Simplifying Progress

August 2025

Cell & Gene Therapy in Conversation: Q&A With Seven Experts

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SARTORIUS

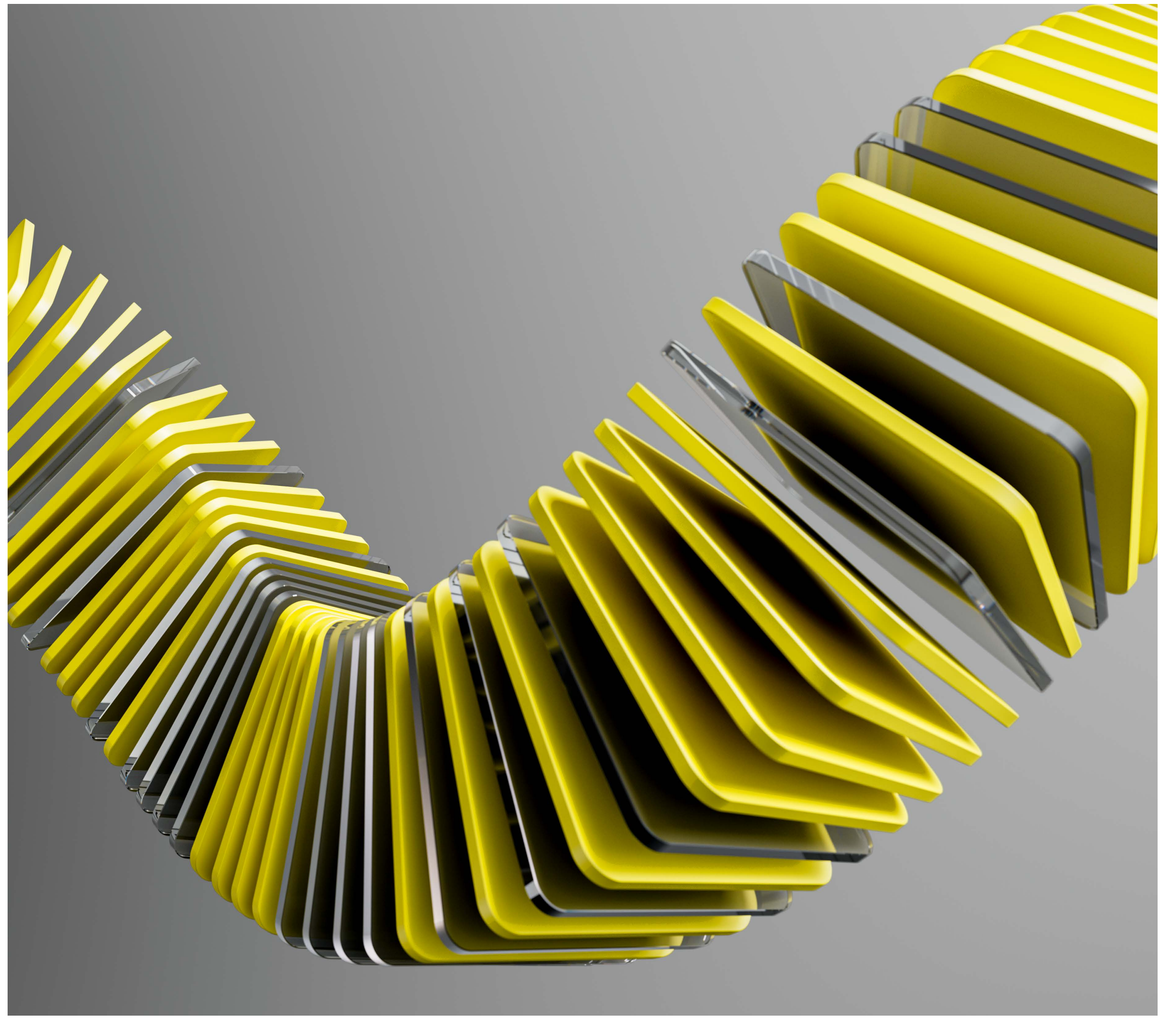
A View on Cell & Gene Therapy

As the cell and gene therapy landscape rapidly evolves, the ability to navigate complex development hurdles while leveraging cutting-edge technologies is critical to accelerating progress. In this expert Q&A session, seven leaders in the field share their insights on the most pressing challenges and how innovation is reshaping the path forward.

