

Cell Sheet-based Gene Therapy Market - A Global and Regional Analysis: Focus on Technology Type, Cell-sheet Type, Source Type, Application Type, End User, and Regional Analysis - Analysis and Forecast, 2025-2035

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Abstracts

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Introduction of Cell Sheet-based Gene Therapy

Key players in the cell sheet-based gene therapy market include leading biotech and regenerative medicine firms such as Abeona Therapeutics, Inc. and Foundation ENEA Tech Biomedical, alongside established players such as CellSeed Inc. and J-TEC. Abeona operates a fully integrated, cGMP-compliant manufacturing facility in Cleveland, Ohio, enabling clinical and commercial-scale production of advanced therapies. Its flagship product, ZEVASKYN (prademagene zamikeracel), is an autologous, gene-corrected cell therapy for recessive dystrophic epidermolysis bullosa (RDEB), demonstrating strong commercial potential in rare dermatological conditions.

Foundation ENEA Tech Biomedical has significantly expanded its regenerative medicine portfolio through the acquisition of Holostem S.r.l. in December 2023. Holostem, the first biotech company dedicated to epithelial stem cell-based ATMPs, is behind therapies Holoclar, targeting corneal regeneration. ENEA is building national biomedical hubs to connect translational research with clinical application, emphasizing industrial scalability and public-private collaboration. These strategic efforts aim to advance therapies for complex epithelial diseases affecting the skin and eye, while safeguarding Italy's biomedical autonomy.

Market Introduction

The global cell sheet–based gene therapy market is expected to witness significant expansion, projected to reach \$3,335.1 million by 2035. This growth is driven by the rising prevalence of chronic, degenerative, and rare conditions such as limbal stem cell deficiency, ischemic heart disease, and inherited skin disorders that are poorly served by conventional therapies. Cell sheet–based gene therapy offers a regenerative, scaffold-free solution that delivers intact, functional cell layers directly to damaged tissues, enabling superior tissue repair, integration, and localized gene expression.

This transformative platform merges regenerative medicine with gene delivery, allowing for personalized, minimally invasive interventions. Key clinical milestones such as EMA’s approval of Holoclar for corneal regeneration and FDA’s approval of Zevaskyn for RDEB have validated the therapeutic model, establishing a new frontier in autologous and gene-corrected regenerative treatments.

Growth is further fueled by supportive global frameworks such as FDA’s RMAT designation, EMA’s ATMP pathway, and Japan’s conditional approval model, which have accelerated the clinical and regulatory trajectory of these therapies. Public investments through NIH (U.S.), AMED (Japan), and Horizon Europe are fostering translational research, while countries such as Italy, the U.S., South Korea, and Germany are scaling GMP-certified infrastructure and manufacturing capacity.

The market is also witnessing technological convergence with innovations in temperature-responsive polymers, gene editing integration, and cryopreservation techniques, enabling more stable and scalable product delivery. While monolayer cell sheets, autologous cell sources, and oncology applications currently dominate, expanding indications in ophthalmology, cardiology, and dermatology signal broad therapeutic relevance.

Despite this momentum, challenges such as high manufacturing costs, limited reimbursement clarity, and fragmented late-stage clinical data remain. However, growing payer confidence, successful real-world outcomes, and cross-sector partnerships are steadily addressing these barriers.

The competitive landscape is led by companies such as Abeona Therapeutics, CellSeed Inc., Japan Tissue Engineering Co. (J-TEC), and Holostem, all of which are advancing first-in-class therapies and building robust commercialization strategies. As healthcare systems increasingly embrace regenerative, precision-based approaches,

cell sheet–based gene therapy stands at the intersection of high clinical need and disruptive innovation, with the potential to redefine treatment paradigms across multiple medical disciplines.

Industrial Impact

Cell sheet–based gene therapy is reshaping the healthcare industry by introducing regenerative, patient-specific treatments that offer improved healing and functional recovery across a range of conditions. For instance, in ophthalmology, Holoclar, a stem cell–based cell sheet therapy, has transformed treatment for limbal stem cell deficiency, enabling vision restoration using the patient’s own epithelial cells. This personalized approach enhances safety and long-term outcomes by eliminating the risks associated with immune rejection.

