

BioSpect

the business of Bio

24 years of leveraging the business of Bio
www.biospectrumindia.com

CAR-T Therapy in India: Market challenges, opportunities and path to scalable manufacturing

15 May 2026 | Views | By Archana Ganesh, M.S., Scientist II, Cellares Corporation, Bay Area, California

One of the most encouraging developments in India's CGT ecosystem is the active evolution of its regulatory framework



India stands at a pivotal moment in the evolution of cell therapy. Once considered a frontier accessible only in the United States and Europe, CAR-T therapy is now beginning to take root on Indian soil. With the approval of ImmunoACT's NexCAR19 — India's first homegrown CAR-T therapy — and the emergence of pioneering companies such as Immuneel Therapeutics and Intas Pharmaceuticals, the country has taken its first meaningful steps toward building a domestic CAR-T ecosystem. Translating this early momentum into a scalable, globally competitive industry will require addressing critical gaps in manufacturing infrastructure, process development capability, and regulatory readiness.

Understanding CAR-T Therapy and Its Manufacturing Complexity

CAR-T therapy represents a paradigm shift in oncology — engineering a patient's T cells to recognise and eliminate cancer cells, offering potentially curative outcomes for patients who have exhausted conventional treatment options. These therapies fall into two categories: autologous therapies, derived from the patient's own cells, which are operationally complex and patient-specific; and allogeneic therapies, derived from healthy donors, which offer off-the-shelf scalability but introduce challenges related to immune compatibility and persistence.

At a high level, the manufacturing process involves leukapheresis, T-cell activation, viral vector-mediated genetic modification, cell expansion, harvest, quality control testing, cryopreservation, and cold chain delivery to the patient. Each step introduces variability and requires meticulous control under GMP conditions.

Having worked across multiple CAR-T and viral vector manufacturing programmes in the United States — spanning process development, process characterization, and GMP process validation — and having contributed to multiple IND submissions for therapies that have advanced into clinical trials, I have seen firsthand what separates successful programmes from those that struggle.

Rigorous process development is the foundation — insufficient investment at this stage is the single most common cause of GMP scale-up failures. Process characterization builds the data-driven understanding of relationships between process inputs and product quality that FDA and EMA require in regulatory submissions, with starting material variability being a particularly

underappreciated challenge. Finally, process validation requires qualified equipment, trained personnel, and mature quality systems — preparation that in my experience takes 18–24 months even for well-resourced organisations.

India's Evolving Regulatory Landscape

One of the most encouraging developments in India's cell and gene therapy (CGT) ecosystem is the active evolution of its regulatory framework. The New Drugs and Clinical Trials Rules of 2019 established a clearer legal pathway for CGT clinical trials, and the landmark approval of NexCAR19 demonstrated that CDSCO has both the scientific capacity and institutional will to evaluate complex living cell therapies. In 2024, CDSCO released draft guidelines specifically for CAR-T therapies — addressing starting material characterisation, manufacturing controls, quality testing, and post-market surveillance.

CAR-T developers must also navigate the Genetic Engineering Appraisal Committee (GEAC), which provides oversight for activities involving large-scale use of recombinant products — an important layer of India's multi-body regulatory framework. While this pragmatic approach has enabled pioneering approvals like NexCAR19, a more streamlined, dedicated CGT regulatory pathway — harmonized with FDA and EMA standards — would significantly accelerate development timelines and build global investor confidence.

Gaps, Opportunities and the Path Forward

India's emerging CAR-T sector faces several interconnected challenges — and equally significant opportunities.

Building dedicated process development capability is the most critical near-term need. India's scientific talent pool is exceptional, producing world-class researchers across its IITs, IISc, and other premier universities. Translating that talent into industry-ready CGT manufacturing expertise requires dedicated infrastructure — specialised bioreactor systems, automated cell culture platforms, and analytical tools — along with structured training programs that bridge academic science and the practical demands of CGT manufacturing. In my experience, robust process development is what determines whether a program succeeds or fails when it reaches GMP, and building this capability requires sustained investment that India's growing CGT sector is actively beginning to make.

Raw material self-sufficiency is equally strategic. Almost every critical input for CAR-T manufacturing — cytokines, viral vectors, specialized media, and cryopreservation solutions — has historically been imported from the US or Europe. A new generation of Made-in-India innovators is changing this. Cellogen Biotech, a subsidiary of Cellogen Therapeutics, is building a self-reliant CGT component ecosystem — manufacturing plasmids, lentiviruses, reagents, and QC kits domestically to reduce India's dependency on imported critical biological materials. CellBios in Chennai complements this by pioneering specialised cryopreservation bag solutions for CGT — products previously available only from international suppliers. Together, these companies represent the indigenous supply chain innovation India needs at scale.

India's opportunity is equally compelling. A 30–40% manufacturing cost advantage, a vast and underserved patient population, and a growing domestic supply chain position India uniquely — particularly as the industry shifts toward allogeneic, off-the-shelf platforms that play directly to India's strengths in scalable, cost-competitive manufacturing. India's diaspora is also an underutilized asset — Indian scientists working at the forefront of CGT manufacturing in the US carry knowledge and expertise that can be channeled back through advisory roles, collaborations, and knowledge transfer partnerships.

Conclusion

India's CAR-T future will be built in manufacturing facilities — not just in laboratories. As an Indian scientist who has spent over a decade developing and scaling cell therapy manufacturing programs in the United States, and who is now actively engaged with India's growing CGT ecosystem, I believe India has everything it needs to lead the next chapter of the global cell therapy story. The science is proven. The pioneers are in place. What remains is the sustained investment in manufacturing excellence — across both autologous and allogeneic platforms — that will translate India's early momentum into lasting impact for patients.

Archana Ganesh, M.S., Scientist II, Cellares Corporation, Bay Area, California