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Translating Cell And Gene Therapy Innovation Into Scalable Manufacturing Requires Early Strategic Planning

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Sam Chuang of Charles River highlights the need for stronger regulatory alignment, early CMC planning, and AI driven manufacturing efficiencies to accelerate advanced therapy development.

On the sidelines of the **APAC Biomanufacturing Leadership Summit 2026 in Singapore, organised by Charles River, BioSpectrum Asia spoke with Sam Chuang, PhD, Executive Director at Charles River.** With experience spanning academic research, translational development, and viral vector CDMO operations, Chuang offers insights into the evolving landscape of cell and gene therapy development across Asia Pacific. In this conversation, he discusses the challenges of translating academic innovation into pharmaceutical products, the growing role of artificial intelligence in biomanufacturing optimisation, and the importance of regulatory harmonisation and strategic CMC planning in accelerating advanced therapies to the clinic.

Q: Your career spans academia, translational research, and industry consulting. How has this multidisciplinary experience helped support the development of advanced therapies in APAC?

Cell and gene therapy development is a rapidly evolving field, and many of the foundational innovations originate within academic research environments. Having an academic affiliation allows me to remain closely connected with emerging scientific developments, particularly in areas such as gene therapy modalities.

At the same time, my experience in translational development, clinical research, and viral vector manufacturing has allowed me to understand the practical challenges involved in bringing these innovations into the clinic.

Ultimately, developing advanced therapies requires collaboration across multiple stakeholders. It is very much a community effort where academic researchers, developers, manufacturers, and regulatory experts must work together to translate promising discoveries into viable pharmaceutical products.

Q: What is one of the biggest misconceptions about the journey from discovery to commercial manufacturing in cell and gene therapies?

A common misconception is that once a promising discovery is made in the laboratory, the transition to pharmaceutical development will be relatively straightforward.

In reality, there is a long and complex pathway between early scientific discovery and the development of a safe and effective therapeutic product. These therapies often begin as highly innovative concepts emerging from academic research settings, but translating them into regulated pharmaceutical products requires extensive development work.

Developers must carefully address issues such as manufacturing consistency, product quality, regulatory expectations, and patient safety. Ensuring that the product performs as originally intended while meeting strict regulatory standards is a critical and often underestimated part of the process.

Q: Regulatory harmonisation across the APAC region is often discussed as an industry priority. What challenges remain?

The Asia Pacific region is extremely diverse, encompassing countries with different levels of economic development, regulatory maturity, and technological capability.

When we consider emerging modalities such as cell and gene therapies, regulatory expectations can vary across jurisdictions. One of the ongoing challenges is working toward greater alignment in regulatory frameworks and development pathways.

Greater harmonisation would help developers navigate the region more efficiently and ultimately accelerate the availability of transformative therapies for patients.

Q: Artificial intelligence is increasingly being discussed in both drug discovery and manufacturing. Where do you see the greatest opportunities?

Artificial intelligence has already begun transforming drug discovery, and we are now seeing growing interest in applying AI within biomanufacturing.

Advanced therapies such as cell and gene therapies involve highly complex biological systems. AI can help analyse large datasets generated from clinical trials and manufacturing processes, enabling developers to better understand key parameters that influence product quality and performance.

In manufacturing, AI driven analytics could help optimise process control strategies, improve efficiency, and ultimately reduce the cost of goods while maintaining high standards of quality and safety.

Q: Many advanced therapy programmes originate in academic environments. What should developers consider early in the development process?

One of the most important factors is early planning, particularly when it comes to CMC strategy.

Developers are often under pressure to move quickly toward clinical trials, but taking the time to carefully plan manufacturing strategies and regulatory pathways can make a significant difference later in development.

Investing resources into translational development and establishing a clear CMC roadmap early on will help developers scale their programmes more effectively as they move beyond early phase clinical studies.

Q: Looking ahead, what emerging trends in advanced therapies excite you most?

We are currently entering an exciting phase in the development of cell and gene therapies.

We have already seen strong clinical efficacy from several approved therapies, and the next phase of innovation will focus on improving manufacturing efficiency and scalability.

At the same time, we are seeing exciting developments in in vivo gene therapy approaches that could potentially transform how certain treatments are delivered. Continued advances in both modality development and manufacturing science will be critical to expanding patient access to these therapies.

Q: Why are forums such as the APAC Biomanufacturing Leadership Summit important for the sector?

The development of advanced therapies truly requires a collaborative ecosystem.

No single organisation or technology can address all aspects of the development process. We need contributions from CROs, CDMOs, academic researchers, consultants, regulators, and developers.

Events such as this summit provide an important platform for these stakeholders to connect, exchange ideas, challenge assumptions, and share best practices. This kind of dialogue is essential for accelerating innovation and expanding access to advanced therapies across the APAC region.