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Navigating, manufacturing, infrastructure & regulatory hurdles in CAR T-Cell therapy growth

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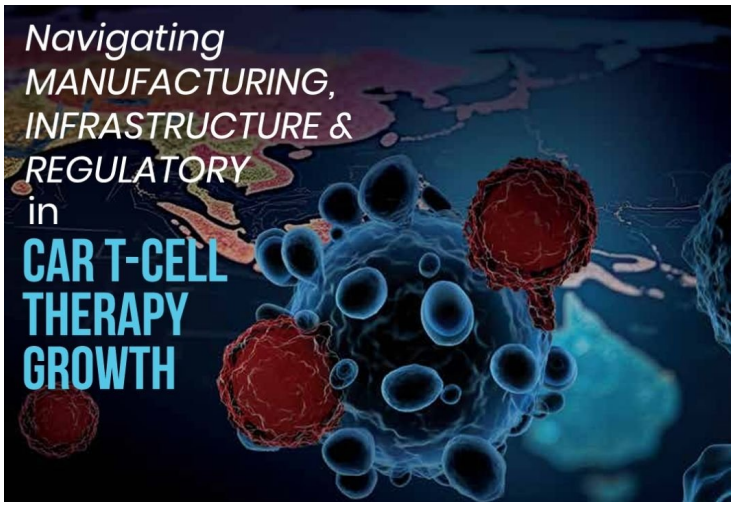
CAR T-cell therapy is a highly personalised treatment that depends on a unique and complex manufacturing and delivery process to reach patients quickly and reliably. From leukapheresis to final product delivery, the process is continuous and time-sensitive, posing significant operational challenges. How is the industry addressing them, and what steps are needed to build a sustainable manufacturing ecosystem? Let's dig deeper.



Global demand for cell and gene therapies is rising, with the Asia-Pacific (APAC) region playing an increasingly significant role in clinical development and early commercialisation. To date, nine CAR-T therapies have been approved in the region. Nearly 220 companies are developing around 1,200 CAR-T candidates for both oncological and non-oncological indications, while more than 1,000 CAR-T trials are active worldwide, over half of them in Asia-Pacific, according to Roots Analysis, a market research and consulting firm specialising in the pharmaceutical, biotechnology, and medical technology industries.

Turning this scientific progress into accessible therapies remains a challenge. Being inherently complex, production of CAR-T therapies involves patient-specific processing, advanced infrastructure, and stringent quality requirements, inevitably contributing to high costs, operational inefficiencies, and uneven accessibility.

Scaling hurdles

The Asia-Pacific region has incredible momentum and patient demand, but as elsewhere, scaling cell therapy manufacturing has never been straightforward. Turning a patient's living cells into a personalised therapy is a highly manual and often bespoke process. The very nature of cell and gene therapies presents unique challenges throughout the assets' lifecycle which drive significant costs and infrastructure requirements.

“Cell therapies are inherently more complex to develop and manufacture than traditional medicines. For autologous products, the priority is scale-out - managing parallel, patient-specific lots - where allogeneic and iPSC-derived products bring true scale-up challenges and opportunities,” observed **Sabrina Xu, Head of Novel Modality APEC, Process Solutions, Life Science business of Merck**.

In May 2024, Merck announced its largest investment in Asia with the launch of its €300 million Bioprocessing Production Center in Daejeon, South Korea. The facility is set to accelerate the development of the biotech and pharmaceutical industry by supporting the manufacturing of cell and gene therapies, among other products.

One key challenge is the limited access to specialised manufacturing facilities, GMP-compliant cleanrooms, and experienced personnel capable of supporting scalable autologous and allogeneic production. In addition, high costs for quality control (QC) and specialised equipment, combined with the absence of standardised QC protocols across countries, further increase manufacturing expenses and contribute to variability in batch success.

“Scaling up cell therapy manufacturing in Asia faces several critical challenges, including a limited number of Good Manufacturing Practice (GMP)-compliant facilities, a shortage of fully closed and automated cell processing systems to support commercial-scale manufacturing, and the slow adoption of digital solutions to manage the complexity of personalised therapies,” said a spokesperson from BioCell Innovations, Singapore.

BioCell Innovation has developed a streamlined, scalable CAR-T manufacturing process designed to minimise inflammatory cytokine release without affecting CAR-T therapeutic activity, thereby supporting its potential for a safer, more effective CAR-T manufacturing.

