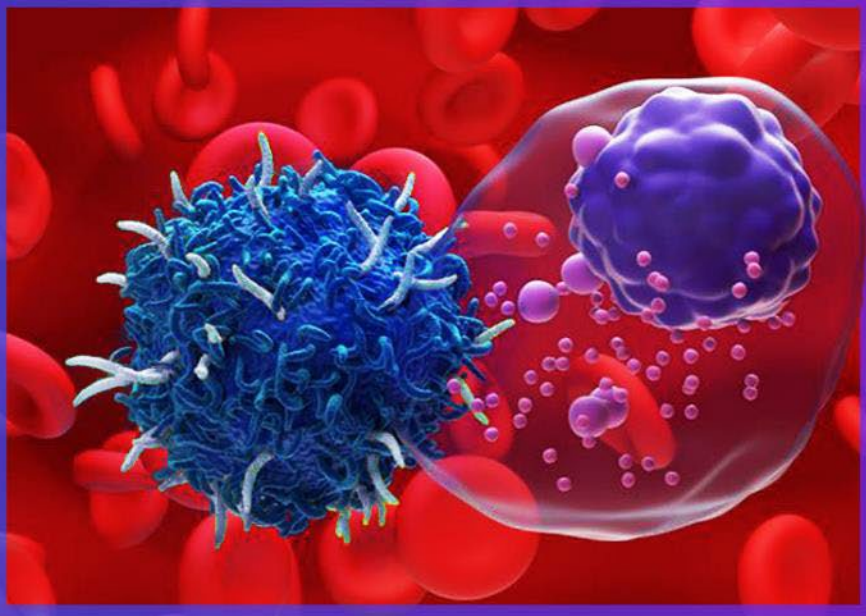
KPMG

The USD 30k CAR-T therapy: a future within reach?

How Life Sciences leaders can increase accessibility and drive CAR-T costs down through supply chain innovation

2025



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Executive Summary

CAR-T therapy delivers impressive 80% response rates for hematological malignancies, yet

fewer than 20% of eligible patients

in the U.S. currently receive these potentially life-saving treatments.

This article explores

critical bottlenecks across the CAR-T ecosystem: healthcare system constraints including limited apheresis capacity and geographic disparities; manufacturing complexities that extend vein-to-vein times and impact reliability; and untapped potential of third parties in commercial-stage production. Coordinated value chain transformation is imperative to expand access while addressing concerning disparities in treatment distribution.

Strategic innovation across these domains could dramatically improve patient access while reducing costs manyfold - potentially bringing prices from current levels toward an aspirational USD 30,000, making these revolutionary therapies both clinically effective and economically sustainable.

Contents

Introduction

Less than 20% of eligible patients in the U.S. currently have access to Chimeric Antigen Receptor T (CAR-T) cell therapy[1,2].

With projected increases in demand, payer pressure, and funding concerns, autologous cell therapy providers and stakeholders face a critical challenge:

- **How can we make these life-saving therapies widely available?**
- **Can Western production facilities achieve a USD 30,000 cost per dose?**

The need for faster turnaround times, lower costs, and greater proximity to patients has never been more urgent.

Achieving this vision requires a unified and strategic effort across the entire autologous cell therapy ecosystem. From manufacturers to logistics providers, CDMOs to raw material suppliers, each part of the value chain has a critical role to play in driving this transformation.

In this article, we examine current value chain challenges and explore how key players can work together to reshape the future of autologous cell therapies.

Navigating the CAR-T ecosystem

Despite its rapid adoption, CAR-T still faces manufacturing, cost, and scalability challenges. **Delivering these personalized therapies requires close coordination among a wide spectrum of stakeholders** – pharmaceutical companies, healthcare professionals (HCPs), hospitals, payers, logistics providers, contract manufacturing organizations (CMOs), and raw material suppliers. Patients are also uniquely involved in the process by providing critical raw material in the form of their T cells. The successful setup of this collaborative network has enabled the initial deployment and delivery of thousands of CAR-T treatments to patients since the first commercial approval in 2017.

Until recently, most pharmaceutical companies had significant cost associated with CAR-T manufacturing, averaging around USD 170 000 to 220,000 per dose[3]. In 2024, Indian CAR-T biotech, ImmunoACT, achieved an unprecedentedly low production cost of USD 30,000 to 50,000 per dose, dramatically undercutting industry norms, and making it more urgent for established CAR-T players to consider cost-reduction strategies to remain competitive and increase treatment accessibility[4].

As demand grows,

scaling up manufacturing capacity, reducing costs, and enabling broader patient access

will require greater alignment across the entire value chain.