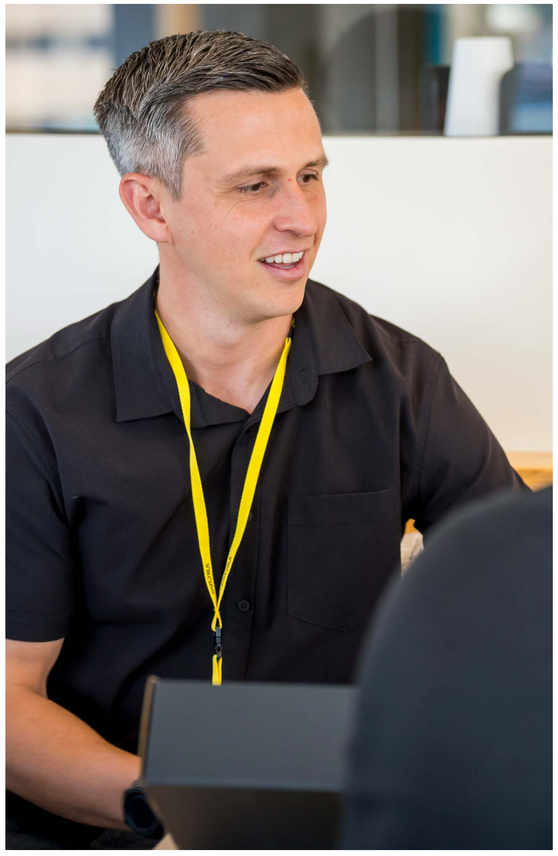
The discussion opens with an in-depth look at key barriers to cell and gene therapy development, including reproducibility, scalability, and regulatory compliance. The experts examine how Sartorius solutions address these pain points—highlighting the importance of precision-engineered instruments and advanced data analytics in delivering consistent, high-quality results. They also explore strategies to streamline scale-up, demonstrating how Sartorius platforms enable seamless transitions from R&D to commercial manufacturing.

Finally, the conversation turns to regulatory compliance, with concrete examples of how Sartorius technologies support robust data integrity, traceability, and documentation to meet global standards.

Together, these insights present a clear and actionable view of how science-driven innovation enables faster, more reliable development of advanced therapies.



Expert Interviews



Josh Sonico

Platform Development Specialist for Cells and Extracellular Vesicles

What are today's top challenges when it comes to developing cell and gene therapies?

One of the interesting challenges in cell therapy is the choice of technology. Drug developers face this challenge due to the novelty of some options and the uncertainty about their commercial feasibility. It's crucial to understand not only the technology but also the developer presenting it, ensuring they have the bandwidth and performance to provide a robust and scalable solution to the marketplace.

How does technology from Sartorius support reproducible performance?

The solutions we bring to the market are designed to be commercially viable and consistent, reducing variability from raw materials in the consumables portion of Sartorius products. We also offer data analytics solutions that support the development of platforms for reproducible performance, allowing tracking and monitoring to adapt or tune processes. This enables the development of a repeatable and robust process that transitions into a commercial setting, ultimately serving patients in need.

Can you explain how the tools in this portfolio help streamline scale-up?

Streamlining is crucial for entering clinical trials and proving efficacy. Our bioreactor technologies are built with scale-up in mind, featuring geometric similarities consistent across the board. We provide comprehensive technical support to enable faster scale-up, along with digital solutions like SIMCA® for multivariate data analysis in scaling and tech transfer. By leveraging our solutions and technical support, a streamlined approach to scale-up can be achieved.

How does the technology help simplify the route to regulatory compliance?

Our technology is built with regulatory compliance in mind, facilitating a seamless transition from process development to manufacturing. We offer supporting services to enable easier compliance with regulatory agencies, including validation services that allow our technical teams to support you in development and partner with you throughout the commercial and clinical development of drug therapies.

Expert Interviews

Aslan Dehghani

Manager of Nanoparticle Technologies, Corporate Research

What are today's top challenges when it comes to developing extracellular vesicle (EV) therapies?

We have identified three major challenges in the field of extracellular vesicles: the lack of reliable and optimized analytics, limitations in manufacturing scalability and reproducibility, and the knowledge gap and lack of partnership between academia and industry.

What is Sartorius doing to address some of those analytical challenges within the EV therapy?

