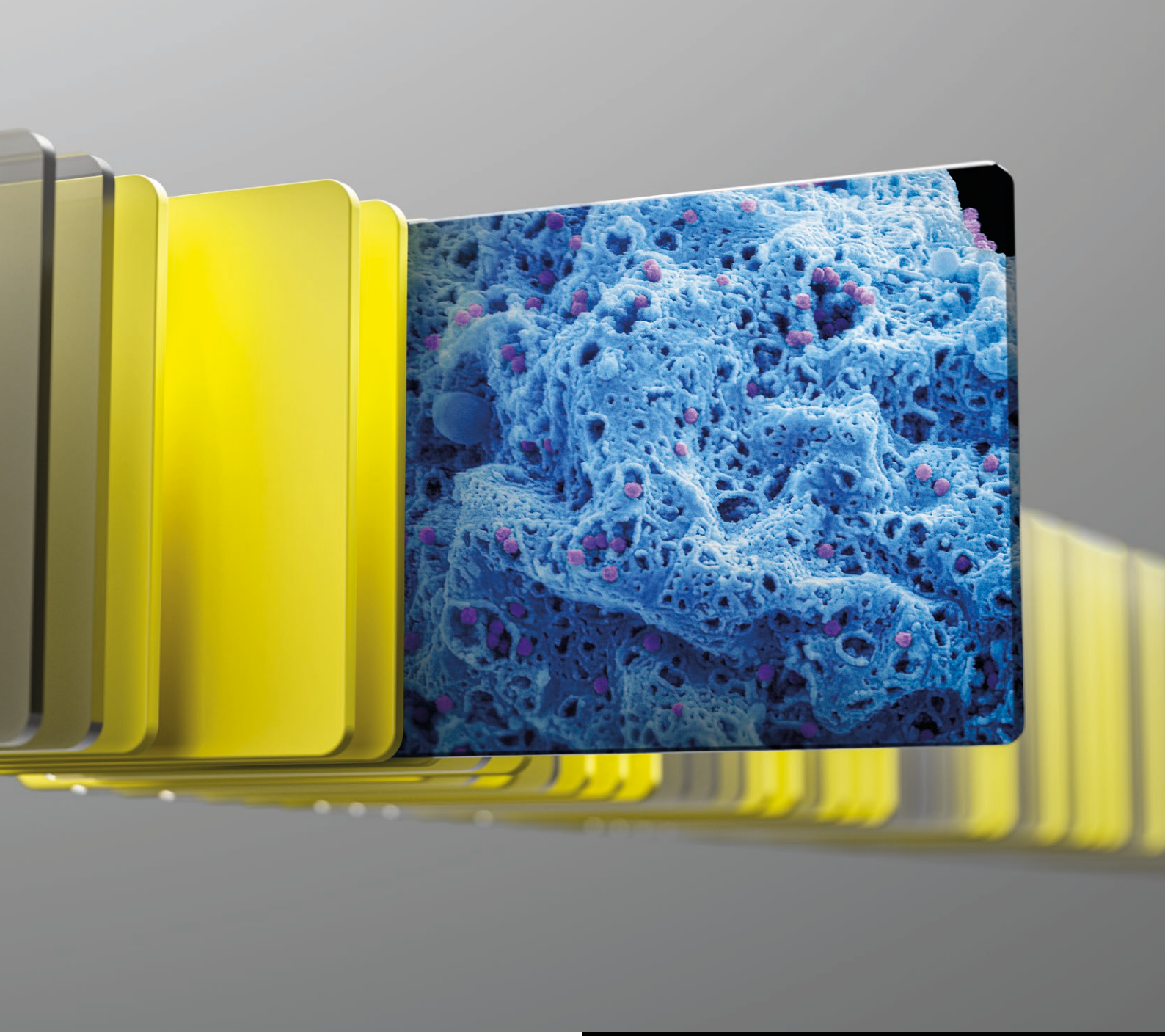

Simplifying Progress

Downstream AAV Production: Tools for Efficient and Reliable Gene Therapy Manufacturing

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SARTORIUS

Foreword

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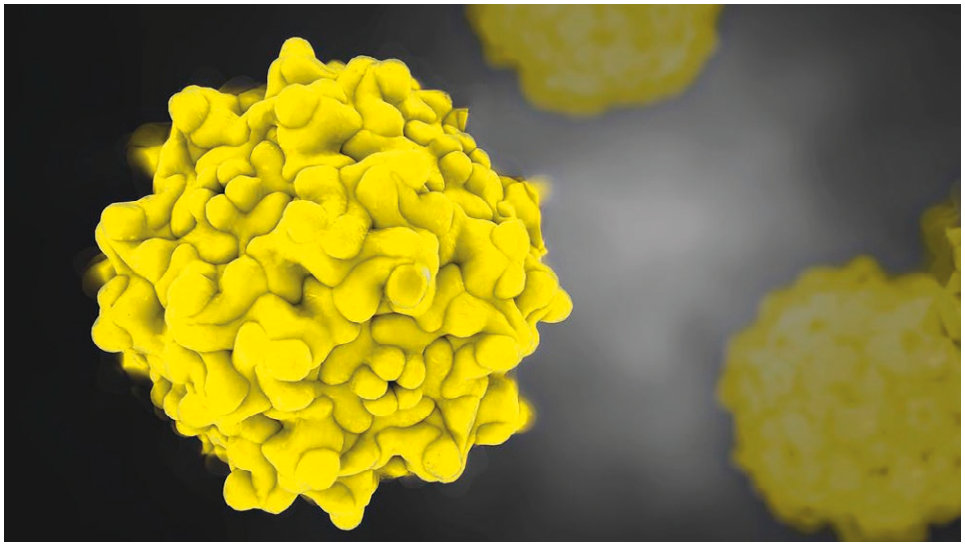
Adeno-associated viruses (AAVs) are the leading platform for in vivo gene therapy delivery due to their ability to establish long-term gene expression with minimal pathogenicity. Additionally, multiple AAV serotypes exist, enabling specific tropism for different organs and tissues within the body. Currently, there are seven rAAV-based gene therapy products that have received regulatory approval. However, safety concerns around patient immune response and adverse effects caused by high-dose viral-based therapies persist.