“From a quality/CMC perspective, there is a fragmented regulatory landscape. APAC comprises numerous countries with diverse, sometimes nascent regulatory frameworks for cell and gene therapies (CGTs), including differing definitions, GMP standards, and biosafety requirements. This hinders simultaneous multi-country development and complicates cross-border CMC regulatory strategy,” said **Tamie Joeckel, Global Business Lead, Cell and Gene Therapy Centre at ICON plc** . ICON helps navigate the unique Cell and Gene Therapy journey from early phase consulting to clinical development through commercialisation.

These challenges can sometimes be compounded by the lack of a local technical support team for specialised equipment, and a shortage of trained personnel with experience in cell therapy manufacturing, quality assurance, and regulatory affairs.

“Another bottleneck is talent, because cell therapy is relatively new, and no one has been able to meet commercial demand, it is difficult to find enough people with hands-on cGMP and QC experience,” said **Fabian Gerlinghaus, CEO and Co-founder, Cellares**, the first Integrated Development and Manufacturing Organization (IDMO), applying an Industry 4.0 approach to the mass production of living drugs. A pioneer in automated cell therapy manufacturing, Cellares is establishing Japan’s first next-generation commercial production facility for CAR-T cell therapies.

Tamie agrees, “While some APAC countries like Japan, South Korea and Singapore have developed more advanced capabilities, many regions have economic, workforce expertise and infrastructure limitations that are further complicated by diverse regulatory environments.”

High cost of raw materials is another major challenge in scaling up cell therapy manufacturing. **Spandan Mishra, Global Director- Technical Marketing- Cell Culture Solutions, Evonik Health Care** explains, “During the scale-up of cell therapy manufacturing, cells from patients or donors are grown in bioreactors until there are enough for treatment. One of the major challenges is the high cost of materials, especially growth factors and cytokines, which are essential for supporting the cells, but are expensive and unstable under culture conditions. They drive the majority of the raw material cost but they often degrade fast due to instability and need to be replenished in the cell culture process, which leads to increasing costs and the risk of batch failures during cell therapy development.”

Headquartered in Germany, Evonik is among the few CDMOs that can support the entire process from initial formulation feasibility to scale-up and cGMP commercial production. The company brings over 30 years of nanomedicine expertise and a broad range of non-viral delivery technologies for gene therapies, supporting manufacturing through extrusion, microfluidics, microencapsulation, and other platforms, with FDA-registered sites and aseptic filling lines.

Adding to this, the spokesperson from BioCell Innovations Singapore highlights border costs and supply chain pressures and further adds “High-cost burden associated with the use of GMP-grade reagents, single-use consumables, coupled with the requirement of an extensive series of rigorous quality control assays to certify the safety, purity, and potency of CAR-T products before they can be released for clinical use. Because most cell and gene therapy consumables are sourced from Europe and the USA, the supply chain adds an additional layer of complexity, particularly in ensuring timely access to critical

reagents and materials."

Reliable supply of materials, maintaining the cold chain, and transferring technology across multiple sites are often additional bottlenecks in cell therapy manufacturing. "For autologous or personalised therapies, challenges include maintaining cell viability during shipping, managing temperature-controlled logistics, dealing with customs and local documentation, especially across long distances," said **Dr Meghan Morgan-Smith, Director of Therapeutic Expertise, Drug Development, ICON plc** .

She added, "In most autologous therapies, the clinical sites must coordinate the patients' schedules for apheresis to the available manufacturing slots and to receive those shipments overnight due to the shelf life and viability of the cells. These logistical and supply chain complexities make distribution across the diverse, sometimes remote APAC regions more difficult and adds risk."

Unlike conventional therapies, which can be produced in large quantities, CAR-T cell therapy requires real-time manufacturing and therefore, manufacturers must adhere to strict regulatory requirements which vary across the Asia-Pacific region.

"Unlike the FDA & EMA, who harmonised their regulatory framework, APAC has country-specific authorities that support different standards for quality, safety and efficacy which impact the entire process from manufacturing to delivering the clinical trials at the site level to commercial access. This lack of harmonisation makes cross border trials and decentralised manufacturing more challenging," said Meghan.

The spokesperson from BioCell Innovations adds, "A major challenge for cell therapy development in Asia is the widely variable regulatory standards across the APAC region. The frameworks can differ from conditional or time-limited approval pathways in Japan, to risk-based regulatory models in Singapore, and breakthrough therapy designation policies with priority review channels in China. These inconsistencies add complexities in compliance requirements, approval timelines, and market access, posing barriers to the seamless development and commercialisation of CAR-T therapies."

Industry moves

Industry players across the Asia-Pacific region are taking steps to overcome the bottlenecks in cell therapy manufacturing, from infrastructure, talent, logistics, and raw materials.