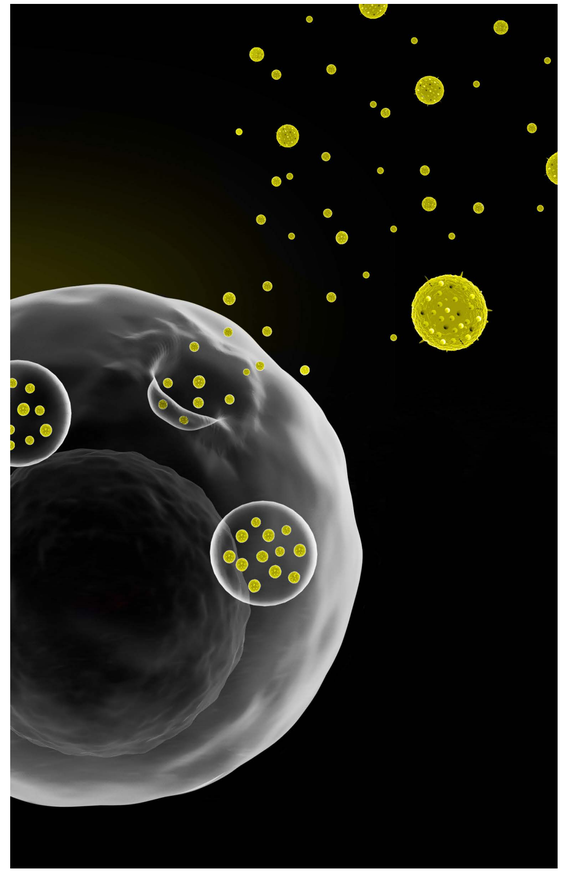
Since I joined the Corporate Research Team in 2020, we have been focusing on optimizing and establishing reliable analytics for the recovery and purity of extracellular vesicle processing.

How is Sartorius addressing the manufacturing challenges when it comes to EV therapy?

Sartorius processing products are specifically designed and developed for scalability and reproducibility across different therapeutic modalities. Over the last couple of years, we have been generating the data needed to ensure manufacturing consistency in extracellular vesicle therapy.

How is our team addressing the partnership gap between academia and industry?

In the Corporate Research Team, we have two approaches: collaborating and partnering with leading academic groups, and conducting fundamental research studies in an industrial environment. With these approaches, we aim to make the translation from small-scale basic research to clinical practice more efficient and smoother.



Expert Interviews

What are today’s top challenges when it comes to developing cell and gene therapies?

One of the challenges when developing gene therapy processes is to create a robust and versatile process that can be used for multiple molecules and can be quickly adapted. Therapy developers are often working on multiple potential therapies, which requires flexibility and adaptability in the process.

How does technology from Sartorius support reproducible performance?

Sartorius helps streamline scale-up using a high-throughput process development portfolio that's directly scalable to our larger-scale solutions. This ensures seamless scale-up with reproducible results from process development through commercial manufacturing, allowing for seamless scalability.

Can you explain how the tools in this portfolio help streamline scale-up?

Sartorius' product portfolio supports scale-up through the supply of consistent and high-quality raw materials, as well as technologies that allow for automation. This enables a seamless transition from small-scale preclinical efforts to commercial scale-up and scale-out initiatives.

Padraic Philbin

Platform Development Specialist for Viral Vector, mRNA, and Plasmid DNA Applications

Expert Interviews

Randall Alfano

Segment Technology Manager, Cell Therapy

What are today's top challenges when it comes to developing cell and gene therapies?

Some of today's top challenges for cell and gene therapy include the cost of these therapies and the broader accessibility of these novel treatments for patients. I remember the first time I heard about CAR-T therapies was as a graduate student at Texas A&M, attending a talk by Malcolm Brenner from Baylor College of Medicine. I've witnessed this field evolve from the question of "What if we can actually do this?" to "How are we going to do this?" The primary questions now revolve around reducing costs and making these therapies more accessible.

How does technology from Sartorius support reproducible performance?

Technology from Sartorius supports reproducible performance in cell and gene therapy through the supply of high-quality, extremely consistent, and well-characterized materials.

Can you explain how the tools in this portfolio help streamline scale-up?

Sartorius' product portfolio supports scale-up through the supply of consistent and high-quality raw materials, as well as technologies that allow for automation. This enables a seamless transition from small-scale preclinical efforts to commercial scale-up and scale-out.

Lastly, how does this technology help simplify the way to regulatory compliance?

Sartorius' high-quality and consistent raw material product portfolio is crucial in cell and gene therapy manufacturing. The removal of human-derived and animal-derived components facilitates the regulatory approval process. For example, our high-quality recombinant albumin, Recombumin®, is used across cell and gene therapy manufacturing platforms. Utilizing a well-characterized recombinant version mitigates consistency issues associated with blood-derived products and streamlines the regulatory approval process by removing components that may raise concerns with regulatory agencies.

Expert Interviews

Rukmini Ladi

Segment Technology Manager for Cell Therapy

What are today's top challenges when it comes to developing cell and gene therapies?

The field of cell and gene therapies is incredibly promising, yet significant challenges remain in making these treatments widely accessible and effective. One major challenge is regulatory compliance. The regulatory landscape for cell and gene therapies is complex and continuously evolving, requiring manufacturers to follow stringent Chemistry, Manufacturing, and Controls (CMC) guidelines. Because of the novel and complex nature of these therapies, regulators demand thorough testing to ensure safety, efficacy, and consistency. This results in a lengthy and often complicated approval process. Additionally, differences in regulatory frameworks across regions add complexity, making early regulatory engagement and strategic planning critical to overcoming these challenges.