In recent years, there have been several high-profile rejections of gene therapy products by the U.S. Food and Drug Administration (FDA) due to a lack of chemistry, manufacturing, and controls (CMC) documentation.[1,2] While it may be tempting to speed through process development activities in favor of progressing into production, some key principles must be considered at each developmental phase to ensure that rAAV-based products are successful at clinical manufacturing stages.

Downstream AAV processes are particularly challenging due to the diverse purification options, different chromatography chemistries, choice of tangential flow filtration (TFF) filters or hollow fibers, and retention ratings for filtration steps. Some technologies scale into manufacturing more effectively than others, and this must be considered when selecting technologies in early research and development.

This white paper provides guidance for designing and executing an efficient downstream AAV production process using a selection of technologies that can be implemented in early-phase discovery and R&D to screen for optimal process conditions, and then scaled up for clinical and commercial production. For guidance on upstream AAV production, please refer to the associated white paper "Navigating Upstream AAV Production: A Checklist for Efficient and Reliable Gene Therapy Manufacturing".[3]



Downstream AAV Processing Challenges

The industry requires robust and reproducible AAV purification platforms to maintain progress toward increased accessibility for advanced therapeutics. However, as a relatively new modality, AAV purification processes lack standardization and are not yet entirely optimized.

Product Diversity

There is no 'one-size-fits-all' approach to AAV purification because individual serotypes require specific optimization, leading to longer development timelines. The level of impurity removal or the desired concentration of the drug substance influences the number of steps needed, leading to differences in product yield and purity.

Low Yield

The final volumes of high-dose applications are very small, typically smaller than most GMP systems. For some therapies, the bulk drug substance (BDS) has to be concentrated up to 10,000-fold to reach the administration titer. This means that host cell protein (HCP) | host cell DNA (hcDNA) impurities (that could not be removed during purification) are also concentrated, potentially putting them at an unsafe level for patient administration.

Removal of Impurities

The presence of empty AAV capsids and residual DNA fragments creates issues in the final drug product; hcDNA increases the risk of oncogenicity,[4,5] HCPs in large quantities are associated with various immunogenicity-related effects (such as inflammation or anaphylactic shock),[5] and the risks associated with empty capsids have not yet been fully determined. However, it can be difficult to separate empty capsids and DNA from functional AAV capsids without losing significant yield.

Evolving Regulatory Guidance

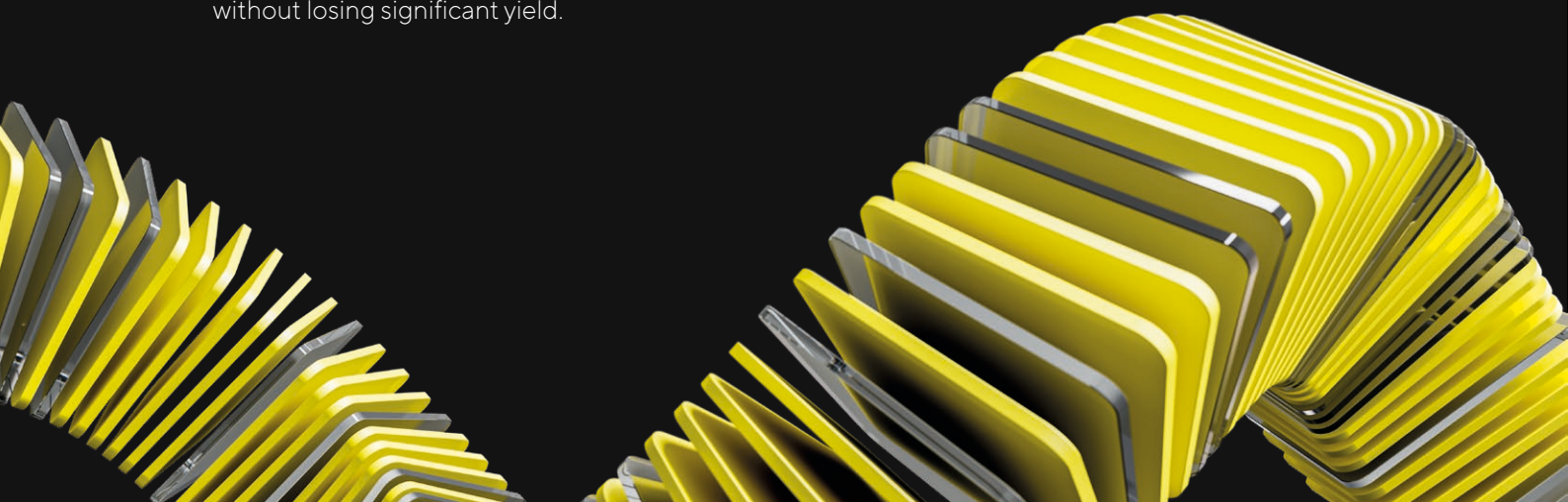
Regulatory guidance for other modalities, e.g., monoclonal antibodies, does not broadly apply to gene therapy. Regulatory guidance is constantly evolving, with regulators looking to manufacturers for help: The effects of specific product-related impurities, e.g., empty or partially full capsids, are still largely unknown, and viral clearance guidance is still not fully established due to the technical challenge of implementing this step in a viral vector process.

Sensitivity and Throughput of Analytical Methods

Standard assays typically require long preparative times, making them unsuitable for in-process measurements due to extended turnaround times. Long potency assay development results in an increased time to market.

Scalability From Research to Clinic

Multiple serotypes make designing a platform process difficult. Interaction between unit operations needs to be considered for every step of the process, with variance across each product. The final manufacturing scale of the process is also important, as this may determine what technologies can or cannot be used, causing further variance within the process.