[1] Estimation of eligibility for and response to CAR-T therapy in the United States, December 2023, Blood Advances

[2] Chimeric Antigen Receptor T-Cell Therapies: Barriers and Solutions to Access, September 2021, JCO Oncology Practice

[3] Manufacturing innovation to drive down cell therapy costs, October 2023, Trends in Biotechnology

[4] The effort to make a breakthrough cancer therapy cheaper, April 2024, MIT technology Review

Three key challenges

will define the next evolution of the CAR-T cell therapy landscape (see Figure 1) :

I. Healthcare system infrastructure and treatment accessibility.

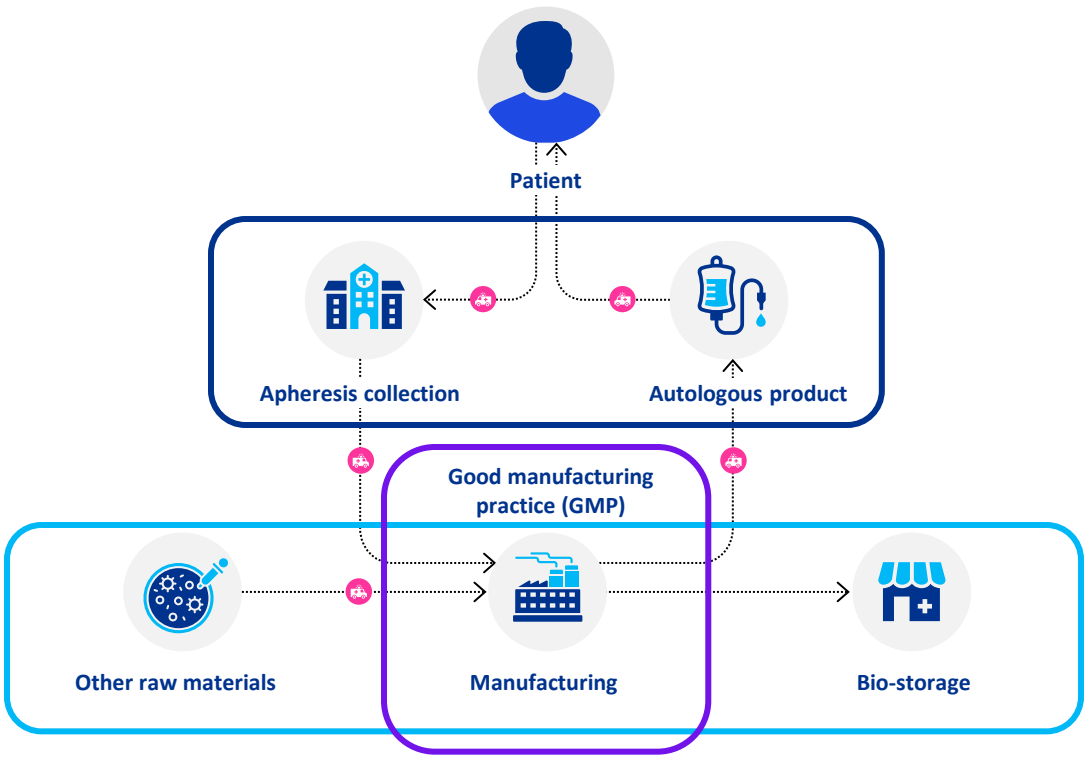
II. Manufacturing process robustness and automation.

III. Third-party ecosystem and strategic partnerships.

Stakeholders who proactively address these challenges will enhance their competitiveness and drive meaningful advances in patient outcomes and market growth.

Figure 1: the CAR-T value chain relies on multiple stakeholders, each addressing a distinct set of challenges.

CAR-T value chain



Challenges

I. Healthcare system infrastructure and treatment accessibility

II. Manufacturing process robustness and automation

III. Third-party ecosystem and strategic partnerships

Stakeholders concerned

I.	II.	III.
Hospitals ATCs	Biotech & pharma	Analytical labs
Logistics providers	Equipment manufacturers	CMOs
	Digital solutions developers	Raw material suppliers

I.

Healthcare system infrastructure and treatment accessibility

While the initial use of CAR-T cell therapies successfully met the needs of a limited patient population, the anticipated increase in demand will require a more robust and scalable ecosystem.

Early challenges in access

Initial CAR-T approvals targeted relapsed or refractory hematologic cancers as third- or fourth-line therapies, limiting the patient base to a relatively small cohort. Access was further limited by high costs, reliance on certified centers with specialized capabilities, and geographic disparities in treatment availability. For instance, Kite Pharma, the CAR-T player with the largest network of partner treatment centers, has onboarded approximately 500 centers worldwide for sample collection and treatment.

Significant regional disparities remain, forcing some patients to travel three to four times farther than others to access care. In addition, CAR-T cell therapies have been predominantly accessible in established economies such as the United States (U.S.), France, the United Kingdom (U.K.), Germany and China. The limited uptake in middle- and low-income countries is due to cost and infrastructure barriers. In the U.S., less than 20% of eligible patients currently have access to CAR-T cell therapies.