On the infrastructure front, companies are investing in advanced manufacturing facilities and GMP-capable cleanrooms, often through international partnerships. Teijin Limited and Hilleman Laboratories have signed a memorandum to expand CDMO operations in cell and gene therapy, while Cellares Japan, with CBRE Japan's support, is establishing its first Smart Factory in Asia, scheduled to open in 2027. AGC Biologics has also expanded its global footprint with a new Yokohama facility to serve autologous and allogeneic therapies across three continents. Japan-headquartered Astellas Pharma Inc. and Yaskawa Electric Corporation have signed a definitive agreement to establish a joint venture for the development of a cell therapy product manufacturing platform utilising the dual-arm robot 'Maholo'. In addition, the joint venture will offer platform access to startups and academic institutions, fostering collaboration and innovation in the field of cell therapy.

Talent development is another priority, with Asian countries fostering skilled workforces through seminars, workshops, and partnerships with industry and government bodies. Singapore, for instance, leverages SGInnovate and Enterprise Singapore to train professionals and provide infrastructure support. Gilead and Kite also remain committed to fostering expertise and expanding capabilities in the Asia-Pacific region through collaboration with key stakeholders. In South Korea, they are actively working with healthcare centres to conduct extensive training to upskill healthcare professionals, with a target of establishing various qualified treatment centers (QTCs) by 2026.

Logistics and supply chain challenges are being addressed by optimising cold-chain management, establishing multi-site manufacturing hubs, and adopting hub-and-spoke models. Singapore, for example, is emerging as a key regional centre, providing CAR-T therapies to neighboring countries such as Indonesia, Vietnam, and the Philippines.

Raw material bottlenecks are also being tackled through strategic partnerships and technology development. Sartorius Stedim Biotech's investment in Nanotein Technologies, for example, supports the commercialisation of NanoSpark reagents designed to enhance T and NK cell expansion. Terumo Blood and Cell Technologies and FUJIFILM Irvine Scientific are also collaborating to accelerate T cell expansion for therapy developers.

Governments in the region are also actively promoting cell therapy manufacturing. Notable government-supported hubs include the Peter MacCallum Cancer Centre in Australia, the Foundation for Biomedical Research and Innovation in Japan, Curocell and Vaxcellbio in South Korea, India's Department of Biotechnology, the Shanghai Cell Therapy Group in China, the

Thailand Center of Excellence for Life Sciences, and Singapore's Advanced Cell Therapy and Research Institute (ACTRIS), along with many other emerging hubs across the region. If these manufacturing facilities could establish cross-border partnerships and operate under a harmonised regulatory framework, they could significantly enhance efficiency, optimise facility utilisation, and create a competitive manufacturing ecosystem that accelerates access to CAR-T therapies for patients.

Regulatory harmonisation efforts, including Project Orbis, aim to streamline approvals and align standards across multiple jurisdictions, enabling faster patient access and reducing cross-border complexity.

Building a Sustainable Manufacturing Ecosystem

Sustainability and global competitiveness in cell and gene therapies depend on tackling challenges in scalability, quality control, cost, and access. As Dr Diego Santoro, General Manager and Head of International Region, Gilead and Kite Oncology puts it, "Firstly, continuing to implement innovative solutions to improve the delivery of CAR T-cell therapy to eligible patients who are in urgent need of this treatment option."

Gilead claims to have the largest in-house cell therapy manufacturing network in the world, operating at a high manufacturing success rate to deliver products reliably to patients. In 2022 Gilead and Kite invested in establishing a Cell Therapy Business Unit to bring the innovation of cell therapy to Singapore to fulfil the current unmet need amongst those who have relapsed with specific blood cancers. Since that time, its footprint has grown across Asia, with the latest business unit opening in South Korea earlier this year to accommodate growing demand for CAR T-cell therapies across the region.

Cost pressures remain significant, particularly with raw materials such as growth media. "Cost is another major challenge. Growth media, which nourishes the cells, is expensive and often needs frequent replacement. Using more stable ingredients can reduce this cost and simplify the process. For example, Evonik's cQrex peptides provide stable sources of key nutrients like glutamine and cysteine, improving cell growth and reducing oxidative stress. This leads to better cell viability and more efficient manufacturing," said Mishra.

Manufacturing processes are still highly manual, but automation and advanced platforms are beginning to reshape the landscape. "Standardise around closed, automated platforms; embed a robust digital backbone (e.g., electronic batch records/MES, data integrity by design); and move toward in-line analytics to ease QC bottlenecks. Build comparability-by-design, and advance allogeneic approaches and in vivo engineering to enable scalable models over time," said Sabrina.