Beyond individual patient care, cell sheet–based gene therapy is driving innovation across biomanufacturing and clinical delivery systems. The integration of temperature-responsive culture surfaces and scaffold-free platforms is enabling the scalable production of high-integrity cell sheets, which is revolutionizing how advanced tissue therapies are developed and deployed. Companies such as J-TEC and CellSeed Inc. are pioneering late-stage clinical programs for indications such as cartilage repair and skin regeneration, backed by robust regulatory support in markets such as Japan.

In parallel, public-private partnerships such as those initiated by Foundation ENEA Tech Biomedical in Europe are establishing biomedical hubs that bridge translational research with commercial-scale deployment, reinforcing industrial scalability and healthcare resilience. These advancements are not only improving individual outcomes but also optimizing treatment workflows, reducing surgical complications, and accelerating the pathway to broader access in regenerative care.

The continued evolution of cell sheet–based therapies promises to redefine the role of regenerative medicine in mainstream healthcare by promoting durable, biologically integrated treatments that align with the growing shift toward precision and minimally invasive care.

Market Segmentation

Segmentation 1: By Technology Type

Cell sheet-based Engineering Techniques

Light-induced cell sheet technology

Temperature-Responsive Culture Surfaces

Scaffold-Free Techniques

Layer-by-Layer Assembly

Other Techniques

Gene Delivery Methods

Viral Vector-Based (e.g., Lentivirus, Adenovirus)

Non-Viral Vector-Based (e.g., Liposomes, Nanoparticles)

CRISPR/Cas9

Other Gene Delivery Methods

Cell sheet-based engineering techniques remain the leading segment by technology type in the cell sheet-based gene therapy market, holding a 75.32% market share in 2024 with a projected CAGR of 14.79% during the forecast period 2025–2035. Among its key subsegments—Light-induced cell sheet technology, Temperature-Responsive Culture Surfaces, Scaffold-Free Techniques, and Layer-by-Layer Assembly—Light-induced cell sheet technology leads the market, owing to its precise control over cell detachment and viability without chemical or enzymatic treatments. This technology is gaining traction for its ability to preserve cell functionality, improve sheet integrity, and support advanced tissue engineering applications across ophthalmology, dermatology, and orthopedics.

Segmentation 2: By Cell-Sheet Type

Monolayer Cell-sheet Type

Co-culture Cell-sheet Type

Multilayered Cell-sheet Type

Others

Based on cell sheet type, the global cell sheet–based gene therapy market was led by the Monolayer Cell-sheet Type segment, which held a 35.69% share in 2024. Monolayer cell sheets are projected to maintain dominance due to their simpler fabrication process, preserved cell–cell junctions, and suitability for early-stage regenerative applications. Their widespread use in skin, ocular, and mucosal therapies supports consistent demand, while ongoing clinical advancements continue to expand their therapeutic potential across various indications.

Segmentation 3: By Source Type

Autologous

Allogenic

Stem-cell Derived

Based on source type, the global cell sheet–based gene therapy market was led by the Autologous segment, which held a 78.65% share in 2024. Autologous cell sources are expected to continue dominating the market due to their lower risk of immune rejection, better biocompatibility, and established clinical outcomes. These therapies are particularly favored in personalized regenerative treatments, offering safer and more effective options for conditions such as skin injuries, corneal damage, and cartilage repair.

Segmentation 4: By Application

Oncology

Ophthalmology

Genetic Disorders

Cardiology

Others

Based on application type, the global cell sheet–based gene therapy market was led by the Oncology segment, which held a 43.46% share in 2024. Oncology is expected to continue leading the market due to the rising demand for innovative, localized treatment approaches that offer enhanced tissue regeneration and targeted delivery. Cell sheet therapies show strong potential in solid tumor management by supporting reconstruction post-resection and improving therapeutic outcomes through scaffold-free, biocompatible platforms.