Drivers of increased demand for CAR-T cell therapies

Pharmaceutical companies and analysts expect a significant rise in CAR-T demand in the coming years, driven by the following factors:

Earlier lines of treatment

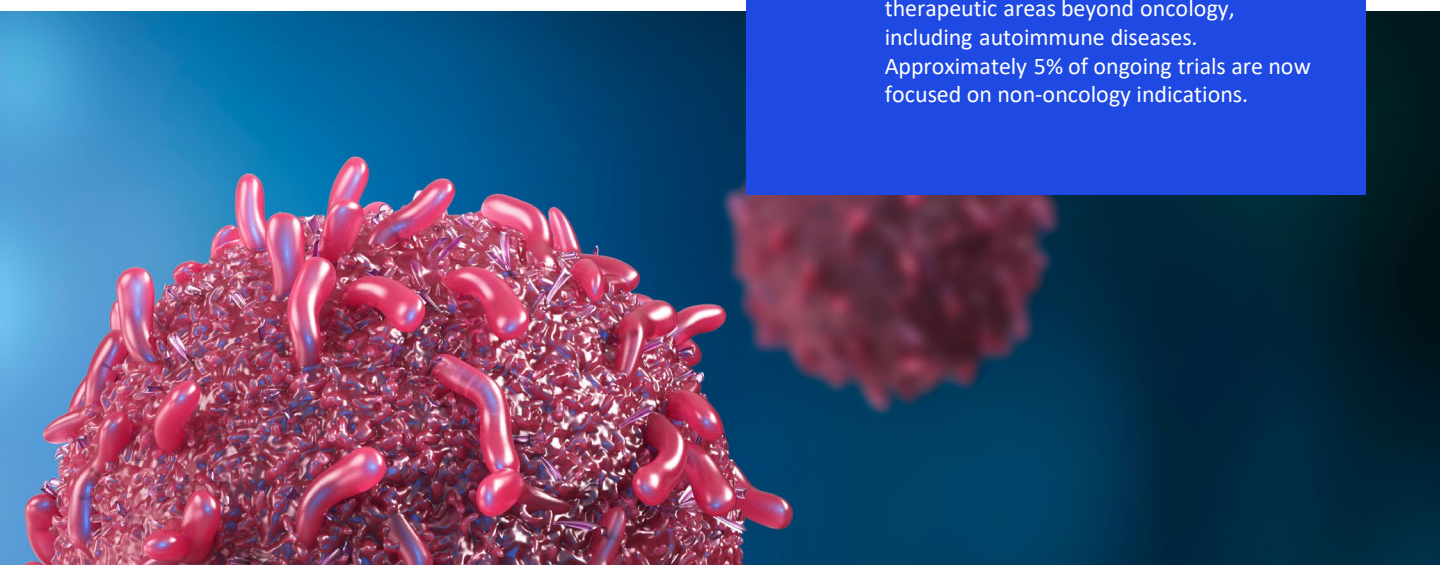
Regulatory approvals for earlier-line treatments are increasing the addressable patient pool. For example, ABECMA and CARVYKTI, initially approved for late-stage patients, have recently received approval for second-line treatment.

New product development

An increasing number of clinical trials is expected to increase the volume of approved products. This will be driven by larger pipelines, new players, new antigen/targets (BCMA, CD20, B7-H3) and new CAR constructs (bi- or tri-specific CARs and switchable CARs for solid tumors).

Expanding indications

Clinical trials have shifted to broader therapeutic areas beyond oncology, including autoimmune diseases. Approximately 5% of ongoing trials are now focused on non-oncology indications.



01 Addressing apheresis capacity constraints

As the demand for CAR-T therapies grows, the first step in the process – apheresis – is under pressure.

Apheresis is the **collection of a patient's cells for manufacturing** and is primarily performed at academic centers equipped with leukapheresis facilities. In addition to CAR-T, hospital apheresis units also collect various cellular and blood components for a range of applications, including **research**, **diagnostics** and **therapeutic purposes** such as **stem cell transplantation**.

Demand from multiple applications, including the growing clinical production of CAR-T, requires **prioritization** and creates **competition for apheresis slots**, further straining the system.

A shortage of

more than 30%

in cell therapy apheresis capacity compared to patient demand is expected in the U.S. within the next five years[5].

To mitigate this, a new strategy called **«holding therapy»** has emerged to manage disease progression until a leukapheresis slot becomes available.

To efficiently bridge the anticipated capacity gap, stakeholders have considered both short- and long-term solutions:

Expand academic and community infrastructure

Investment in additional chairs, equipment, staff and staff training programs for personnel is essential to maximize throughput in existing facilities . This is a **costly initiative** that may also require **significant infrastructure expansion**.

Some hospitals are transforming their apheresis departments into **specialized centers** that function as **independent service providers**, while community centers are being integrated into the CAR-T ecosystem to **reduce travel burdens** and relieve pressure on academic centers.

