivers a functional copy of the *SMN1* gene to the neurons to treat patients with certain types of spinal muscular atrophy.

Luxturna (2017)—Recombinant AAV2 delivers *RPE65* to retinal pigment epithelium cells in order to treat vision loss due to inherited retinal dystrophy associated with *RPE65* mutation.

"Sartorius are offering complete end-to-end solutions for cell and gene therapy; from upstream cell culture to downstream chromatography, we're able to propose products and services to help AAV developers build a platform to suit their needs."

Catherine Buchere
Product Manager,
Virus-Based Therapeutics,
Sartorius

"If you look at oncological applications and other typically age-related diseases, the population is often substantial enough that you will need to scale up processes to very large volumes to meet future demands."

Harm Niederländer
Platform Development Specialist,
Sartorius

Solving these challenges requires access to innovative, reliable equipment and raw materials across the entire workflow. High-quality reagents, process development tools, and robust analytics are required to quickly design, establish, and maintain productive workflows that deliver the required yields while keeping costs to a minimum.

Critical raw materials include high-performing transfection reagents to increase AAV infectivity and process titers to expand the number of doses per batch, allowing manufacturers to meet increasing pressure to improve patient access to cost-effective therapies.

Intuitive data analytics will facilitate deep process exploration, including identifying sources of variability, predicting future behavior, and supporting informed decision-making.

Setting the Standard in Streamlined Scale-Up

Meeting patient demand requires early consideration of technologies and consumables to ensure that they support an easy transition to large volumes in the future. If AAV processes are not high-yielding and are not developed with scalable and cost-effective tools, transferring to clinical and commercial production will require significant and expensive revalidation and optimization in order to meet CQAs and drive yields.

Selecting flexible technologies with conserved parameters across different volumes will help maintain consistent performance during process transfer across scales. Scalable downstream purification solutions that promote high recovery for multiple AAV serotypes, reduce the overall cost of goods (COGs). For example, monolithic chromatography columns provide fast, high-capacity purification with excellent recovery rates and are available in ready-to-use GMP formats with proven scalability.

Setting the Standard in a Simplified Journey to Regulatory Compliance

Owing to its relative nascency, the gene therapy regulatory landscape is complex and highly dynamic. Manufacturers must manage an effective CMC strategy, including employing qualified assays to demonstrate a well-characterized and controlled process with adequate patient safety procedures to overcome regulatory hurdles.

Selecting GMP-compliant technologies, consumables, and reagents will simplify and accelerate regulatory submissions. Implementing closed processing with automation and single-use solutions will minimize contamination risk by avoiding open handling and operator interventions.

Accessing AAV testing services can support the characterization of AAV products required at every stage of drug development. Processes can be further validated with extractables and leachables studies, toxicology assessment, and stability studies as part of a wider risk mitigation strategy.

"When bioprocess scientists develop an AAV therapy, they often overlook the quality part until the end of the process. This extends development timelines and creates cost implications."

Ahmed Youssef
Senior Manager USP,
Ascend Therapies

"It is typically not possible to perform sterile filtration at the end of your viral vector production process. Our fully contained and single-use solutions provide a unique opportunity to avoid associated regulatory complications."

Harm Niederländer
Platform Development Specialist,
Sartorius

AAV Therapy Workflow

Sartorius is a one-stop shop for AAV production equipment and consumables. Our upstream portfolio includes diverse solutions like chemically defined media and transfection reagents, scalable bioreactors, and analytical tools. Our downstream solutions include high-performing filters for clarification and chromatography solutions tailored for large, shear-sensitive biomolecules.

For a detailed process view, visit sartorius.com/en/applications/cell-and-gene-therapy/gene-therapy/aav-gene-therapy

1 Fluid Management, Media and Buffer Prep


Flexsafe® Pro Mixer & Flexsafe® 2D


Biowelder® TC


Extractables and leachables testing


Sartopore® 2


Virosart® Media

2 Vector Engineering and Production


Recombumin® rHA


FectoVIR® AAV


pPLUS® plasmids


HEK media


Ambr®


Biostat STR®

3 Analytics


MODDE® DOE


SIMCA® MVDA


CIMac™


Octet®


PATfix®

4 Harvest and Clarification


Sartoclear®


Sartopore® 2 XLG


Recombumin® rHA

5 Ultrafiltration and Diafiltration (UF|DF)


TFF cassettes:


Ambr® Crossflow


Sartoflow® Smart


Sartoflow® Expert

6 Capture and Polishing


CIMmultus®


Cornerstone®

7 Cold Chain Management

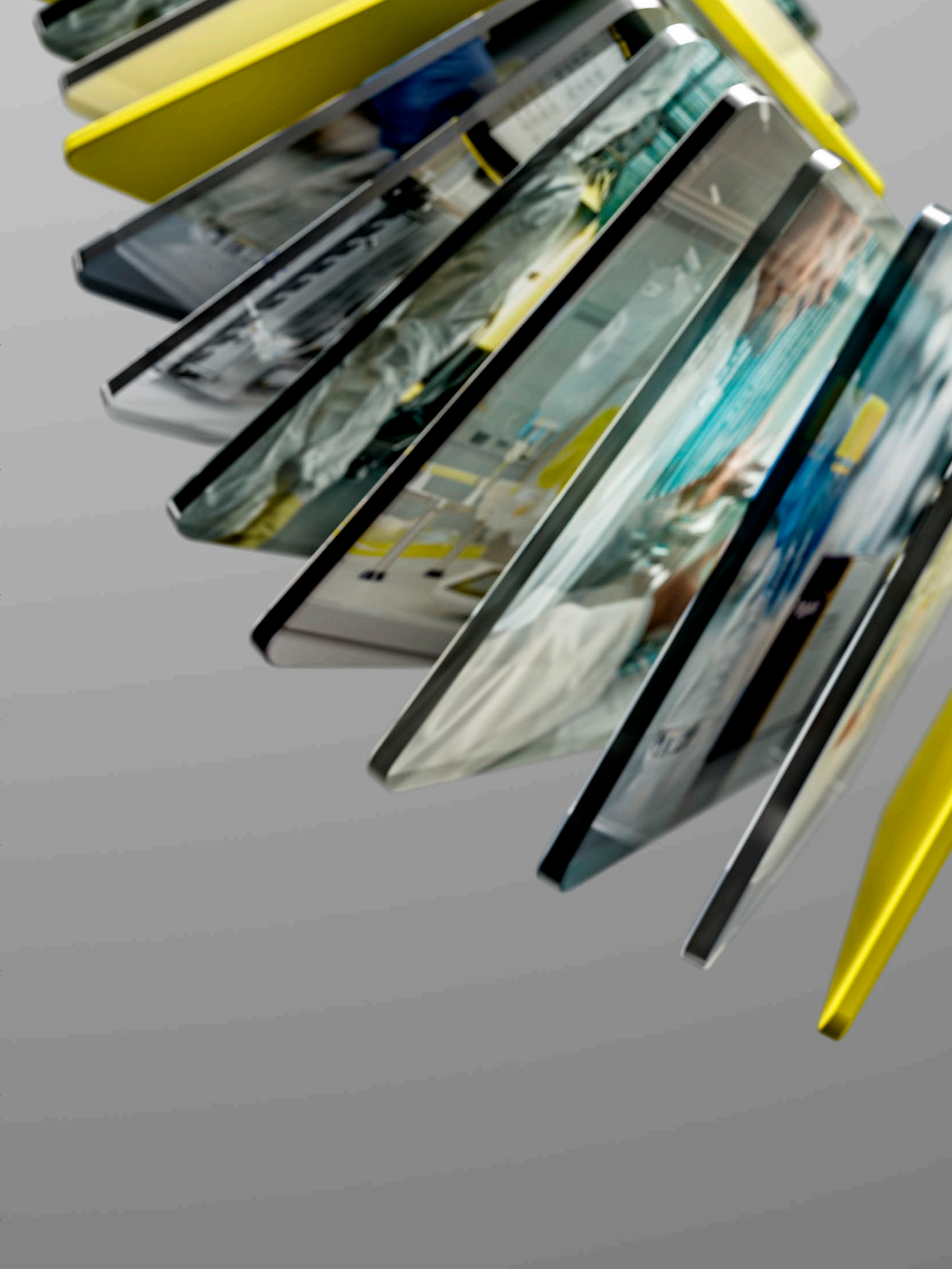

Celsius®

8 Final Filtration, Fill and Finish


Sartopore® 2 XLG


Sartocheck® 5 Plus


Recombumin® rHA



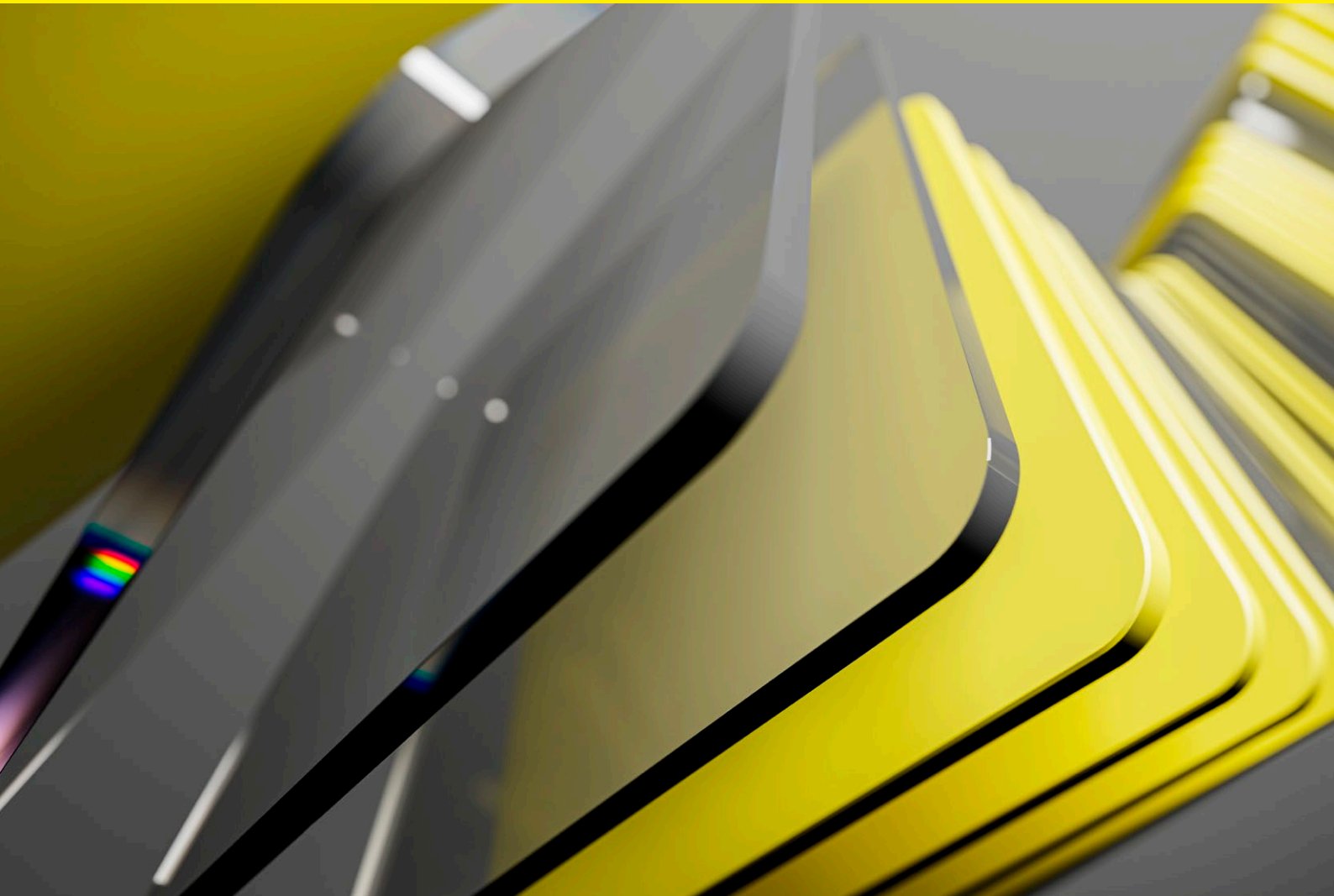
Conclusion

The rapid advancements in cell and gene therapies are revolutionizing the treatment landscape for previously incurable or untreatable diseases. However, the journey from development to commercialization is paved with hurdles, including achieving reproducible performance, streamlining scalability, and navigating complex regulatory landscapes. These challenges must be overcome to provide patients with a reliable supply of high-quality treatments.

Sartorius is committed to partnering with you to overcome these obstacles. By leveraging our end-to-end solutions, you can ensure high-quality, scalable, and compliant processes that meet the stringent demands of the industry. By prioritizing quality from the start, you can adopt scalable, compliant tools and take advantage of regulatory expertise to accelerate time to market.

Together, we are setting the standard in cell and gene therapy.

For more information, visit
sartorius.com/cell-gene-therapy



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Katy McLaughlin
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Scientific Content Writer,
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Katy is part of the Marketing Communications team at Sartorius, where she supports the creation of a variety of written pieces, from published articles to web content.

Before joining Sartorius in 2021, Katy was employed as a Post-Doctoral Research Associate at the University of Edinburgh, where she also completed her doctoral studies. Here, she carried out research in genetics and cellular biology and began taking on writing projects, eventually entering into a career as a freelance writer for various biotech companies and agencies.

Rukmini Ladi
External Collaborations Manager,
Cell and Gene Therapy,
Sartorius

Rukmini is a Bioprocess Development Engineer with over several years of experience, specializing in the process development of immune and stem cell therapies.

As an External Collaborations Manager she leads strategic partnerships with industry leaders and academic partners in the field of cell therapy for end-to-end process optimization and intensification by leveraging Sartorius' advanced therapies solutions.

David Ede
Process Technology Manager
Viral-based Therapeutics,
Sartorius

David is a biomedical and chemical engineer and has a background in process development and manufacturing for viral vectors.

In his current role as Process Technology Manager at Sartorius, David supports viral-based biotechnology stakeholders and helps bring their bioprocess from R&D to commercial scale.

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