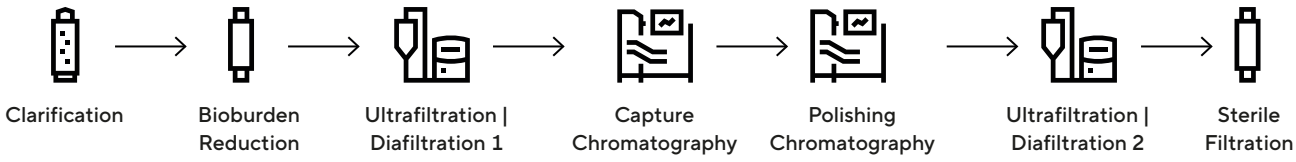
Downstream AAV Purification Workflow

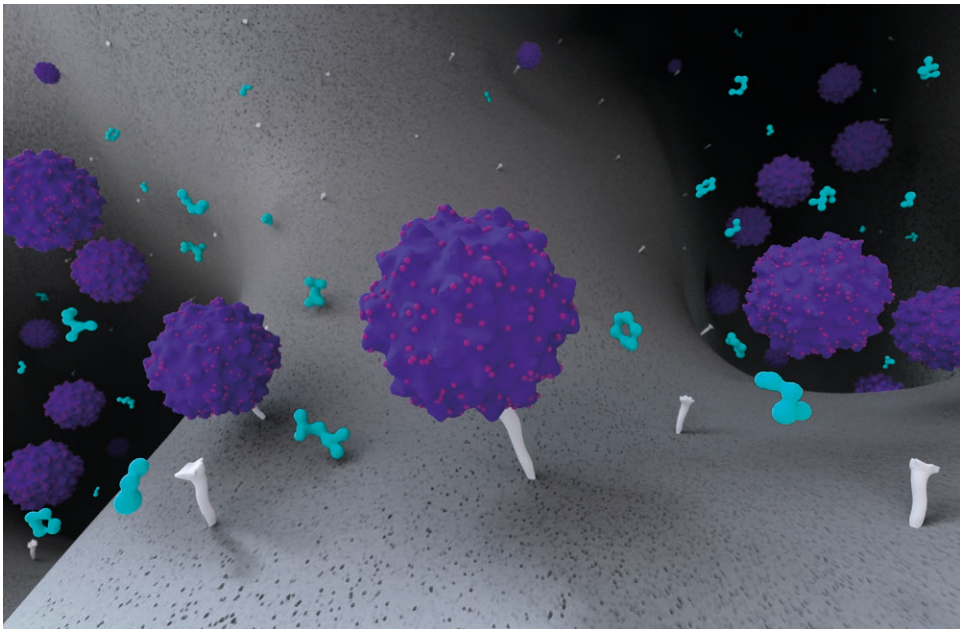
Despite the challenges in designing a platform process, a framework for what a "typical" AAV purification process looks like has been somewhat accepted by the industry, with the expectation that the consumables may change, but the process steps largely remain in the same order.

At the point of harvest, cell lysis is performed via the addition of detergent or a high salt buffer along with endonuclease for DNA digestion. Following this, clarification is performed primarily by depth filtration to remove the bulk of cellular impurities. Depending on the concentration and buffer composition of the product, a pre-chromatography concentration and buffer exchange via ultrafiltration | diafiltration (UF | DF) may be carried out.

AAV capture is primarily performed using either affinity or cation-exchange chromatography, followed by neutralization and buffer exchange into a suitable buffer for polishing chromatography, which is designed for full capsid enrichment (empty | full capsid separation). An additional UF | DF step is implemented to concentrate and buffer exchange the vector into into an appropriate drug substance formulation before a final sterile filtration step is performed.

Figure 1: *Typical Steps in a Downstream AAV Process*





Scaling From Pre-Clinical Research and Early Development to Clinical and Commercial Production

During research and early development, the priority is to maximize throughput by screening numerous conditions simultaneously to optimize multiple factors. A design of experiments (DoE) approach maximizes the number of parameters that can be examined in the fewest experiments, increasing the likelihood of identifying optimal conditions, particularly important for critical AAV process steps such as chromatography.

In the early stages of process development, purification operations are usually designed with a single goal in mind: to produce a sufficient amount of product as quickly as possible to meet key milestones for the progression of the project. This often means employing technologies that are inexpensive and easy to use, but have poor scalability and productivity, such as ultracentrifugation for product | impurity separation or spin filtration for buffer exchange.

However, without a clear vision of how this process will translate (or scale) to volumes suitable for commercial manufacturing, more resources will need to be dedicated to additional process development and optimization, potentially causing long delays. Changes to the purification process during clinical trials and beyond can also heavily impact regulatory submission timelines.

To maximize the likelihood of success, it is important to take a holistic view of the entire production and purification process during the pre-clinical phase and consider how the process will ultimately be implemented in the manufacturing stage. The decisions taken in one process step will directly affect the performance of every subsequent step; often, a poor-performing step in a process is due to an issue stemming from a previous step. As such, it is important to balance product quality with process performance.

Key decisions at the beginning of the development stage will have a great influence on the ease or difficulty of the regulatory submission process (which could occur 6-10 years after the initial development starting point). Non-scalable or poor-performing technologies need to be eliminated early and replaced with technologies that produce similar product quality from the pre-clinical stage, through clinical phase I, II & III, and into clinical manufacturing.

