Camie Chan – CEO, Xellera Therapeutics

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05.05.2025

Tags: Hong Kong, China, CAR-T, Cell and Gene, Oncology, Manufacturing, CDMO

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With Asia-Pacific poised to become a global force in cell and gene therapy, Xellera Therapeutics is positioning itself at the heart of this transformation. Led by CEO Camie Chan, the Hong Kong-based company is bridging critical infrastructure gaps by offering GMP-certified manufacturing, regulatory compliance aligned with global standards, and a cross-border model designed to accelerate commercialisation. In this exclusive interview, Chan shares her vision for scaling CGT innovation across jurisdictions, the challenges of operating in a diverse regulated environment, and why building regional partnerships is the path to sustainable growth.

How did your career evolve towards cell and gene therapy, and what led you to establish Xellera Therapeutics?

My academic foundation lies in oncology and immunology, with training at Johns Hopkins University and the Sidney Kimmel Comprehensive Cancer Center, where I was fortunate to witness the early development of immunotherapy by some of the field's pioneers. This formative experience shaped my commitment to addressing hard-to-treat diseases such as cancer through advanced therapeutic modalities. I began my professional career as an assistant professor at the University of California, later transitioning into the biotech sector, where I spent over a decade leading a biotech group comprising a clinical-stage company and contract research organisations. During this time, I

successfully guided one public listing and am currently involved in another, broadening my perspective across scientific, operational, and financial dimensions. My experience also includes involvement in CMC and operational efforts for gene therapy programs advancing through clinical trials in the United States, further deepening my understanding of regulatory, manufacturing, and commercialization pathways for advanced therapies.

Most recently, I led the establishment and launch of Xellera Therapeutics' current Good Manufacturing Practice (cGMP) facility in Hong Kong, the first of its kind in the city to obtain a manufacturing licence for Advanced Therapy Products (ATPs). To date, Xellera remains the first and only commercial facility in Hong Kong dedicated to manufacturing such products, marking a significant milestone for the region's cell and gene therapy (CGT) ecosystem.

What was the strategic rationale behind establishing a GMP-certified advanced therapy facility in Hong Kong, and how does Xellera position itself within the broader CGT landscape?

Xellera was founded to address a critical gap in Asia-Pacific: the lack of GMP-compliant manufacturing infrastructure and technical expertise required to bring CGT innovations from bench to bedside. Although CGT innovation is advancing rapidly across the region, many developers often face roadblocks in scaling production, achieving global regulatory compliance, and executing cross-border clinical strategies.

Recognising this gap, we established a Contract Development and Manufacturing Organisation (CDMO) in Hong Kong, purpose-built to meet international regulatory standards, including Pharmaceutical Inspection Co-operation Scheme (PIC/S) and the European Medicines Agency (EMA) for advanced therapy products (ATPs). Our ambition was to build a facility that not only serves the local ecosystem but also enables cross-border product development and regulatory alignment. In 2023, we became the first company in Hong Kong to obtain a manufacturing licence for CAR-T therapies for clinical trials. Since then, we've completed our first Department of Health audit, supported clinical manufacturing of CAR-T therapies for patients in local clinical trial, and expanded our capabilities to serve a broader range of cell therapies.

Xellera's role extends far beyond regulatory firsts. We work closely with clients as partners, offering not just physical infrastructure, but also deep scientific expertise, robust process development, cGMP manufacturing, and a client-centric operating model. Through global strategic collaborations with leading CGT experts in the US and Europe, we ensure that our technological

capabilities remain current and competitive. While CAR-T was our initial focus, our multi-product facility supports process development and manufacturing of a broader spectrum of immune cell types, including natural killer cells, dendritic cells, virus-specific T cells, and mesenchymal stem cells. We have also established the first Southern Chinese clinical-grade human induced pluripotent stem cells (iPSCs) haplobank, enabling future development of allogeneic and off-the-shelf therapies.

Delivering this breadth of service requires not only adaptable platforms but also specialised talent. We have built a team that combines operational rigour with scientific acumen, translating complex development programs into standardised, GMP-compliant procedures. Our approach allows us to deliver true end-to-end CDMO solutions for CGT innovators across Asia-Pacific and globally.

