

Gene Therapy's Future Will Be Won on the Manufacturing Floor

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CEO Stefano Colloca explains how next-generation AAV platforms, transfection-free production and integrated manufacturing could help overcome one of gene therapy's biggest bottlenecks and position Italy as a specialised force in the global advanced therapies landscape.



As gene therapy moves from scientific promise towards a new phase of commercial maturity, manufacturing has emerged as one of the industry's defining challenges. **For Stefano Colloca, CEO of ReiThera, the answer lies not simply in producing more, but in fundamentally rethinking how viral vectors are developed, scaled and manufactured.**

In this conversation with BioSpectrum Asia, Colloca discusses Italy's growing role in the global cell and gene therapy ecosystem, the lessons ReiThera has carried from vaccine development into advanced therapies, and the technologies that could reshape AAV manufacturing. He also outlines the company's ambitions to expand towards commercial manufacturing and support the next generation of gene therapy developers, including those emerging across the rapidly growing Asia-Pacific market.

Italy is emerging as an important hub for cell and gene therapy innovation. What differentiates the country's ecosystem, and how is ReiThera contributing to this momentum?

Italy has a long-standing tradition in biomedical research, vaccine development, and advanced manufacturing. Over the past two decades, the country has developed a unique ecosystem where academic excellence, clinical expertise, and industrial capabilities work closely together to accelerate innovation in advanced therapies.

What differentiates Italy is its ability to translate scientific discoveries into clinically relevant technologies through highly specialized organizations. Rather than competing on volume, Italian companies often compete on scientific excellence, flexibility, and technological innovation.

At ReiThera, we are proud to contribute to this ecosystem by combining proprietary viral vector technologies with integrated CDMO services. Our expertise spans vector engineering, process development, analytical development, regulatory support, and GMP manufacturing, enabling biotech companies to advance programs from early research

through clinical development. We believe that innovation becomes meaningful only when it can be translated into therapies that reach patients, and that philosophy continues to drive our strategy.

ReiThera's platform has supported vaccine development for infectious diseases such as Ebola and Marburg. How has that experience influenced your approach to developing viral vectors for advanced therapies?

Our experience in developing viral vector-based vaccines for emerging infectious diseases taught us that successful platforms must combine preclinical/clinical performance with manufacturability. A vector may show excellent biological activity, but unless it can be produced consistently, scaled efficiently, and meet regulatory expectations, its clinical impact will remain limited.

This philosophy has shaped the development of all our platforms, including GRAd, MVA, and our AAV technologies. We focus on designing vectors that are not only biologically effective but also compatible with robust manufacturing processes, scalable production platforms, and well-characterized analytical methods.

Many of the challenges encountered in vaccine development: vector optimization, process scalability, analytical characterization, and regulatory readiness are equally relevant for vaccines and advanced therapies. Our experience allows us to approach gene therapy development with a comprehensive understanding of the entire product lifecycle rather than considering vector design and manufacturing as separate activities.

What are the biggest technical challenges in developing robust and scalable AAV cell lines, and how has ReiThera addressed them?

AAV manufacturing remains one of the major bottlenecks for the gene therapy field. The challenge is not only achieving high productivity, but doing so while maintaining product quality, scalability, and manufacturing consistency.

Traditional transient transfection approaches are effective for research but become increasingly complex and costly at commercial scale. This is why the industry is actively pursuing more robust production platforms.

At ReiThera, we have invested significantly in proprietary HEK293-derived production cell lines and novel manufacturing strategies designed to simplify AAV production. Our ReiCell-AAV platform was developed to support high-density suspension culture in chemically defined media while providing the flexibility required for multiple AAV serotypes.

In parallel, we are developing proprietary transfection-free production technologies that have the potential to reduce manufacturing complexity while improving process robustness and scalability. We believe that innovation in cell lines, together with optimized upstream and downstream processes, will play a central role in making gene therapies more accessible worldwide.

As demand for gene therapies continues to grow globally, what manufacturing innovations do you believe will be most critical over the next five years?

The next generation of manufacturing innovation will focus on simplicity, scalability, and platformization.

First, the industry needs production systems that reduce process complexity. Stable producer cell lines, transfection-free approaches, and intensified upstream processes will significantly improve manufacturing efficiency.

Second, digitalization and advanced analytics will become increasingly important. Better process monitoring and data-driven manufacturing will improve consistency while reducing development timelines.

Third, platform technologies will continue to transform development. Rather than creating a completely new manufacturing process for every product, companies will increasingly rely on established platform processes, analytical methods, and regulatory strategies that can be adapted to multiple programs.

Ultimately, manufacturing innovation is not simply about increasing productivity; it is about making advanced therapies more reliable, reproducible, and economically sustainable.

How do you see Europe—and Italy in particular—positioning itself in the increasingly competitive global cell and gene therapy manufacturing landscape?

Europe remains one of the world's leading regions for advanced therapy innovation, supported by excellent academic research, a strong regulatory framework, and significant scientific expertise.

Italy has the opportunity to become an even stronger player by focusing on highly specialized technologies rather than competing solely on manufacturing capacity. Expertise in viral vectors, advanced process development, analytical sciences, and regulatory support represents a significant competitive advantage.

We also believe that collaboration will become increasingly important. The future of advanced therapies will depend on global partnerships connecting innovators, CDMOs, technology developers, and healthcare systems across different regions.

As an Italian company working with international clients, ReiThera sees itself as part of this global ecosystem. Our objective is to combine European scientific excellence with flexible development and manufacturing solutions that support partners worldwide, including the rapidly growing Asia-Pacific market.

Looking ahead, what are ReiThera's strategic priorities for expanding its capabilities and supporting the next generation of gene therapy developers?

Our strategy is centered on continuous innovation across both technology platforms and manufacturing capabilities. This effort includes the current transition toward the possibility to offer commercial manufacturing services including support for the range of activities required for the registration process up to the submission of the BLA.

We will continue investing in proprietary viral vector platforms, next-generation production cell lines, and manufacturing technologies that improve scalability and reduce development complexity. In parallel, we are expanding our analytical capabilities, regulatory expertise, and GMP manufacturing infrastructure to provide increasingly integrated support throughout product development.

Another strategic priority is strengthening our intellectual property portfolio, particularly in areas such as viral vector engineering and novel AAV production technologies.

Equally important is our commitment to being a trusted long-term partner for our clients. Backed by decades of experience in viral vector development, process optimization, and GMP manufacturing, we provide the scientific expertise, operational reliability, and regulatory know-how needed to advance complex programs with confidence. By combining integrated capabilities with platform-based development strategies, we help our partners reduce timelines, optimize development costs, and accelerate the path from innovation to patients.

We believe the future of gene therapy will depend on close collaboration between innovators and technology developers, and our mission is to help bring the next generation of transformative therapies to patients worldwide.