Segmentation 5: By End-User

Hospitals and Clinics

Research and Academic Institutions

Biotech and Pharma Companies

Others

Based on end-user, the global cell sheet–based gene therapy market was led by the Hospitals and Clinics segment, which held a 40.18% share in 2024. Hospitals and clinics are expected to dominate the market as they serve as primary centers for administering advanced regenerative therapies. Their access to specialized surgical infrastructure, trained professionals, and controlled clinical settings makes them ideal for cell sheet transplantation procedures, especially in oncology, ophthalmology, and orthopedic indications.

Segmentation 6: By Region

North America

U.S.

Canada

Europe

Germany

U.K.

France

Italy

Spain

Rest-of-Europe

Asia-Pacific

Japan

India

China

Australia

South Korea

Rest-of-Asia-Pacific

Rest-of-the-World

The cell sheet-based gene therapy market in the Asia-Pacific region is expected to witness substantial growth over the next five years, driven by Japan's progressive regulatory environment, expanding clinical activity, and strong academic-industry collaboration. The region benefits from advanced regenerative medicine frameworks such as Japan's Act on the Safety of Regenerative Medicine and the PMDA's fast-track approval pathways, which have accelerated the development and approval of therapies such as JACC and Holoclar. Key developments include the late-stage clinical advancement of autologous and allogeneic cartilage cell sheets for osteoarthritis and

ongoing efforts in iPS cell-derived retinal therapies. Companies such as CellSeed, J-TEC, and Abeona Therapeutics are actively exploring scalable, clinically viable platforms with a focus on skin, corneal, and cartilage repair. Additionally, public-private initiatives and academic partnerships are fostering translational research, while increasing investment in biomanufacturing and infrastructure is expected to support broader commercialization and access.

Recent Developments in the Cell Sheet-based Gene Therapy Market

In May 2025, Japan Tissue Engineering Co., Ltd (J-TEC) received regulatory approval for an expanded indication of its autologous cultured cartilage product, JACC, to include the treatment of knee osteoarthritis, extending its orthopedic applications beyond initial indications.

In September 2023, CellSeed Inc. submitted a Phase III clinical trial notification for an allogeneic chondrocyte sheet targeting knee osteoarthritis, marking a major milestone toward commercialization of off-the-shelf regenerative cartilage therapies.

In December 2024, J-TEC entered a capital and business alliance with VCCT Inc. to jointly develop iPS cell-derived retinal regenerative therapies using cell sheet engineering. VCCT will support preclinical development and pipeline scale-up, reinforcing both companies' positions in the ophthalmic regenerative space.

In February 2023, CellSeed Inc. partnered with Tokai University to conduct a clinical trial for CLS2701C, an autologous cartilage cell sheet therapy for knee cartilage defects. Tokai University is leading surgical procedures and clinical feasibility studies under ethical oversight at its affiliated hospital.

Demand –Drivers, Challenges, and Opportunities

Market Demand Drivers:

Advancement in Regenerative Medicine: One of the main drivers of the market is the advancement in regenerative medicine technologies. Cell sheet-based gene therapy leverages stem cells and other cell types to regenerate damaged or degenerated tissues. As the understanding of stem cell biology and tissue engineering grows, the feasibility and effectiveness of cell-sheet therapies

become more prominent. These technologies enable the repair of tissues that cannot naturally regenerate, such as cartilage in joints, heart muscle after a heart attack, and corneal tissue in the eye.

Cell Sheet Engineering and Culture Technology

Thermoresponsive Culture Systems: One of the significant innovations in cell-sheet technology is the use of thermoresponsive culture dishes, which allow cells to be grown in sheets and then detached easily without the need for harsh enzymatic treatments. This innovation helps preserve the integrity of the cells, ensuring that they are viable for transplantation. A study published in *Stem Cell Research & Therapy* in 2024¹ discusses the use of thermoresponsive culture dishes for fabricating patterned cell sheets. These sheets, when transplanted, have shown improved survival and functionality due to the preservation of native cell structures during harvesting.