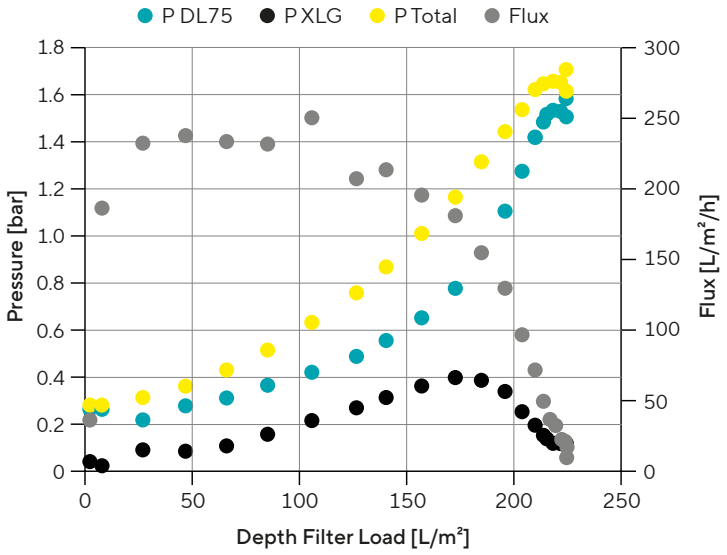
Addressing the Challenges

Overcoming a Challenging Feed Stream

The clarification step is often a bottleneck in the purification of AAV due to the difficult-to-filter cell lysate, which can quickly clog membranes and lead to high costs over time, particularly on large scales. Using complementary tools, such as filter aids, can boost filter capacity, improving the overall efficiency of the step. A recent publication tested Sartoclear Dynamics®, using diatomaceous earth (DE) to boost the performance of filters in the clarification of different AAV serotypes, finding DE filtration to be an efficient clarification aid for AAV2, AAV5, and AAV8.[6] It maintained high AAV yields while reducing manual handling time 3-fold and increased the filter capacity 3.5-fold compared to standard methods, representing significant potential for efficiency improvement. In addition, combining 1 L bottle top filters with the Sartolab® Multistation Stand allows for up to 6 L of lysate to be processed in parallel. In another study, we demonstrated the efficiency of using DE to shorten process times by 6-fold.[7]

High turbidity suspension cultures can limit filter capacity and lead to AAV product loss, limiting product recovery and, ultimately, yield. It is important to establish a scalable solution that can handle high biomass and turbidity loads. For example, Sartoclear® DL75 and DL60 depth filters demonstrated excellent performance in clarifying AAV8 viral vectors from HEK293 suspension cells.[8] Product recovery rates ranged between 80 – 100%, with minimal virus particle loss and high viral titer recoveries after both depth and sterilizing grade filtration. The Sartoclear® system also has the added benefit of being highly scalable with similar robust performance from bench to process scale, even under challenging feed conditions (Figure 2).

Figure 2: *Scaled-Up AAV8 Clarification With Sartoclear® DL75 0.2 m² Cassette*



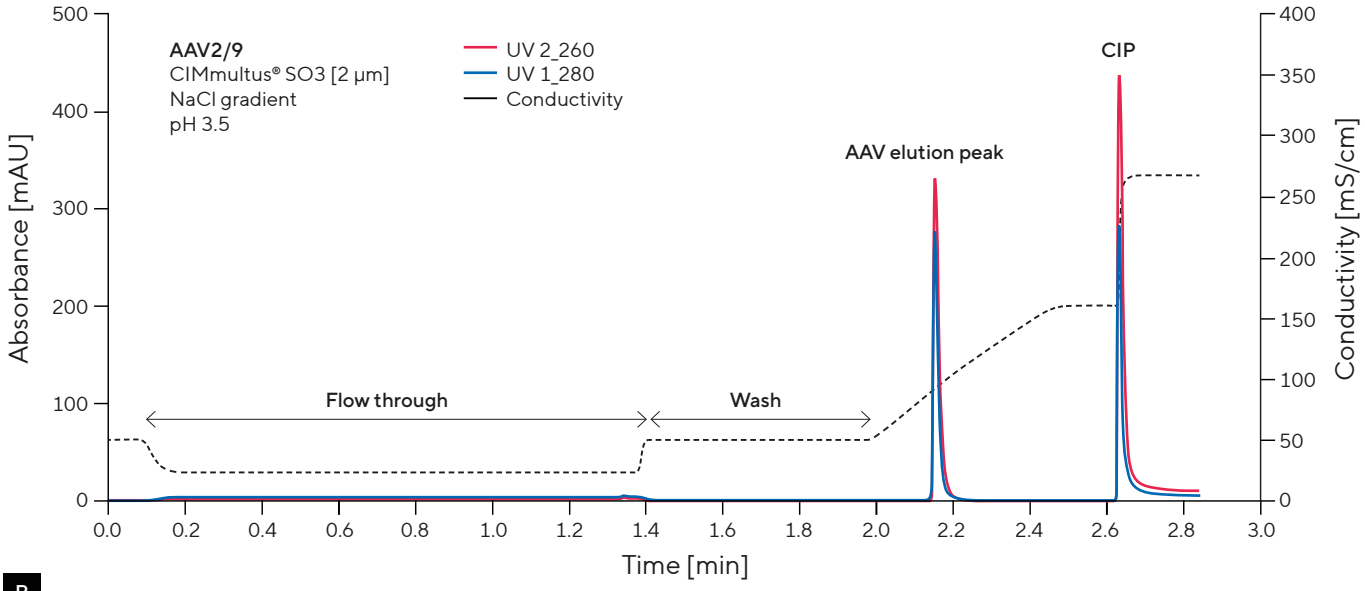
Note. Figure taken from the application note Sartoclear® Depth Filters for the Clarification of AAV.[8]

Exploring Alternative Chromatography Methods

Considering alternatives to chromatography resins can also improve AAV capsid recovery and separation of full and empty capsids. Cationic AAV capture using CIMmultus SO3 monoliths overcomes the limitations of serotype-specific resins. Using scalable multiwell chromatography plates facilitates the efficient screening of purification parameters, which can then be scaled to industrial levels. For example, Sartorius CIM® 96-well plates support the efficient screening of parameters for monolithic chromatography, which can be scaled up to a preparative scale using the CIMmultus® line.[9] The composition of the mobile phase (pH, NaCl concentration, and Poloxamer 188 additive) can be fine-tuned to enhance AAV binding efficiency and titer, with automated analytics further reducing manual input and increasing overall efficiency. Our study demonstrated successful scalability with high viral purity, showcasing the method's industrial applicability for rAAV purification (Figure 3).