Push for standardization

Accreditation bodies such as the **Foundation for the Accreditation of Cellular Therapy (FACT)**, the **Joint Accreditation Committee ISCT-Europe & EBMT (JACIE)** and the **American Society for Apheresis (ASFA)** are promoting uniform practices and quality standards for cellular therapy programs and therapeutic apheresis.

The ST-018 ISBT-128 labeling standard has been introduced by the **Standards Coordinating Body (SCB)** to ensure consistency and safety of apheresis products, benefiting centers, manufacturers and patients.

The active involvement of pharmaceutical companies in regulatory efforts and operational audits can ensure compliance, scalability and product quality.

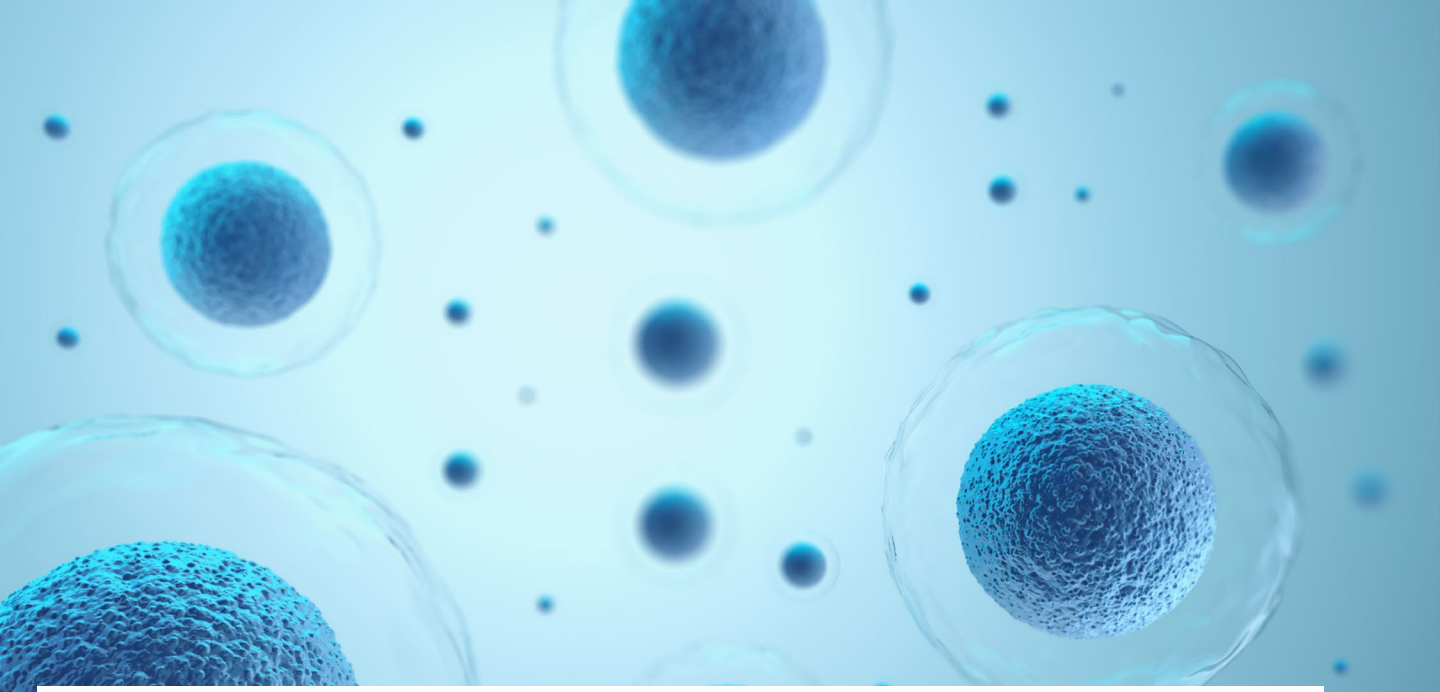
Innovate through alternative solutions

New innovations and players are **entering the field** to support apheresis services. **Mobile apheresis units**, which are portable laboratories equipped for **leukapheresis**, could offer additional capacity and expand access in underserved or rural areas to **address geographic disparities**.

In addition, plasma therapy manufacturers and blood banks have **infrastructure** and **expertise** that could be leveraged to expand apheresis capacity and relieve pressure from academic centers.

Technological advances such as the use of whole blood as a starting material and allogeneic therapies may significantly **lower the need for traditional apheresis** in the CAR-T manufacturing process in the future.

[5] The Class Battle for US ATC Slots: Implications for BCMA, CD19, & Solid Tumors, October 2024, Leerink Partners



02 Streamlining logistics and cold chain infrastructure

CAR-T cell therapy depends on reliable cold chain logistics.

Apheresis material as well as finished products must be transported under strict conditions – **either fresh (4°C) or frozen (<-150°C using liquid nitrogen)** – depending on company-specific protocols. Any variation in temperature risks compromising product integrity, delaying hospital workflow or disrupting the patient experience.

