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The Manufacturing Shift Powering In Vivo Gene Therapy

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Natalia Elizalde, Chief Business Development Officer at VIVEbiotech, discusses how scalable lentiviral vector manufacturing, advanced analytics and next-generation production platforms are enabling the future of in vivo gene therapies.



The rapid expansion of in vivo gene therapy is reshaping expectations for viral vector manufacturing, placing greater emphasis on scalability, purity, analytical characterisation and commercial readiness. As developers move beyond early-stage research towards larger clinical programmes, manufacturing strategy has become as critical as scientific innovation. **In this exclusive interview with BioSpectrum Asia, Natalia Elizalde, Chief Business Development Officer at VIVEbiotech,** explains how advances in lentiviral vector production, stable producer cell lines and integrated manufacturing platforms are helping overcome key bottlenecks and accelerating the next generation of gene therapies.

In vivo gene therapy programmes are expanding rapidly. How is demand for lentiviral vector manufacturing evolving?

Demand for lentiviral vector manufacturing is growing at a very strong pace, driven by two converging dynamics within the gene therapy field. On one hand, ex vivo therapies, particularly CAR-T and other cell-based approaches, continue to expand and mature, maintaining a steady baseline demand for high-quality lentiviral vectors. On the other hand, we are seeing a significant acceleration in the development of in vivo approaches, which is reshaping the overall demand profile for vector manufacturing.

Lentiviral vectors remain a cornerstone technology in gene delivery due to their versatility, ability to transduce both dividing and non-dividing cells, and their well-established clinical track record. Their flexibility is further enhanced by the availability of different pseudotypes that enable targeting of diverse tissues and therapeutic applications. As a result, developers are increasingly exploring lentiviral vectors as a viable option for direct administration therapies, including vaccines, virus-like particles, autoimmune diseases and in vivo CAR-T programmes.

This shift is not only increasing demand volumes but also raising expectations around manufacturing performance. In vivo applications require significantly higher levels of purity, more extensive analytical characterization, larger manufacturing

scales and greater cost efficiency. Consequently, there is a growing need for highly specialized CDMOs capable of combining deep process knowledge with manufacturing platforms that can consistently deliver quality at scale

What are the biggest technical differences between supporting in vivo and ex vivo programmes?

The transition from ex vivo to in vivo programmes represents a fundamental shift in manufacturing requirements and product expectations. While ex vivo applications involve modifying cells outside the patient and reintroducing them, in vivo approaches rely on direct administration of the vector. This difference has a significant impact on how the product must be designed, manufactured and controlled.

One of the most important distinctions lies in the level of purity and safety required. Because the lentiviral vector is administered directly to the patient, impurities such as residual DNA, host cell proteins and process-related contaminants must be reduced to extremely low levels. This requires highly optimized downstream purification strategies and robust process control throughout manufacturing.

In vivo programmes also tend to require larger manufacturing scales than many ex vivo applications, while maintaining tight control over product quality and functionality. At the same time, developers face greater pressure to reduce cost of goods, making manufacturing efficiency a critical factor for long-term success.

Analytical requirements are equally demanding. There is a need for deeper characterization of vector potency, infectivity, stability and critical quality attributes, supported by increasingly sophisticated analytical methodologies. This data is essential not only for product understanding but also for meeting evolving regulatory expectations.

Another important consideration is the growing use of different pseudotypes and advanced vector designs. These innovations create exciting therapeutic opportunities but also introduce additional manufacturing and characterization challenges. Fortunately, VIVEbiotech has developed a platform that supports both ex vivo and in vivo programmes, allowing us to leverage our accumulated expertise across a broad range of vector configurations and therapeutic applications.

How has VIVEbiotech built capabilities to ensure consistent vector quality at scale?

At VIVEbiotech, we have developed our capabilities with a clear focus on addressing the evolving requirements of both ex vivo and in vivo gene therapy programmes, with particular emphasis on scalability, consistency and product quality.

Our approach is based on a dedicated lentiviral vector platform that has been specifically designed to preserve vector integrity throughout the manufacturing process. This includes upstream optimization strategies aimed at improving productivity while reducing variability. By optimizing transfection conditions and minimizing cellular stress during production, we are able to maintain high levels of vector functionality while supporting robust scale-up.

In parallel, we have invested significantly in downstream processing to achieve high levels of purity without compromising yield. Advanced purification strategies enable the efficient removal of impurities such as residual DNA and host cell proteins, which is particularly critical for in vivo applications. This allows us to meet the stringent quality expectations associated with direct patient administration.