How has Xellera addressed the talent gap in Hong Kong's CGT sector, and what role has public sector support played in building local capacity?

Establishing Hong Kong's first GMP-certified CGT facility required not only infrastructure, but also a highly skilled workforce in a largely nascent field. While the city benefits from a strong pharmaceutical base in generic drug manufacturing, there was a clear shortage of professionals with the scientific and operational expertise specific to advanced therapy experience.

To address this, we pursued a dual-track recruitment strategy: attracting experienced GMP professionals motivated to pivot into advanced therapies and scientific researchers, whom we train in-house through structured onboarding and hands-on GMP exposure. Encouragingly, many view CGT as the future of biotechnology in Asia and are eager to contribute to its advancement. Today, our team comprises 40 to 50 cross-functional professionals, with expertise spanning multiple cell types and platform technologies, reflecting both the technical complexity of our operations and our strong commitment to developing cross-functional, specialised talent to support the region's growing CGT ecosystem.

Alongside our internal efforts, we have received valuable support from the Hong Kong Special Administrative Region Government through the Innovation and Technology Commission (ITC). Their funding has enabled collaborative research with academic institutions, including the University of Hong Kong. A notable outcome of this support is the establishment of our GMP-grade human iPSC haplobank. Such initiatives not only enhance our scientific capabilities but also contribute to the broader development of Hong Kong's CGT ecosystem.

As a CDMO, building and sustaining a technically proficient team remains a central part of our mission, and we continue to invest in both **talent and partnerships** to support long-term regional leadership in advanced therapy manufacturing.

How does Xellera manage regulatory compliance for advanced therapies, and how does Hong Kong's approach compare with other frameworks across Asia-Pacific?

Xellera operates under a manufacturing licence issued by the Pharmacy and Poisons Board of Hong Kong, a regulatory body aligned with the PIC/S standards. While this local framework provides a strong regulatory foundation, our operations are designed to meet both EMA and FDA standards, enabling us to support clients across global markets. It reflects our commitment to global best practices in advanced therapy manufacturing.

Across Asia-Pacific, regulatory systems for CGTs vary widely in structure and maturity. Japan has taken a pioneering stance, implementing a dual-track approach that allows hospital-based applications of CGTs without full commercial authorisation, expediting early access to patients. For full-scale commercial development, oversight falls under the country's Pharmaceuticals and Medical Devices Agency (PMDA). South Korea and Singapore, on the other hand, follow centralised, regulation-driven frameworks that require formal GMP licensing, aligned with PIC/S principles. Taiwan also offers a dual-track system, balancing investigational new drug (IND) programmes through the Taiwan FDA with a hospital-based exemption pathway for earlier clinical access.

In China, the National Medical Products Administration (NMPA) governs formal IND pathways, while the National Health Commission (NHC) oversees hospital-based Investigator-Initiated Trials (IITs), a system that has enabled China to become the global leader in early-stage CAR-T trials. This flexibility has fostered remarkable growth, particularly at the Phase I stage.

By contrast, Hong Kong has opted for a far more stringent regulatory framework. All ATPs, whether for clinical trials or commercial use, must be manufactured in licensed GMP facilities, with no exemptions permitted, even at early development phases. While this imposes a higher bar for compliance, it also ensures exceptional quality assurance. For Xellera, this regulatory clarity strengthens our role as a trusted CDMO partner and reflects our ambition to help establish Hong Kong as a regional centre of excellence in CGT manufacturing.

The quality of Chemistry, Manufacturing, and Controls (CMC) is critical to the success of clinical trials, as it directly impacts product consistency, safety, and efficacy. In advanced therapies, even small variations in raw materials, cell handling, or process timing can lead to significant differences in patient outcomes. Without robust CMC, clinical data may become unreliable, or even rejected,

due to inconsistent product characteristics. Poor CMC planning can also result in supply delays, protocol amendments, or trial holds, jeopardizing timelines and budgets. High-quality manufacturing enables reproducibility, regulatory approval and patient safety.

In addition, strong CMC and regulatory alignment are not critical for clinical success but also foundational for commercialization. Without validated, consistent manufacturing processes and a compliant regulatory framework, sponsors could face major roadblocks when scaling from clinical development to commercial supply.