As demand grows, CAR-T logistics and cold chain systems must evolve to become more efficient, scalable, and resilient. **Key strategies for improvement revolve around the use of advanced digital tools and robust systems integration.**

The implementation of accurate **temperature monitoring** and **real-time tracking technologies** is essential to ensure end-to-end visibility and **maintain product integrity** throughout the supply chain.

At the same time, the adoption of flexible cryogenic logistics solutions will be increasingly important as evolving clinical protocols and growing demand for both frozen and fresh materials – especially with the emergence of new modalities such as **allogeneic** and **in vivo cell therapies** – require a scalable and adaptable cold chain.

In parallel, seamless integration of logistics systems across all stakeholders is crucial to enhance operational efficiency and reduce the risk of disruptions. This should be supported by advanced supply and demand management tools and forecasting systems that drive more precise planning and scheduling across the network.

An example of a digitalized solution is **Kite Konnect,** a proprietary system developed by Kite Pharma to streamline and optimize CAR-T operations.

It provides:

- Centralized management and scheduling that monitors apheresis centers, supports reimbursement and logistics coordination, schedules apheresis, and redirects materials based on manufacturing site utilization, geography, and regulatory requirements.
- Enhanced visibility for HCPs for real-time insight into sample management to improve transparency and coordination.

Implementing such innovative solutions will be critical to ensuring the efficiency, scalability, and resilience of CAR-T logistics and cold chain systems as demand for these life-saving therapies continues to grow.

03 Treatment infrastructure: maximizing outpatient setups

Currently, CAR-T cell therapies are **primarily administered in hospital settings** to manage potential critical side effects. However, with increasing approvals for earlier lines of treatment, new indications and healthier patient profiles, **outpatient settings present a viable alternative**. The transition to outpatient care can reduce the burden on academic centers, **freeing up slots and improving overall accessibility**.

Pharmaceutical companies are playing a key role in enabling this shift by developing **clinical segmentation methods** to identify patients eligible for outpatient treatment. Accurate visibility and reliability of drug product reception dates are critical to optimizing workflows, including initial lymphodepletion steps, CAR-T administration and post-infusion monitoring.

Several **retrospective studies** have demonstrated the feasibility of administering cell therapies in outpatient settings. This initiative requires a **geographically connected network of service providers** to ensure accessibility and rapid patient management. The potential for high rates of adverse events such as **cytokine storms** underscores the need for swift and critical medical intervention capabilities.

Key enablers include telemedicine solutions, 24/7 expert availability, proximity to intensive care facilities and the adoption of real-time home monitoring technologies. These innovations allow even **lower-risk patients to receive timely treatment** while being closely monitored for complications, reducing the need to wait for hospital slots.

II.

Manufacturing process robustness and automation

As CAR-T therapies scale up, manufacturers face increasing pressure to shorten production timelines, improve reliability, and reduce costs.

To meet the expectations of patients, healthcare providers and payers, they must address key challenges in process robustness and automation.

The primary goal is to **build reliable and scalable manufacturing environment** including production workflows, quality control and automation.

There are **three levers** for a reliable and cost-effective scale-up:

01	02	03
Economies of scale	TAT reduction	Automation

Economies of scale 01

A key lever for cost reduction is economies of scale driven by higher production volumes.

CAR-T manufacturing has traditionally relied on manual processes in costly, highly regulated Grade A/B cleanroom facilities. As production scales, operational efficiencies improve, leading to a **dilution of overhead and a lower cost per unit**. Similarly, bulk procurement and large-scale production of critical raw materials, such as viral vectors, will significantly reduce costs and strengthen the financial sustainability of high-volume manufacturing.

Turnaround time (TAT) reduction 02

Reducing turnaround time is a critical competitive advantage.

Historically, TAT has ranged from three weeks to several months, increasing the difficulty of patient coordination and the risk of missed therapeutic windows, particularly for **critically frail patients requiring rapid intervention**.

The industry is now striving to reduce TAT to **less than 10 days**[6,7], significantly improving both patient outcomes and operational workflow. Of note, TAT may not be as critical for certain future products used to treat less aggressive conditions such as autoimmune diseases.