Figure 3: ***(A)*** *Preparative Chromatogram Using CIMmultus® SO3 1 mL Column (Conditions Selected From CIM® SO3 96-Well Plate Screening);* **(B)** *SDS-PAGE Analytics for Tested Fractions*

A



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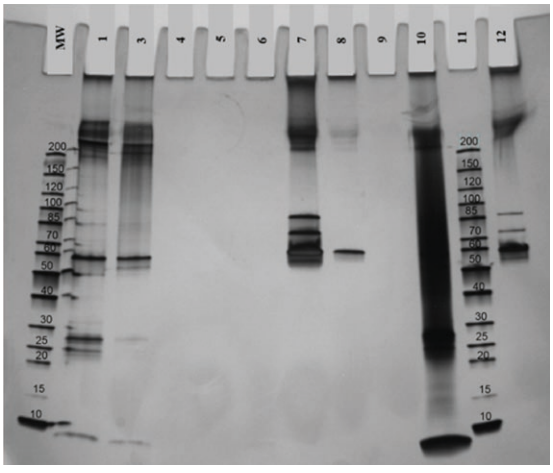
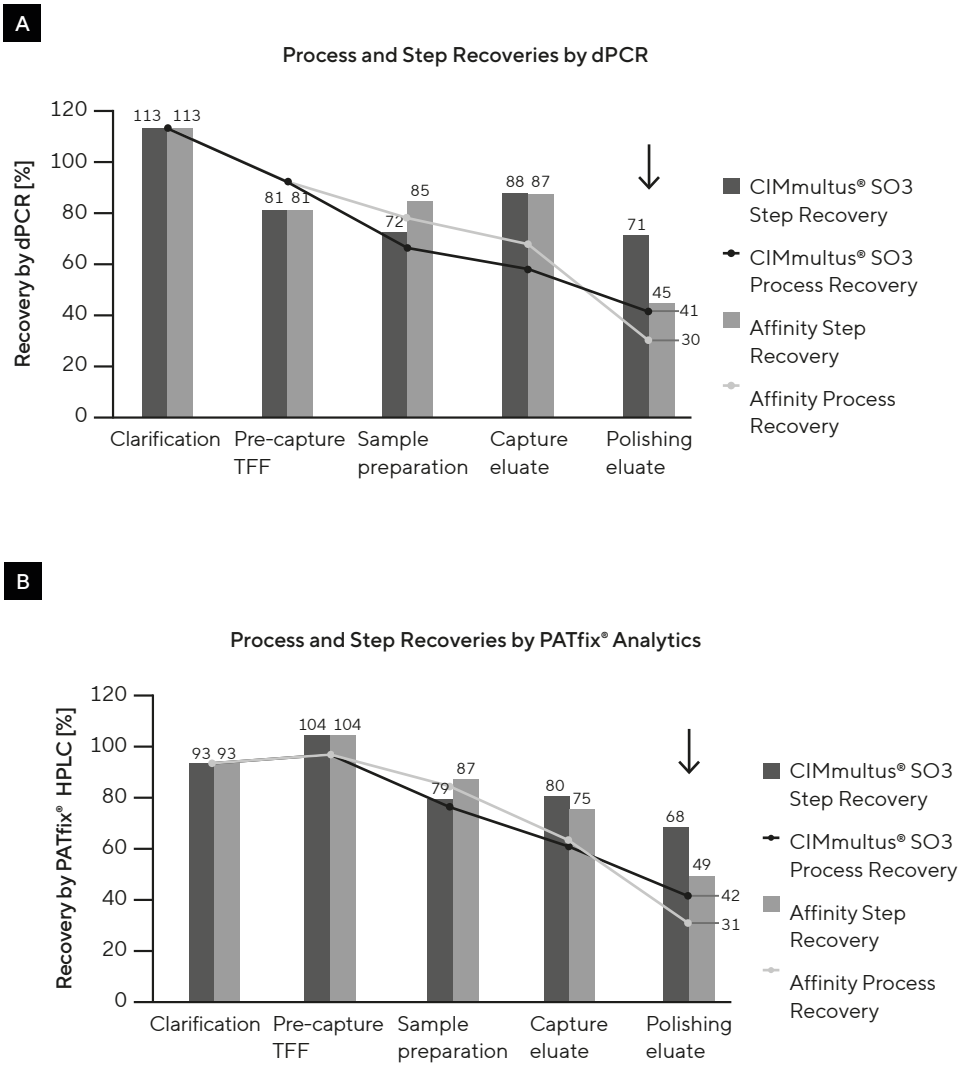


Lanes
1: Size marker
2: TFF retentate 2
3: Load
4: Flowthrough
5: Wash
6: E1
7: E2
8: E3
9: E4
10: CIP
11: Size marker
12: E2 (diluted 5x)

Note. Figure taken from the application note Fast and Semi-Automatic Optimization of Capture Step for rAAV Purification Using CIM® SO3 96-Well Monolithic Plate.[9]

Monolithic chromatography is ideally suited to the purification of large molecules like AAVs and offers increased throughput from improved yields and faster run times, benefitting from high capacity and ready-to-use formats. In a study comparing the purification performance of CIMmultus® SO3, an ion-exchange monolith, with a commercially available affinity resin in AAV8 purification (Figure 4), we found that the process employing monolithic chromatography was faster (two-fold reduction in process times) and delivered a 30% increase in the number of doses available to the clinic, while achieving a comparable or better reduction of impurities.[10]

Figure 4: *Process and Step Recoveries for Both Processes.* ***(A)*** *Analyzed by dPCR.* ***(B)*** *Analyzed by Cation Exchange Chromatography Fingerprint (CEX-FP) on the PATfix® System*