What refinements could enhance Hong Kong's regulatory framework for CGTs, and how might the city deepen its integration within the regional innovation ecosystem?

Hong Kong has made commendable progress in establishing a robust and credible regulatory framework for ATPs, which has laid a strong foundation for clinical-grade manufacturing. Although the city entered this space later than some regional counterparts, the framework it has adopted serves as a powerful quality signal to the market. For many clients, particularly those unfamiliar with the technical nuances of manufacturing, this level of regulatory rigour functions as de facto due diligence. It instils confidence that products manufactured in Hong Kong meet international expectations and are produced under the highest standards.

However, such a rigorous compliance environment can prove challenging for early-stage biotech companies, especially those entering Phase I trials where full commercial-level GMP adherence may not yet be financially feasible. To address this, Hong Kong could significantly benefit from adopting more flexible and expedited clinical approval pathways. For instance, conditional approvals based on a plausible scientific mechanism, rather than traditional randomized controlled trials, could be considered, particularly for extremely rare conditions, as FDA Commissioner Marty Makary recently suggested. Implementing adaptive regulatory mechanisms, including accelerated or conditional approval processes for innovative CGTs, could facilitate quicker progression from early-phase trials to clinical application, benefiting both patients and innovators.

Further enhancing Hong Kong's integration within the Greater Bay Area (GBA) innovation ecosystem is also pivotal. The establishment of the Greater Bay Area International Clinical Trial Institute (GBAICTI), with the involvement of Henry Yau and Professor Lo Chung-mau, reflects a strategic effort to streamline trial registration and regulatory processes across jurisdictions. With its relatively small domestic patient pool, Hong Kong stands to benefit significantly from enhanced integration with neighbouring markets. This also creates a bridge for Mainland Chinese companies,

many of which have conducted early-stage development through investigator initiated trials (IITs) but will require upgraded Chemistry, Manufacturing and Controls (CMC) systems to pursue FDA or EMA approval. In such cases, Xellera is well-positioned to offer the necessary GMP-compliant manufacturing that meets global regulatory expectations.

Ultimately, while the bar for regulatory compliance in Hong Kong remains high, balancing this rigor with adaptive and accelerated clinical approval mechanisms will position Hong Kong as a leading CGT hub, effective bridging regional innovation with global commercialization pathways.

What kinds of clients is Xellera currently engaging with, and how does the company's offering respond to the evolving demands of the CGT investment and development landscape?

The CGT investment landscape has shifted: while the focus once centered on scientific innovation and early clinical milestones, today's investors increasingly demand that commercial viability be integrated from the earliest stages of development. This shift reshapes how companies approach manufacturing, regulatory planning, and strategic partnerships.

At Xellera, we are seeing increasing interest from companies that have conducted early-phase IITs in China and are now preparing to transition into IND-stage programs targeting global markets. These companies recognise the need to integrate CMC planning early in development to avoid the inefficiencies, delays, and cost escalations that come from retrofitting GMP compliance later in the process. Having a well-defined, phase-appropriate manufacturing plan from the start allows developers to move swiftly from Phase I to commercial production without requiring disruptive changes in process or material sourcing, thereby avoiding regulatory setbacks and additional comparability studies.

Xellera's client base reflects this strategic shift. We work with early-stage biotechs transitioning from preclinical to first-in-human trials, offering process development, GMP technology transfer, and regulatory documentation support. We also support international CGT companies entering the Asia-Pacific region that require access to PIC/S-compliant facilities without investing in internal infrastructure. In addition, we support APAC developers seeking to elevate their manufacturing standards in order to meet the requirements of the US FDA and EMA standards for global market entry.

Despite a more cautious macroeconomic environment, CGT market remains resilient and continues to grow. We see broad interest across the Asia-Pacific region, with clients actively preparing for the next stage of CGT development. Many are investing now to elevate their GMP manufacturing

standards—reflecting a regional shift toward higher-quality, internationally compliant therapeutic products.