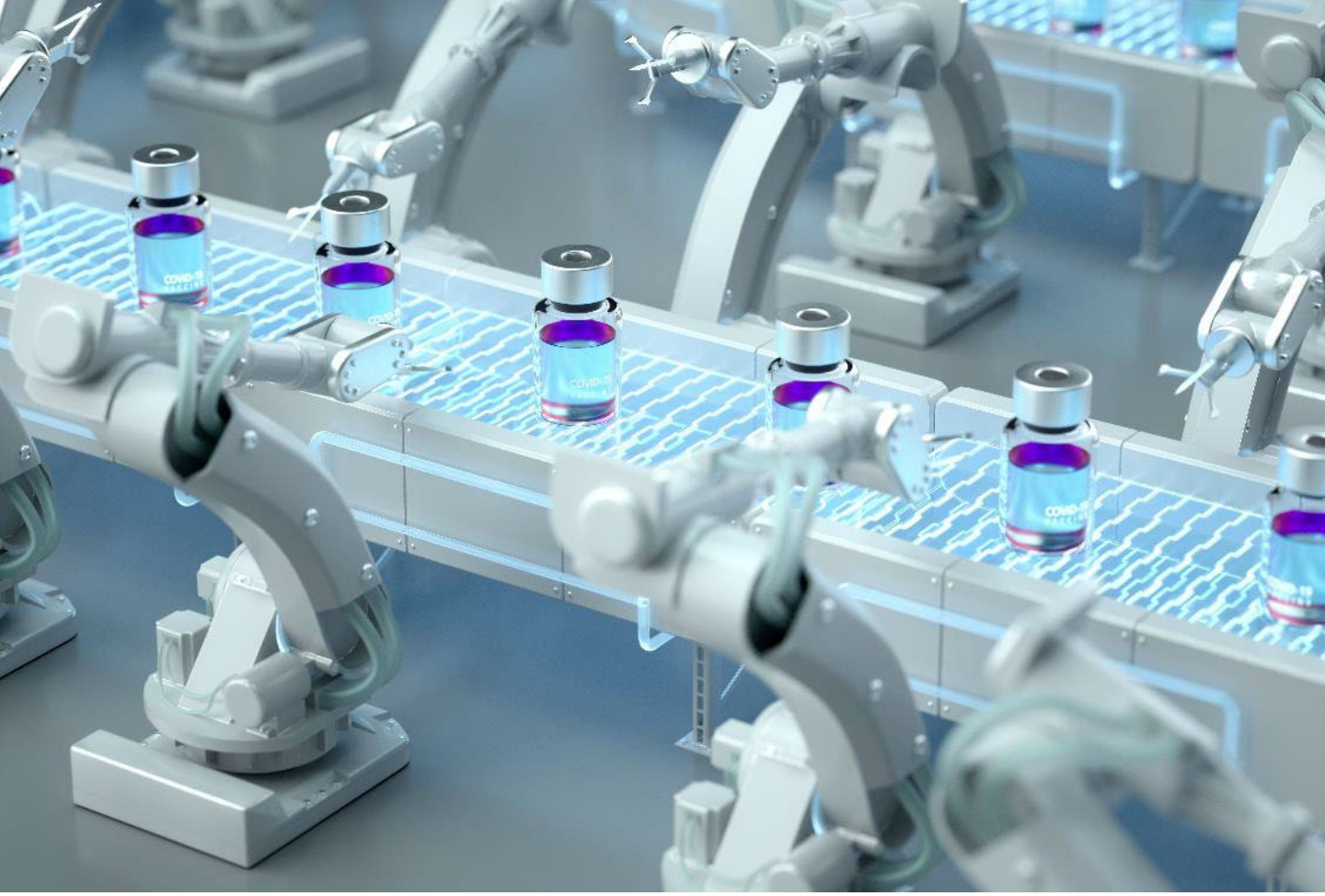
To achieve this efficiency, manufacturers are implementing **several process innovations** aimed at accelerating workflows and improving product quality:

- **Optimized cell expansion protocols** that reduce the number of days required for cell growth without compromising therapeutic efficacy.
- **Next-generation quality control (QC) solutions** such as innovative rapid sterility testing for faster product release.
- **Digital technologies** such as electronic batch records and dynamic quality inspection that increase QC and QA efficiency, reduce batch release times and decrease out-of-specification (OOS) rates.

Looking ahead, next-generation therapies and manufacturing approaches, such as in vivo CAR-T therapies that bypass in vitro manufacturing altogether, could further reshape timelines **by eliminating traditional manufacturing bottlenecks** and improving patient access.

[6] CAR-T cell manufacturing: Major process parameters and next-generation strategies, January 2024, Journal of Experimental Medicine

[7] Accelerating CAR T cell manufacturing with an automated next-day process, January 2025, Current Research in Translational Medicine



Automation 03

Pharmaceutical companies have begun to optimize their processes by transitioning from manual to semi-automated approaches.

Key players have introduced **automation for critical steps** in the manufacturing value chain, albeit **with continued manual intervention**. This shift often requires regulatory submissions for post-approval process changes and creates operational complexity by managing parallel workflows or processes cohabitation for legacy and new products.

Ultimately, the gold standard for manufacturing frameworks will be a **"no touch", fully closed, end-to-end automated system**. This will include robotic arms, liquid handlers and integrated equipment capable of processing patient samples into finished products without human intervention. Emerging technology providers are positioning their systems as solutions for this ideal framework.