Stem Cells in Regenerative Medicine: Stem cells are central to regenerative medicine, as they can differentiate into a variety of cell types, aiding in tissue regeneration. In cell-sheet-based gene therapy, stem cells (especially mesenchymal stem cells and induced pluripotent stem cells) are often used to form cell sheets. According to a 2018 report by the National Institutes of Health (NIH), stem cell-based therapies have seen a 25-30% increase in successful clinical outcomes for patients with heart disease and cartilage regeneration when combined with cell-sheet technology.

Some of the other driving factors include:

Growing Investment in Personalized Medicine

Technological Advancements in Cell Sheet Therapy

Note: All of the above factors will be evaluated in detail in the report.

Market Challenges:

Regulatory Approval and Ethical Issues: Gene therapies, particularly those involving complex technologies such as cell-sheet engineering, face stringent regulatory scrutiny from bodies such as the FDA and EMA. The approval process can be long, expensive, and uncertain, and the regulatory frameworks

for these therapies are still evolving. The lengthy and costly regulatory approval process delays the availability of these therapies to patients and adds to the overall cost of development. There is also the challenge of establishing clear guidelines for cell-sheet-based gene therapies, as these therapies are still relatively new to the field.

Genetic editing raises significant ethical concerns, particularly when it involves altering human DNA. In gene therapies involving cell-sheet technology, concerns include the potential for germline editing (altering DNA in a way that affects future generations) and the risk of unforeseen consequences from permanent genetic modifications. Ethical concerns can lead to public resistance, regulatory delays, and heightened scrutiny, all of which may slow down the development and acceptance of cell-sheet-based gene therapies.

Some of the other factors challenging the market growth include:

Limited Commercial Scalability

Note: All of the above factors will be evaluated in detail in the report.

Market Opportunities:

Substantial Surge in the Rise of Cell Sheet Approaches: Cell sheet-based gene therapy stands at a strategic inflection point, anchored in the multi-billion-dollar growth of CGT, clinical expansion into diverse indications, validated ultra-high pricing models, parental-level investments in manufacturing, and emerging reimbursement frameworks. Taken together, these signal strong momentum for accelerating clinical translation and commercial adoption of this transformative platform.

Cell sheet-based gene therapy is expected to witness significant growth, driven by powerful trends across the cell and gene therapy (CGT) and regenerative medicine sectors. With the global CGT market valued at over \$21 billion in 2024 and projected to exceed \$100 billion by the early 2030s, opportunities for cell-sheet technologies are expanding rapidly. The regenerative medicine segment alone is expected to grow from around \$35 billion to over \$90 billion by 2030. Cell sheet therapies are particularly well-

positioned to meet the growing demand for personalized, non-oncology treatments, as evidenced by the increasing share of gene therapy trials targeting non-cancer conditions

Some of the other factors creating an opportunity for market growth include:

Rising Application for Localized and Minimally Invasive Treatments

Note: All of the above factors will be evaluated in detail in the report.

Market Trends:

Emerging Convergence of Regenerative Medicine and Genetic Engineering: Cell sheet-based gene therapy has transitioned from foundational tissue engineering into a clinically and commercially viable modality. Practices have been advancing from preclinical demonstrations to early clinical use, enhanced by gene editing integration and improved manufacturing processes. Positioned within the rapidly expanding cell and gene therapy market, this hybrid technology is set to expand across fields such as regenerative medicine, ophthalmology, and orthopedics, driven by robust regulatory support and emerging investment trends.

Current Trends Driving the Field:

Scaffold free, extracellular matrix preserving techniques: These methods support complex tissue regeneration (e.g., cartilage, cardiac patches, cornea) with high viability, enhancing clinical translation.

Some of the other emerging trends in the market include:

Expansion into Oncology and Cardiology

Note: All of the above trends will be evaluated in detail in the report.

How can this report add value to an organization?