Another key component of our capabilities is our integrated analytical framework. We have developed advanced analytical tools to ensure comprehensive characterization of lentiviral vectors, including potency assays and detailed product profiling. This enables us to monitor consistency across batches and ensure that quality attributes are maintained throughout development and manufacturing.

Our platform is also designed to support multiple pseudotypes and a broad range of vector configurations, providing flexibility as therapeutic approaches continue to evolve. In addition, we are actively investing in next-generation manufacturing technologies, including stable producer cell line approaches. One example is EvoLVcell, a platform that has the potential to significantly improve scalability, process robustness and manufacturing efficiency. Stable producer cell lines represent an important step forward for the industry, helping reduce manufacturing variability while supporting larger-scale production and improved cost-efficiency.

Importantly, scalability has been a central consideration in our development strategy. As programmes move towards later-stage clinical development and commercialization, access to large-scale manufacturing capacity becomes increasingly important. The ability to manufacture at larger scales while maintaining vector performance, purity and consistency is essential not only for supply security but also for reducing cost of goods and supporting broader patient access.

What manufacturing bottlenecks still need to be solved to unlock wider adoption of in vivo therapies?

Despite the strong momentum behind in vivo gene therapies, several manufacturing challenges still need to be addressed to enable broader adoption and commercialization.

One of the most significant bottlenecks is achieving the right balance between scalability, cost-efficiency and product quality. In vivo therapies frequently require larger doses and larger manufacturing campaigns, creating additional pressure on production processes. Developing manufacturing platforms capable of delivering high yields while maintaining stringent quality standards remains a major challenge for the industry.

The ability to reduce cost of goods will also be critical for the long-term success of many in vivo programmes. Manufacturing innovation must continue to improve productivity and process efficiency if these therapies are to reach larger patient populations and achieve commercial sustainability.

Another important limitation is the increasing complexity of analytical requirements. As vector designs become more sophisticated and new pseudotypes are introduced, deeper characterization is needed to ensure consistent performance and product understanding. This increases development effort but is essential for maintaining quality and meeting regulatory expectations.

Process consistency and robustness also remain important areas of focus, particularly as programmes move towards commercial-scale manufacturing. Reproducibility across batches, sites and manufacturing scales will be critical to ensuring reliable supply and patient safety.

Finally, continued investment in manufacturing infrastructure and enabling technologies will be required. Advances such as stable producer cell lines, intensified manufacturing processes and next-generation analytical tools have the potential to address several of the industry's current bottlenecks simultaneously by improving scalability, robustness and overall manufacturing economics.

What do you see as the next major innovation in viral vector development and production?

Looking ahead, we expect innovation in viral vector development and manufacturing to focus on improving both performance and efficiency, with a strong emphasis on enabling the next generation of gene therapies.

On the vector design side, advances in pseudotyping and targeting capabilities are likely to play a major role. More sophisticated vector designs will facilitate increasingly precise delivery to specific tissues and cell types, improving both efficacy and safety, particularly for in vivo applications.

From a manufacturing perspective, significant innovation will focus on increasing productivity while reducing cost of goods. Technologies such as stable producer cell lines have the potential to transform lentiviral vector manufacturing by enabling more scalable, robust and efficient production processes. At VIVEbiotech, we see initiatives such as the EvoLVcell platform as an important part of this evolution, helping address some of the industry's key challenges around scalability, process consistency and cost of goods. These approaches could represent an important step change in the industry's ability to support larger patient populations and commercial-scale demand.

We also expect major advances in analytical characterization. The industry is increasingly moving beyond traditional assays towards more sophisticated technologies capable of providing a deeper understanding of vector quality, particle characteristics and process performance. Techniques such as Videodrop, Leprechaun and other emerging characterization platforms are helping developers gain more detailed insight into lentiviral vector populations and critical quality attributes.

These analytical advances will be complemented by improved approaches for evaluating parameters such as vector integrity, genome size, particle content and overall product consistency. Together, these tools will enhance process understanding, improve manufacturing control and support more efficient regulatory development pathways.

Ultimately, the future of viral vector manufacturing will depend on the integration of innovation across vector design, production and analytics. The organizations that successfully combine these capabilities will be best positioned to support the transition of next-generation gene therapies from promising concepts to widely accessible treatments for patients.