Our location in Hong Kong offers both regulatory alignment with international benchmarks and strategic proximity to the Mainland China market, including integration opportunities through the Greater Bay Area. With a bilingual environment and documentation systems fully aligned with global standards, we facilitate technology transfer between East and West. Moreover, Hong Kong's robust IP protections provide a secure framework for clients sharing proprietary processes and technologies. These combined assets position Xellera as a trusted partner for biotech companies aiming to bridge early innovation with commercial execution in a complex and increasingly globalised CGT environment.

Where is clinical and commercial demand accelerating within the cell and gene therapy space, and which modalities hold the greatest potential for broader adoption?

The initial wave of enthusiasm surrounding CAR-T therapies led many to anticipate rapid, widespread adoption in oncology. While the technology has proven transformative in haematological malignancies, broader expansion—particularly into solid tumors—has been slower and more challenging. At the same time, the limitations of autologous therapies such as their high cost, manufacturing complexity, and limited scalability, have spurred increased focus on allogeneic approaches. These off-the-shelf alternatives promise greater efficiency and accessibility but remain under development. Affordability continues to present a global barrier, particularly in regions where reimbursement systems or public healthcare programmes are not yet adopted to support the high-cost treatments.

In response, the field is seeing innovation aimed at compressing manufacturing timelines and reducing operational burdens. Emerging protocols that shorten the CAR-T production process from twelve days to just two or three could significantly lower the cost of goods, ease cleanroom capacity constraints, and ultimately expand patient access. New modalities are reshaping the landscape: iPSC-derived immune cells offer scalable, off-the-shelf solutions; gene editing tools enhancing T cell functions; novel immune cell types like gamma delta T cells and tumor-infiltrating lymphocytes (TILs) are broadening therapeutic horizons beyond traditional T-cell therapies. Gene therapies are regaining momentum, especially for rare diseases with clearly defined patient populations and supportive regulatory frameworks. Although the commercial reach of these therapies may be narrower, they represent a vital pillar of CGT innovation.

Ultimately, modalities that deliver clinical efficacy combined with scalable, cost-efficient manufacturing will be best positioned for broader adoption in both established and emerging healthcare systems. At Xellera, we are building platform flexibility and scientific depth to support the next generation of cell and gene therapies, offering development and manufacturing solutions that can adapt to a broadening range of modalities. We are built to anticipate and support the evolving needs of CGT innovators, enabling accelerated, compliant, and cost-effective therapeutic development.

What strategic direction is Xellera taking, and how does the company plan to enhance its impact across the Asia-Pacific region?

Xellera's long-term strategy is rooted in building regional and international connectivity. The company is positioning itself as a bridge between East and West, with a mission to facilitate the transfer and commercialisation of advanced therapy technologies across Asia-Pacific and beyond. A cornerstone of this vision is its strategic partnership with Cell Therapies in Australia. Both are GMP-certified Contract CDMOs, and this alliance is designed to offer dual-site manufacturing capabilities, accelerate technology transfer, and enable multi-site clinical trials across jurisdictions. With Hong Kong's proximity to Mainland China and Australia's strong CGT infrastructure, this alliance leverages complementary geographic and regulatory strengths to deliver seamless, PIC/S-compliant services across the region.

While Hong Kong serves as our regulatory and manufacturing anchor, we design client programs with built-in multi-jurisdictional flexibility. In parallel, Xellera is actively exploring potential expansion nodes across APAC region, such as Singapore, and future opportunities in Europe and the Middle East. These initiatives aim to broaden patient access, diversify regulatory pathways, and reinforce our commitment to building a resilient and globally integrated CGT ecosystem.

Looking ahead, Xellera aims to play an active role in shaping a more integrated regulatory environment within Asia-Pacific, inspired by the framework like the EMA's centralised regulatory model. By advocating for clinical data sharing, mutual recognition, and harmonised approval pathways, the company seeks to help establish the region as a cohesive and globally competitive hub for CGT development. This vision is further bolstered by Hong Kong's increasing integration into the GBA, providing access to a larger patient pool and expanding clinical trial opportunities. Xellera continues to cultivate strategic partnerships and defines growth through impact: by enabling scalable, cross-border development, building regional leadership, and a clear commitment to advancing CGT innovation throughout the Asia-Pacific and beyond.

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