Note. The results shown in the step recoveries are the average values of the two repetitions. The highest discrepancies between the two processes are seen in the polishing step (arrow). Figure taken from the poster Comparability Study of an Ion Exchange Monolith and Affinity Resin for the Purification of AAV.[10]

Chromatographic purification of AAV is often implemented in a two-step approach, the second step of which is typically optimised for the separation of empty and full AAV capsids, along with the removal of other impurities. This can be achieved using multiple monoliths within our CIMmultus® portfolio: CIMmultus® QA, a strong anion-exchange monolith, and CIMmultus PrimaS® and PrimaT®, both multimodal monoliths. We have demonstrated that through DoE optimization and a panel of key analytics, all three monoliths can be suitable for the polishing chromatography step in an AAV process (Table 1).[11] The successful scale-up described in this study indicates the potential for large-scale manufacturing, ensuring consistent and high-quality AAV production.

Table 1: *Analytical Assay Results of AAV8 Polishing Runs Using Three Monoliths With Different Chemistries*

Monolith	Peak	vg Recovery [%]	vp Recovery [%]	DNA [ng/1×10^{13} vg]	Proteins [ng/1×10^{13} vg]
CIMmultus® QA	E	5.0±0.8	58±10	704±245	42±9
	F	97±9	35±5	37±7	2.4±0.1
CIMmultus PrimaS®	E	3.2±0.2	44±4	1,687±1,026	54±7
	F	78±36	27±10	68±36	5±5
CIMmultus® PrimaT	E	1.7±0.4	65±3	99,572±12,009	28±3
	F	119±2	24±1	115±158	0.5±0.1

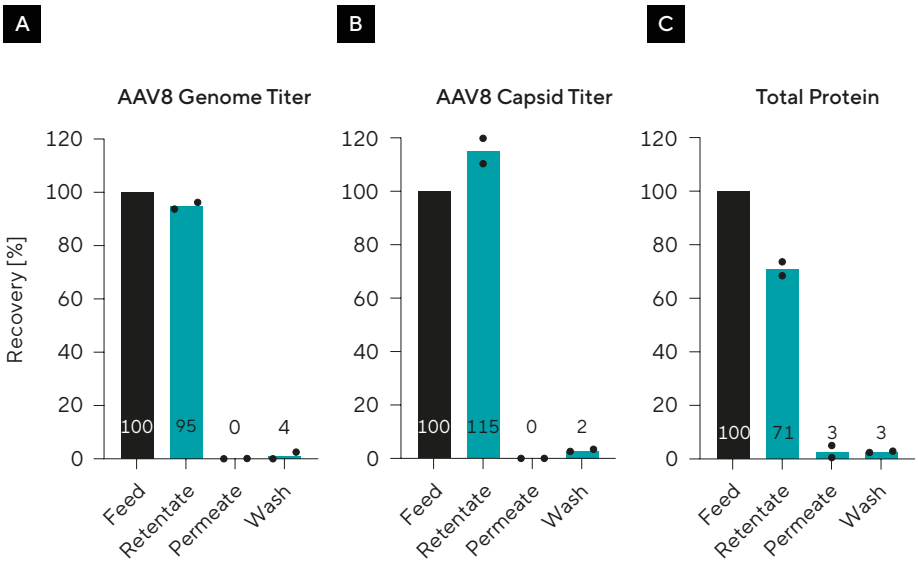
Note. E = empty particle peak, F = full particle peak. Mean (N = 2) ± Std Dev. Table taken from journal article Purification of AAV8 through a scalable two-step monolithic chromatography approach.[10]

Identifying High Performing Filters

TFF is widely used for buffer exchange and concentration in AAV processes. It enables the continuous processing of large volumes, meaning it is higher throughput and more scalable than other methods like centrifugal ultrafiltration, and thus more suitable for clinical and commercial production. However, identifying a high-performing filter—i.e., the optimal membrane material and molecular weight cut-off to achieve high recovery and impurity removal—requires multiple experiments. These are time-consuming and rely on the availability of large amounts (often scarce) of AAV material.

For small volume optimization, Vivaflow® SU cassettes can be used to optimize membrane selection for effective viral vector concentration. Sartorius scientists compared polyethersulfone (PES) and Hydrosart® regenerated cellulose (RC) membranes across molecular weight cut-offs of 30, 100, and 300 kDa.[12] The 100 kDa Hydrosart® RC membrane showed superior performance, achieving a 95% recovery rate of AAV8 genome copies with no detectable loss to the permeate, and removing 29% of total protein from the retentate (Figure 5). This membrane facilitated an 8-fold concentration of AAV8 in 50 minutes, demonstrating its suitability for laboratory-scale production of other AAV serotypes. The study highlights the efficacy of the 100 kDa RC membrane in enhancing AAV8 concentration and purity, making it a promising option for gene therapy applications.

