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In recent years, the Hong Kong Institute of Biotechnology (HKIB) has entered a new phase, shifting from the groundwork of facility-building to the clinical delivery of locally manufactured CAR-T therapies. Managing Director Gina Jiang reflects on this transition and shares how early operational lessons are in forming a wider platform strategy encompassing regulatory development, talent building, and regional integration. "If we truly nurture this platform and understand its potential, it can transform not just healthcare, but the future of biomedical innovation in Hong Kong."

What key milestones have been achieved since the launch of CAR-T manufacturing at HKIB, and how are patients responding to treatment?

Since the recruitment of the first patient and the commencement of GMP operations last summer, significant progress has been achieved. Five patient-specific CAR-T batches have been successfully completed, covering both paediatric and adult cases – male and female – across two key treatment centres: Prince of Wales Hospital (PWH) and Hong Kong Children's Hospital (HKCH). A sixth and a seventh patients are already scheduled for treatment in the coming weeks.

Importantly, the first three patients have now reached their six-month post-infusion milestones. Earlier this month, their experiences were featured in a local press report, offering valuable insight into the comparative benefits of locally manufactured CAR-T therapy. The first patient, a 14-year-

old boy, had previously undergone conventional chemotherapy and experienced profound fatigue. In contrast, during CAR-T treatment, his mother reported minimal side effects, he remained energised and alert, even continuing to play video games throughout the process.

The second testimonial came from a female patient in her early seventies, who described her earlier chemotherapy as physically devastating and emotionally exhausting. Upon being offered participation in the CAR-T trial, she accepted without hesitation and later described her experience as “quick, nice, great” – a stark departure from her prior ordeal.

These accounts underscore not only the potential of CAR-T therapy but also the unique value of a localised manufacturing model. Our facility’s proximity to PWH (Prince Walles Hospital) and HKCH (Hong Kong Children’s Hospital) supports fresh product delivery, and has enabled highly efficient vein-to-vein logistics. Having personally accompanied the journey from cell collection to infusion, I can attest to the operational advantages this setup affords. By contrast, alternative treatment pathways in Hong Kong involve transporting patient cells to the US, where centralised production and complex logistics extend turnaround time to an average of 4 to 6 weeks. Locally, we have reduced that timeline to just two weeks, an extraordinary acceleration that may be critical for patients with late-stage disease.

What lessons have emerged from the early operational rollout of CAR-T therapy, particularly in aligning clinical demand with manufacturing realities?

The initial rollout of CAR-T manufacturing has provided valuable operational lessons, revealing a clear distinction between theoretical planning and practical execution. One of the most striking realisations has been that regulatory approval alone does not translate into immediate patient demand. While we had assumed that securing a licence would lead to swift recruitment, the reality proved more complex. Instead, it became apparent that close, ongoing alignment with clinical teams is fundamental, not only to coordinate patient eligibility but to manage the timing and logistics of manufacturing where every step is highly time-sensitive and materials have limited shelf life.

Cell therapy production requires seamless synchronisation with clinical workflows, and any misalignment can disrupt the entire process. This has highlighted the critical need for real-time communication with treating teams, ensuring that patient readiness is matched with manufacturing availability. Beyond coordination, awareness of CAR-T therapy remains limited across both the medical community and the patient population. Given that treatment is currently

offered through a clinical trial, access is restricted by stringent inclusion criteria, and eligibility ultimately rests with clinicians.

That said, recent media coverage has begun to make an impact. Information is increasingly shared among cancer support groups, where patients and families are taking a more active interest in available treatment options. While such grassroots awareness is encouraging, clinical conversations remain central to determining access. These early experiences have reinforced the importance of a fully integrated ecosystem – uniting manufacturing, clinical decision-making, and informed patient engagement to realise the full potential of locally produced CAR-T therapies.

How does this CAR-T therapy compare to existing commercial products, and what strategic role does the trial play in advancing Hong Kong based cell and gene therapy capabilities?

This CAR-T therapy targets CD19, the same indication used by several approved commercial products from global companies such as Novartis and Gilead. However, the true significance of this trial lies not in the therapeutic target, but in its role as a foundational effort to establish Hong Kong's local capacity to deliver cell and gene therapies. In this domain, where the manufacturing process is inseparable from the product itself, the trial has become a critical exercise in validating the full therapeutic pathway, from localised production to clinical delivery. It has also enabled the development of supporting infrastructure, including logistical coordination and, crucially, a regulatory framework adapted to the specific requirements of advanced therapy products.

Through close collaboration with the Department of Health, we are helping to shape how such therapies are reviewed, approved, and monitored when produced locally under GMP conditions. Ultimately, this trial is paving the way for future innovations in cell and gene therapy, providing both the technical and regulatory blueprint for sustainable, locally delivered treatment solutions in Hong Kong.

How is the HKIB building a specialised talent base for advanced therapy manufacturing, and what part does it play in the Greater Bay Area's broader integration efforts?