Product/Innovation Strategy: The report offers in-depth insights into the latest technological advancements in cell sheet-based gene therapy, enabling organizations to drive innovation and develop cutting-edge products tailored to market needs.

Growth/Marketing Strategy: By providing comprehensive market analysis and identifying key growth opportunities, the report equips organizations with the knowledge to craft targeted marketing strategies and expand their market presence effectively.

Competitive Strategy: The report includes a thorough competitive landscape analysis, helping organizations understand their competitors' strengths and weaknesses and allowing them to strategize effectively to gain a competitive edge in the market.

Regulatory and Compliance Strategy: It provides updates on evolving regulatory frameworks, approvals, and industry guidelines, ensuring organizations stay compliant and accelerate market entry for new cell sheet-based gene therapy.

Investment and Business Expansion Strategy: By analyzing market trends, funding patterns, and partnership opportunities, the report assists organizations in making informed investment decisions and identifying potential M&A opportunities for business growth.

Methodology

Key Considerations and Assumptions in Market Engineering and Validation

The base year considered for the calculation of the market size is 2024. A historical year analysis has been done for the period FY2023. The market size has been estimated for FY2024 and projected for the period FY2025-FY2035.

The scope of this report has been carefully derived based on extensive interactions with experts and stakeholders across leading companies and research institutions worldwide. This report provides a comprehensive market analysis of regenerative medicine, cell-based engineering technologies, and gene-modified therapies within the cell sheet-based gene therapy market.

The market contribution of the precision therapeutics anticipated to be launched in the future has been calculated based on the historical analysis of the products.

Revenues of the companies have been referenced from their annual reports for FY2023 and FY2024. For private companies, revenues have been estimated based on factors such as inputs obtained from primary research, funding history, market collaborations, and operational history.

The market has been mapped based on the available cell sheet-based gene therapy. All the key companies with significant offerings in this field have been considered and profiled in this report.

Primary Research:

The primary sources involve industry experts in cell sheet-based gene therapy , including the market players offering products and services. Resources such as CEOs, vice presidents, marketing directors, and technology and innovation directors have been interviewed to obtain and verify both qualitative and quantitative aspects of this research study.

The key data points taken from the primary sources include:

- Validation and triangulation of all the numbers and graphs

- Validation of the report's segmentation and key qualitative findings

- Understanding the competitive landscape and business model

- Current and proposed production values of a product by market players

- Validation of the numbers of the different segments of the market in focus

- Percentage split of individual markets for regional analysis

Secondary Research:

Open Sources

- Certified publications, articles from recognized authors, white papers,

directories, and major databases, among others

Annual reports, SEC filings, and investor presentations of the leading market players

Company websites and detailed study of their product portfolio

Gold standard magazines, journals, white papers, press releases, and news articles

Paid databases

The key data points taken from the secondary sources include:

Segmentations and percentage shares

Data for market value

Key industry trends of the top players of the market

Qualitative insights into various aspects of the market, key trends, and emerging areas of innovation

Quantitative data for mathematical and statistical calculations

Key Market Players and Competition Synopsis

Profiled companies have been selected based on inputs gathered from primary experts, as well as analyzing company coverage, product portfolio, and market penetration.

Key players in the cell sheet–based gene therapy market include leading biotech and regenerative medicine firms such as Abeona Therapeutics, Inc. and Foundation ENEA Tech Biomedical, alongside established players such as CellSeed Inc. and J-TEC. Abeona operates a fully integrated, cGMP-compliant manufacturing facility in Cleveland, Ohio, enabling clinical and commercial-scale production of advanced therapies. Its flagship product, ZEVASKYN (prademagene zamikeracel), is an autologous, gene-corrected cell therapy for recessive dystrophic epidermolysis bullosa (RDEB),

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Some prominent names established in this market are:

Abeona Therapeutics, Inc.

Foundation ENEA Tech Biomedical

Fujifilm Cellular Dynamics, Inc. (FCDI)

CellSeed Inc.

Japan Tissue Engineering Co., Ltd

Emmaus Medical, Inc.

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