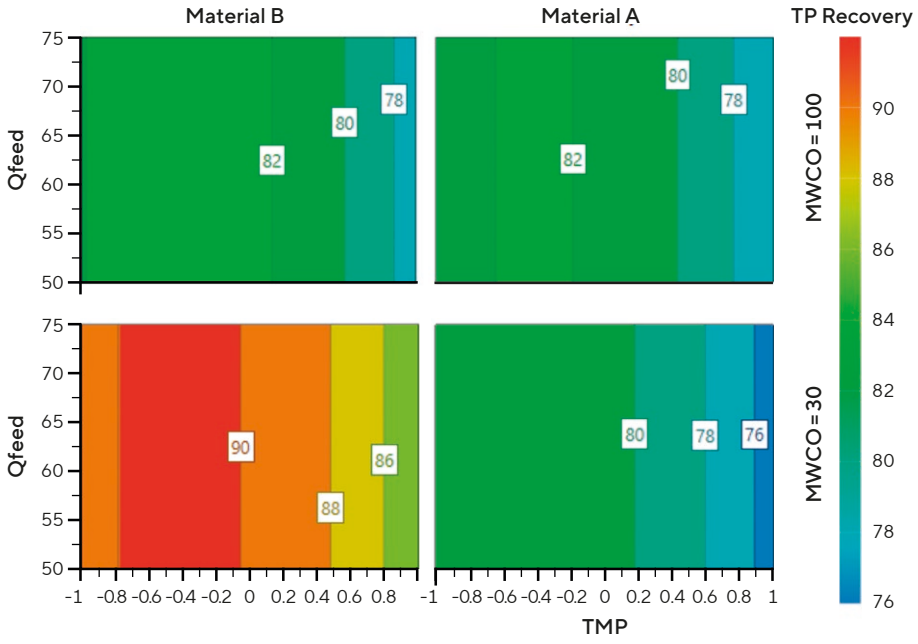
Figure 5: *Assessment of **(A)** and **(B)** AAV8 Recoveries and **(C)** Protein Removal Following Concentration of a Clarified AAV8 Sample Using TFF*



Note. TFF was performed using Vivaflow® SU cassettes with 100 kDa Hydrosart® RC membrane. All values were determined in duplicate. Figure adapted from the application note Lab-Scale Concentration of a Clarified AAV8 Lysate by Tangential Flow Filtration.[12]

High-throughput screening tools, such as the Ambr® Crossflow platform, accelerate these process development activities by allowing multiple experiments to be conducted in parallel in a scaled-down format, simplifying the selection of the optimal filter. We recently showed that the optimal process parameters and TFF cassette type could be efficiently identified by combining multi-parallel TFF screening in the Ambr® Crossflow with a DoE approach (supported by MODDE®, Figure 6).[13,14] The results were verified with a larger membrane on the Sartoflow® Smart system, demonstrating robust scalability.

Figure 6: *Contour Plot from DoE Analysis Showing Total AAV Particle Recovery Across Varying TMP and Feed Flow Rates (QFeed), Using Different Membrane Materials and MWCOs*



Note. Figure adapted from A High-Throughput and Automated Method for AAV Tangential Flow Filtration Process Development.[14]

Protecting Product Integrity

The final steps in AAV production include sterile filtration, final formulation and filling, as well as possible freezing (and, eventually, thawing) operations for storage and transport. These steps must maintain product integrity while ensuring the absence of adventitious agents.

Sterile filtration is challenging in AAV production owing to the large size of AAV molecules, their potential for aggregation, and filter adsorption. Adopting robust, scalable filters like Sartopore® 2 XLG offers manufacturers high capacity and flow performance, reducing filtration costs by 50 – 90%. Additionally, AAV capsids are often sensitive to freeze | thaw cycles. Controlled and validated freezing and shipping solutions are required to prevent their degradation and a reduction in infectious titer. Choosing single-use, "robust-by-design" cold chain solutions, like the Celsius® FFT, helps ensure consistent, reliable performance during freezing, storage, and transport, reducing the chance of batch failures.

Analytics

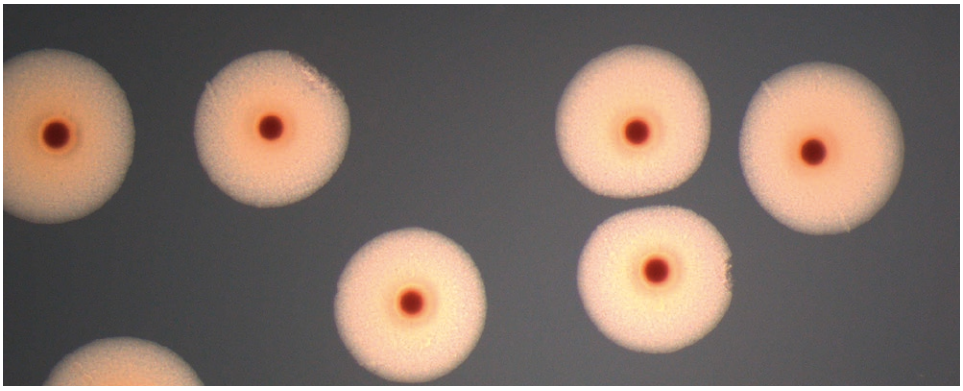
Analytical testing is a vital component of the product development lifecycle, spanning early research to commercial manufacturing. Initially, analytical assays focus on reliably identifying the target product and related impurities. As development progresses, the data from these assays becomes crucial for the CMC package required for regulatory submissions. During manufacturing, these assays help minimize batch-to-batch variation by ensuring process robustness, thereby maintaining consistent product quality. Defining analytical assays early is essential for optimization, qualification, and validation, often requiring orthogonal approaches to ensure robust data. The absence of a universal gold standard assay for establishing AAV titer further complicates this, as many assays are low-throughput and labour-intensive.

Automated monitoring tools such as the Octet® system support the rapid determination of viral titer and empty | full particle ratios. Sartorius developed a fast, high-throughput, and robust AAV2 capsid quantification method using Octet® Bio-Layer Interferometry system that can provide results from multiple 96-well or 384-well plates in less than 1 hour.[15] This saves significant time and labour compared to traditional ELISA or ddPCR assays and can be extended to any AAV serotype with Octet® AAVx Biosensors.

A multi-monitor approach using PATfix® biochromatography—combining dual-wavelength UV monitoring with intrinsic fluorescence, extrinsic fluorescence, and light scattering—has also been shown to improve the sensitivity and accuracy of AAV characterization, particularly in distinguishing between empty and full capsids.[16–18] This method can accelerate process development, provide rapid in-process monitoring, and support process validation activities.