For instance, **Cellares** Cell Shuttle is fully automated system designed to produce multiple CAR-T cell therapies interchangeably that recently received FDA Advanced Manufacturing Technology (AMT) Designation.

Cellular Origins provides the Constellation, an advanced modular system that enables scalable manufacturing. And **Multiply Labs** develops specialized robotic platforms that provide precision in cell therapy manufacturing.

While full automation at scale is **more than five years away**, early adopters testing scalable, cost-effective technologies will lead the next wave of manufacturing innovation.

As production volumes increase, economies of scale can be achieved, but automation and **data-driven process optimization** remain essential to **reduce variability**, **minimize labor-intensive manufacturing**, **lower costs** and **meet demand**. Manufacturers must continue to refine workflows, adopt new technologies and build systems that balance quality, flexibility and affordability in an increasingly competitive landscape.

III.

Third-party ecosystem and strategic partnerships

The CAR-T cell therapy ecosystem relies on a robust network of third-party service providers and strategic partnerships

These include manufacturing and quality control testing services, along with suppliers of critical raw materials such as viral vectors, media and plasmids.

The offerings and capabilities of these players significantly influence whether biotech and pharmaceutical companies choose to internalize or outsource key components of their manufacturing operations.

Strategic decisions in this area aim to

balance cost | quality | scalability

while addressing production bottlenecks.

Internalizing viral vector production 01

Viral vector (VV) production is one of the most critical and challenging components of CAR-T manufacturing, with high batch failure rates and significant impact on cost, quality and scalability.

Despite advances in bioprocessing, VV manufacturing accounts for **10-40% of total production costs.** While many CMOs offer VV manufacturing, most large CAR-T players are now **moving to in-house manufacturing** after initially outsourcing, indicating that existing CMO capabilities are not meeting industry needs.

This shift is primarily driven by three major pain points:

1. **Cost** is a significant factor, as in-house viral vectors production has proven to be **more cost-effective** than outsourcing.
2. **Reliability of supply** is another major challenge, with **lead times of up to 18 months**, making inventory management increasingly difficult.
3. **Quality concerns** have also emerged, as manufacturers have expressed doubts about the consistency and robustness of **CMO-produced batches**.

In response, leading CAR-T players such as **Kite Pharma**, **Bristol Myers Squibb**, **Novartis**, and **Johnson & Johnson** are investing in in-house VV manufacturing capabilities to improve cost efficiency, supply reliability, and quality control.

Beyond CAR-T, the **growing demand for VVs** includes allogeneic, gene, and in vivo therapies. To address this growing market, CMOs need to look into **expanding their capabilities** – from process optimization and skilled labor to innovative technologies that improve yield, quality and scalability.

Manufacturing agility 02

In-house vs. outsourcing, balancing investment and flexibility

Setting up commercial manufacturing of CAR-T cells requires significant investment and substantial time. Given the dynamic nature of the industry **and uncertain demand forecasts**, outsourcing can provide flexibility and access to specialized capabilities. In the broader context, manufacturing agility is crucial for scalability and cost efficiency in CAR-T cell therapies. Accordingly, companies must weigh the pros and cons of internalizing versus outsourcing manufacturing, considering factors such as investment, efficiency, and flexibility.

While most **clinical-scale CAR-T production is outsourced to CDMOs**, commercial manufacturing often remains **in-house** to maintain quality and control lead times. As **CDMOs** continue to **expand their capacity and improve quality**, the outsourcing trends are likely to shift, mirroring trends seen in small and large molecule manufacturing, where initial reliance on in-house manufacturing gradually gave way to more integrated outsourcing models.

Collaborations across pharma and biotech

Leveraging outsourcing to CMOs for cost efficiency and accessibility

Collaborations across pharma and biotech

CAR-T cell therapy has catalyzed collaborations among pharmaceutical companies to meet the unique demands of manufacturing commercial therapies. These agreements aim to increase manufacturing capacity and accelerate access, addressing critical bottlenecks in the value chain.

- **Arcellx and Kite:** Arcellx and Kite, a Gilead company, announced a collaboration in December 2022 to co-develop CART-ddBCMA for multiple myeloma, with Kite providing USD 325 million in upfront and equity funding. Expanded in November 2023, the partnership includes lymphoma treatments and Arcellx's ARC-SparX program, leveraging Arcellx's technology and Kite's cell therapy expertise[8].
- **BioNTech and Autolus**: in February 2024, BioNTech invested USD 200 million in Autolus to accelerate the commercialization of autologous CAR-T cell therapies[9]. The partnership includes options for BioNTech to utilize Autolus' manufacturing capabilities and co-commercialize certain programs, promoting scalability and cost sharing.
- **Novartis and Johnson & Johnson**: Novartis has agreements with J&J to manufacture Carvykti (ciltacabtagene autoleucel) for clinical (April 2023) and commercial (March 2024) production[10]. These collaborations leverage Novartis' established facilities to overcome supply constraints, supporting both clinical trials and market demand for this multiple myeloma therapy.