Gerlinghaus stressed, "Invest in end-to-end automation and digitisation. This is essential to increase throughput, cut failure rates, and drive down price per batch at commercial scale. It also aligns with regulatory agency expectations around supporting product lifecycle management, digital transfer, and faster, more streamlined post-approval changes."

Collaboration is also critical. "Collaborative partnerships and strategic alliances can support global scale and supply chains – especially in emerging APAC markets where economic and infrastructure constraints persist. CDMO's that provide full development and manufacturing services are partnering with biotechs allowing them to reduce capital investments and use their funds to focus on research. We should continue to see collaboration between big pharma and emerging biotech for investment and partnership opportunities," said Tamie.

Sabrina added, "Pair therapy developers with CDMOs and clinical networks to streamline apheresis-to-infusion workflows. Invest in a workforce pipeline (GMP operators, process engineers, QC analysts) and shared infrastructure to speed site readiness and tech transfer."

Ultimately, regulatory alignment will shape the pace of growth. Continued focus on harmonisation of regulatory frameworks is essential to reduce the regulatory burden and support reduced costs overall, global scaling and access.

"Encourage convergence and reliance models to reduce duplicative reviews, with clear expectations on risk-based process changes and lifecycle data. Common data standards for batch, chain-of-identity, and release will enable efficient, cross-border operations," said Sabrina.

Looking ahead, the goal is clear. "Countries need a well-defined policy framework to facilitate timely and equitable access to these innovative treatments. We are committed to partnering with health authorities and stakeholders in Asia Pacific and beyond to help build a patient-centered and sustainable ecosystem for cell therapy," said Dr Santoro.

To sustain industry growth, governments and health systems will need to recognise the long-term value of CAR T-cell therapy, work with companies to improve access, and introduce policies that ensure affordability and sustainability. The integration of digital solutions and artificial intelligence is expected to play a pivotal role in transforming manufacturing across Asia, improving process efficiency, batch consistency, patient identification, and regulatory submissions. Coupled with cross-

border collaboration, regulatory harmonisation, and continued workforce development, Asia-Pacific has the potential to move from being a fast-growing market to a global leader in advanced therapies.

The opportunity is significant, the global cell therapy manufacturing market is estimated at $5.55 billion in 2025 and is projected to reach nearly $18.89 billion by 2034, according to Precedence Research. How effectively the region addresses infrastructure, regulatory, and supply chain challenges will determine its ability to capture this growth and deliver wider patient access to these life-saving treatments.

Leading Cell Therapy Manufacturers in Asia Pacific

Q-Gen Cell Therapeutics (Australia) is recognised as one of Australia's leading contract manufacturers for cell therapy. The company supports clinical and commercial-scale production of advanced therapies and is a key partner for the region's growing cell therapy ecosystem.

Xellera Therapeutics (Hong Kong) is the first GMP-licensed CDMO dedicated to cell and gene therapy. The company provides end-to-end manufacturing and development services for advanced therapy products.

ACTRIS – Advanced Cell Therapy and Research Institute (Singapore) serves as Singapore's national centre for cell therapy. It focuses on research, process development, and GMP manufacturing of cell-based therapies for a range of diseases, supporting both public and private sector collaborations.

BioCell Innovation (Singapore) has developed a scalable CAR-T cell manufacturing platform designed to reduce inflammatory cytokine release while maintaining therapeutic activity. The company's approach aims to improve safety and effectiveness in CAR-T production.

TEIJIN CDMO (Japan), jointly operated by Teijin Regenet and J-TEC, provides contract development and manufacturing services for cell and gene therapy as well as regenerative medicine products, leveraging Teijin Group's expertise in biomanufacturing.

OBiO Technology (China), operating since 2013 as both a CRO and CDMO, offers services spanning cell preparation, recombinant protein and exosome production, and cell storage, with applications in regenerative medicine and anti-ageing.

Takara Bio (Japan) provides a broad suite of services, including single-cell analysis, stem cell services, instrumentation, and manufacturing support for cell and gene therapy development.

Cell Therapies Pty Ltd (Australia) is a GMP-licensed CDMO delivering advanced cell and gene therapies across Australia and the Asia-Pacific region. The company provides clinical and commercial manufacturing services for global partners.

Taiwan Cell Manufacturing Company (Taiwan) (TCMC) offers integrated, end-to-end CDMO solutions to accelerate cell and gene therapy development. Its model is designed to balance speed and cost efficiency for regional and international clients.

Genepeutic Bio (Thailand) operates Thailand's first GMP-certified cell and gene therapy manufacturing facility. The company's initial focus is on developing CAR-T cell therapies and advancing personalised medicine for patients in Asia.

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