Strengthening the talent base for Advanced Therapy Products (ATP) manufacturing remains a strategic priority for the HKIB, given the highly specialised nature of GMP operations in this field. Internally, we maintain a rigorous training matrix to ensure continuous staff development, while

our long-standing GMP Consultation division has delivered accredited training to the local pharmaceutical industry for over 20 years. In collaboration with the Scottish National Blood Transfusion Service (SNBTS), the Institute is now developing a targeted training programme specifically designed for ATP GMP environments. This initiative addresses the certification requirements for key personnel including authorised persons, quality control managers, and production managers. Their qualifications must meet the standards set by the Department of Health, including formal registration for designated roles.

Beyond serving its internal needs, the HKIB is positioning itself as a regional hub for advanced therapy training, with a clear focus on integration within the Greater Bay Area. The programme is being designed to accommodate regulatory expectations from both Hong Kong and mainland China, while anticipating the evolution of national standards in line with the Pharmaceutical Inspection Co-operation Scheme (PIC/S), which China formally began aligning with following its accepted membership application in 2023. By embedding international best practices into its training framework, HKIB aims to facilitate regulatory convergence and enhance the region's readiness for global engagement in cell and gene therapy.

While cross-border product and patient flow still face limitations due to differing standards, this training initiative lays critical groundwork. Establishing a shared foundation of competencies is essential for enabling future collaboration, mutual recognition, and ultimately, the seamless movement of advanced therapies across regulatory borders.

Where does Hong Kong currently stand in aligning its regulatory environment with international standards, and what opportunities would a dedicated local authority unlock?

The potential creation of an independent regulatory authority in Hong Kong, frequently referred to as a "Hong Kong FDA", represents a pivotal step in the city's ambitions to become a hub for advanced therapeutics. Under the current "one-plus" registration model, new therapies must first receive approval in another jurisdiction before being eligible for registration in Hong Kong, creating barriers for local innovation. A domestic regulatory pathway would allow clinical-stage products developed within Hong Kong to seek first registration locally, thereby streamlining translational research and encouraging academic and biotech-driven development.

In parallel, broader alignment with the PIC/S would strengthen Hong Kong's regulatory credibility on the global stage. While the city has not yet fully capitalised on this shift, its bilingual proficiency

offers a significant competitive edge over other PIC/S-aligned jurisdictions in Asia.

Combined with the “one country, two systems” framework, this positions Hong Kong as a strategic interface between mainland China and international markets. In the near term, it could serve as a launchpad for Chinese companies aiming to expand globally. Longer term, it could equally support multinational firms seeking to enter China through a more familiar, internationally aligned regulatory environment. Although full system convergence remains a long-term goal, these developments are steadily shaping Hong Kong’s emergence as a credible and connected node in the global biopharmaceutical ecosystem.

How is the HKIB shaping its collaboration strategy to meet the evolving demands of cell and gene therapy as the field scales?

Rather than pursuing a fixed or branded model, our approach to collaboration is grounded in pragmatism, responding directly to the most pressing challenges in cell and gene therapy today – manufacturing complexity, delivery limitations, and cost. These are issues no single institution can address alone. Our aim is to work collaboratively, leveraging complementary strengths and avoiding the inefficiencies of duplication. This means rethinking the model entirely. For example, not every site needs to perform every function of every stage of product development.

At present, our facility is optimally suited to early-stage development and clinical trials where small-batch production and flexibility are essential. However, as therapies advance through the development pathway, moving from preclinical to Phase I, II, III trials and ultimately to commercialisation, larger-scale capabilities with defined CMC (Chemistry, Manufacturing, Controls) will be required. Instead of building this infrastructure ourselves, we are engaged in discussions with partners who already operate commercial-grade facilities, allowing us to support the full product lifecycle in collaboration. Importantly, our vision goes beyond scaling up or out – we are equally focused on the need to scale down. The future of ATPs lies in increasing diversity and personalisation, which calls for versatile, adaptive facilities. By aligning infrastructure with specific stages of the product lifecycle, and by building networks that balance agility and scale, we can ensure that innovative therapies are developed, manufactured, and delivered efficiently, without compromising on quality or accessibility.

What broader impact could a fully developed, locally anchored CAR-T platform have on Hong Kong's healthcare system, economy, and long-term positioning in global biomedicine?

The development of a locally manufactured CAR-T therapy represents far more than a scientific breakthrough, it marks the establishment of a foundational platform capable of transforming Hong Kong's biomedical ecosystem. Without such infrastructure in the past, much of the city's translational research was forced to take place abroad, along with the talent and opportunities that accompanied it. This new platform provides the foundation for both nurturing homegrown innovation and attracting external collaborations, offering a space where research, education, clinical application, and industrial development can coalesce. Much like the infrastructure behind a digital platform lies in its capacity to host new innovation, the true value of this therapeutic foundation lies in what it enables, research projects, training initiatives, therapeutic advancements, and broader systemic change.

Its impact extends beyond science and medicine, with clear potential to contribute to economic diversification by anchoring a new generation of biomedicine-driven industry in Hong Kong. However, to fully realise this vision, long-term commitment from the government is essential. While policy support has been encouraging, infrastructure of this scale requires sustained and predictable funding, not only for initial development, but across every stage of the platform's evolution, from early operations to regional expansion. A stable funding framework would not only ensure operational continuity but would also serve as a signal of credibility to international partners and investors evaluating Hong Kong as a base for long-term engagement. In this respect, consistent public investment is not simply a financial mechanism, it is a strategic tool for securing the city's future in global life sciences.

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