Additionally, the Incucyte® system can also be used as a live imaging tool for the determination of infective titer with a fluorescent transgene, such as Enhanced Green Fluorescent Protein (EGFP).[19]

Beyond product analysis, it is also important to test for adventitious agents, such as mycoplasma, to ensure the safety and efficacy of biological products. Due to the time it takes to rule out mycoplasma using the compendial mycoplasma test (28 days), there is a high demand for growth-independent rapid assays. The Microsart® ATMP Mycoplasma Kit, used in combination with the Microsart® AMP Extraction Kit, has demonstrated reliable performance for mycoplasma detection in advanced therapy medicinal products (ATMPs), meeting the regulatory requirements of Ph. Eur. 2.6.7 and USP <77>.[20]



Conclusion

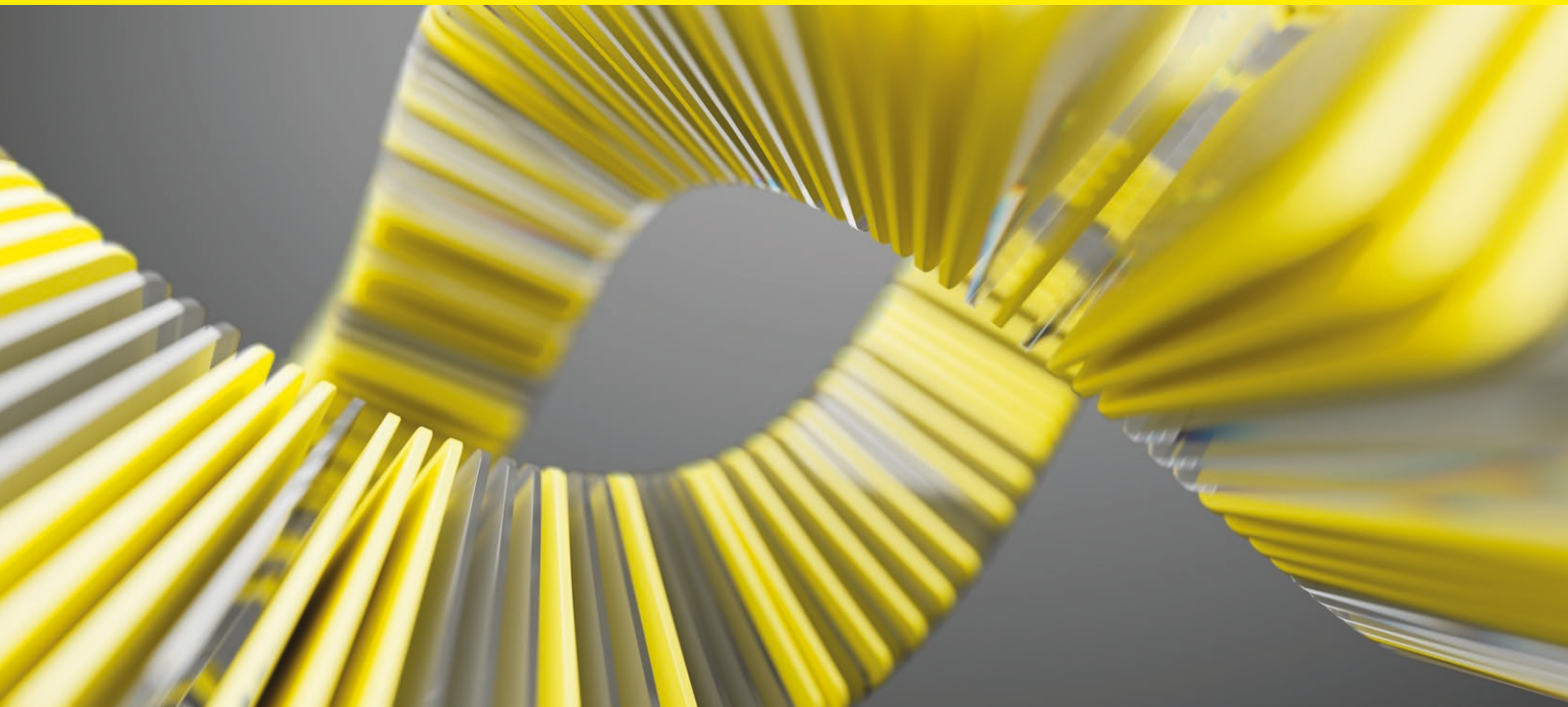
To improve access to life-saving gene therapies, it is crucial to address the complexities of downstream AAV processes. AAV purification currently lacks standardization and optimization in the industry; the diversity of AAV serotypes necessitates specific process adjustments, and unique challenges such as size, turbid feedstreams, and separating empty and full capsids impact product yield and purity.

Efficient downstream processing requires a holistic approach, considering scalability from research to clinical and commercial production. Key decisions made during early development stages significantly influence regulatory submission timelines and overall process success. Implementing robust purification platforms, exploring alternative chromatography methods, and identifying high-performing filters are essential steps in overcoming challenges such as low yield, impurity | empty capsid removal, and scalability.

Moreover, advancements in analytical methods and tools, such as automated in-line monitoring systems, could enhance process efficiency and product characterization, supporting rapid development and validation activities. By integrating innovative technologies and maintaining a focus on product integrity, manufacturers can optimize AAV production processes, ultimately accelerating the delivery of safe and effective gene therapies to patients.

At Sartorius, we deliver comprehensive end-to-end solutions for AAV development, manufacturing, and analytical testing, supported by robust data sets generated from real-life AAV samples. These data validate the efficiency and effectiveness of our technologies and ensure that results are based on actual AAV samples rather than virus-like models.

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



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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.

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Paul has more than 15 years of experience in the biologics industry, with expertise in downstream processing and analytical development. He specializes in the downstream process development, scale-up and manufacturing of ATMPs, such as lentiviral and adeno-associated viral vectors, as well as process intensification strategies for downstream purification.

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He joined Sartorius in 2022 after earning a PhD at the Max Planck Institute for Biophysical Chemistry, where his research centered on downstream process development and optimization of large protein complexes, as well as structural investigations using X-ray crystallography and cryo-electron microscopy.

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