Leveraging outsourcing to CMOs for cost efficiency and accessibility

Global CMOs including **Lonza**, **Samsung Biologics**, **Thermo Fisher Scientific**, **Wuxi Advanced Therapies** and **Catalent** support clinical CAR-T batches manufacturing. While some CMOs have communicated their readiness to manufacture commercial batches, **most commercial CAR-T cell therapies are still manufactured in-house**.

A promising development is **BMS's USD 380 million partnership with Cellares in April 2024**. BMS will use **Cellares' Cell Shuttle platform** for automated clinical and commercial production. Multiple high-throughput *Cell Shuttles* and *Cell Q systems* will operate in Cellares' Smart Factories across the U.S., EU and Japan – **dedicated exclusively to BMS[11].**

Commercial-scale CMO capacity is likely to develop and offer additional options for CAR-T developers to design their manufacturing network and diversify their footprint.

[8] https://www.gilead.com/news/news-details/2023/kite-and-arcellx-announce-expansion-in-strategic-partnership

[9] https://investors.biontech.de/news-releases/news-release-details/biontech-and-autolus-announce-strategic-car-t-cell-therapy

[10] J&J, Legend expand manufacturing deal with Novartis to include commercial production of Carvykti, March 2024, Fierce Pharma

[11] https://www.biospace.com/bms-taps-cellares-in-380m-car-t-manufacturing-agreement

Conclusion

The future of CAR-T therapy depends not only on scientific breakthroughs, but also on **reimagining supply chains**, **logistics**, and **manufacturing at scale**. Every stakeholder – from pharma to policymakers – has a role to play in reducing costs and expanding access.

Achieving this objective will require a range of strategies, from optimizing workflows to relentless process innovation and leveraging economies of scale to ensure sustainable growth while improving equitable access to CAR-T cell therapies.

Driving CAR-T forward

As the industry moves toward achieving a cost of USD 30,000 per dose, there are strategic actions executives can take immediately to manage this transformation and drive long-term success.

Optimizing treatment centers and logistics capacity

The accessibility of CAR-T cell therapy will depend on the readiness of the healthcare infrastructure and logistics providers to scale up.

- **Seize growth potential**: regularly assess capacity and adapt to growing demand for apheresis collection and treatment delivery slots.
- **Close monitoring and strategic investments**: align cold chain logistics with evolving protocols and prepare for shifts in demand driven by emerging modalities such as allogeneic therapies.

Achieving operational excellence

The complexity of CAR-T manufacturing requires a focus on operational optimization.

- **Automation and real-time monitoring:** implement advanced automation systems and real-time monitoring tools to minimize variability, improve consistency and shorten production timelines.
- **Data-driven process robustness:** leverage analytics and artificial intelligence (AI) to refine workflows, predict disruptions and ensure quality at all stages of production.
- **Flexibility for innovation:** build adaptable systems capable of integrating future technologies as well as hybrid manufacturing models.

Ensuring economic viability

As CAR-T cell therapies scale up, balancing costs while maintaining quality and innovation is paramount.

- **In-house vs. outsourcing:** evaluate outsourcing specific manufacturing steps to contract manufacturing organizations (CMOs) to manage costs, scale production and focus internal resources on core innovation.
- **Opportunity for CMOs:** expand capabilities to accommodate diverse treatment modalities while meeting key pharmaceutical industry expectations, including high-quality standards, rapid turnaround times, cost efficiency and scalable production.

The future of CAR-T cell therapy lies not only in scientific and technological advances but also in strategic process and workflow innovations. By optimizing apheresis, adopting flexible manufacturing systems and investing in cost-saving technologies, the industry can overcome current challenges and build a scalable, patient-centric model.

How KPMG can help

KPMG Life Sciences Strategy Switzerland combines deep scientific and healthcare knowledge with world-class business strategy expertise.

We help our clients:

Grow

through M&A, partnerships and go-to-market strategies

We support cell and gene therapy companies identify strategic partnerships, acquisition targets and go-to-market strategies. Our expertise spans due diligence, optimizing operations through integration, and guiding market entry, therapy launch, and commercialization.

Transform

operations for scalable, cost-effective manufacturing

We help cell and gene therapy companies adapt their operations to ensure readiness for large-scale manufacturing and implement end-to-end supply chain strategies to drive long-term efficiency and cost effectiveness.

Transact

with confidence on buy- or sell-side deals

Leveraging our deep understanding of the cell and gene therapy landscape, we help our clients unlock value, mitigate risk, and successfully close deals that drive growth, innovation and market leadership.

Who we work with

01 Investors and private equity firms

02 Large biopharmaceutical companies

03 Biotech and clinical-stage startups

04 C(D)MOs

05 Logistics providers

06 Software, technology and device developers

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