Another significant challenge is manufacturing scalability and consistency. Scaling up cell and gene therapies is difficult due to the biological variability of cells and limited understanding of critical process parameters, leading to batch-to-batch variability. Ensuring each batch meets high-quality standards at a larger scale remains a significant challenge.

Ensuring consistent quality at commercial scale remains a major hurdle. Many current manufacturing processes still rely heavily on manual handling, which not only increases the risk of contamination but also limits throughput. Furthermore, these processes tend to be labor-intensive and costly, creating barriers to patient access. To overcome these challenges, the industry is increasingly focusing on automation, process standardization, and innovative manufacturing models aimed at improving scalability, reducing costs, and expanding patient access.

Expert Interviews

Summer Gunn

Product Specialist, Harvest Technology, Ksep® Systems

What are today's top challenges when it comes to developing cell and gene therapies?

One of the top challenges is having an aseptic harvest solution for processes, especially as customers scale up . In cell and gene therapy, customers seek options that maintain sterility while achieving high product recovery.
For example, with the Ksep® family of single-use centrifuges, we provide aseptic harvest technology that offers higher product recovery and quality.

Can you explain how the tools in this portfolio help streamline scale-up?

As customers scale their processes, they need technology that can transition from smaller scales, like R&D, to commercial scale processes. They require technology that grows with them. The Ksep® offers a scalable option for customers looking to expand their processes without additional optimization as they move to larger scales.

With our Ksep® technologies, customers can start with a small-scale system like the Ksep® 50, develop a process, and then scale into larger systems without needing further optimization. The technology grows with them as they scale up.

Expert Interviews

What are today's top challenges when it comes to developing cell and gene therapies?

In the market today, some of the top challenges around cell and gene therapy include scale-up versus scale-out. This has been known within the industry for quite some time. With autologous cell therapies, the focus is on scale-out, while allogeneic therapies require scaling up. Currently, there are technologies available, but we are still struggling with scaling up, particularly in induced pluripotent stem cells (iPSCs). Several companies have focused on this over the years, but progress is just on the verge of breaking through in the iPSC space.

Sartorius is at the forefront of working with those companies to overcome these scaling challenges.

Another challenge is automation. In the monoclonal antibody space, large companies have started automating more of their processes, both upstream and downstream. While not fully automated, it is more advanced than it was 20 years ago.

We aim to integrate this automation into the cell and gene therapy space, but it is still not fully there due to the biological nature of the process.

How does technology from Sartorius support reproducible performance?

Over the last 11 years with Sartorius, we've made advancements in the software space to support scale-up and scale-down for our technology. We focus on in-process analytics, monitoring the bioreactor, and collecting data through our software packages that are part of our equipment, ensuring our technology is reproducible and scalable.

Can you explain how the tools in this portfolio help streamline scale-up?

In recent years, we've introduced technologies that enhance scale-up capabilities for our customers. One key technology is the Ambr® 15, which allows us to mimic a 2,000 L process at 15 mL scale.

This reduces the time required to transition from small scale to large scale, representing the same process in both scales. Sartorius continues to invest in and develop these technologies with our team of experts.

How does the technology help simplify the route to regulatory compliance?

We focus on building data into every piece of our technology and process, providing data throughout the process. This data can be used in a regulatory package when submitting an IND or BLA. Additionally, we are actively involved with industry groups, engaging with the FDA to understand regulatory needs and ensure our tools and services support market requirements.

Tiffany Pogue

Business Development and Marketing Strategy Lead, Process Development Services for Advanced Therapies

Setting New Standards in the Future

The development of cell and gene therapies presents unique challenges that are critical to addressing the advancement and accessibility of these promising treatments. Our experts discussed the choice of technology, which is complicated by the novelty and commercial feasibility of the options available. Developers must ensure robust and scalable solutions while navigating the complex regulatory landscape that demands rigorous compliance and lengthy approval processes.

Manufacturing scalability and consistency are challenged by biological variability, leading to batch-to-batch inconsistencies. High costs further limit accessibility, necessitating efforts to reduce expenses and broaden patient access. Additionally, the industry faces challenges in aseptic harvesting, scale-up versus scale-out strategies, and automation integration, all of which are essential for efficient and effective therapy production.

Despite these hurdles, the industry is developing rapidly. Sartorius and its partners are helping set new standards through innovation in automation, analytics, and scalable platform design, paving the way for broader patient access to advanced therapeutics.

Get More Insights

Cell and Gene Therapy Resources:

White Paper | Perspectives on Performance, Scalability and Regulatory Compliance
sartorius.com/en/whitepaper-setting-standard-in-cell-and-gene-therapy-1642912

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