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Regenerative Medicine Market - Global Industry Size, Share, Trends, Opportunity, and Forecast, 2018-2028 Segmented By Therapy (Stem Cell Therapy, Gene Therapy, Tissue Engineering, And Small Molecule & Biologic), By Material (Synthetic Material, Biologically Derived Material, Genetically Engineered Material, And Pharmaceuticals), By Application (Cardiovascular, Oncology, Musculoskeletal, Wound Healing, Ophthalmology, And Others), By End User (Hospitals, Specialty Centers, Academic & Research Institutes), By Region and Competition

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Abstracts

The Global Regenerative Medicine Market was valued at USD 14.67 Billion in 2022 and is projected to experience robust growth throughout the forecast period, with a Compound Annual Growth Rate (CAGR) of 9.45% and expected to reach USD 25.11 Billion through 2028. Regenerative medicine, an emerging field, concentrates on the replacement or repair of damaged human organs or tissues. Stem cells are employed in this therapeutic approach to restore function to organs and tissues that lack the ability to self-heal. Scientists foresee the potential for growing organs and tissues in laboratories, which can then be safely transplanted into the human body. The escalating demand for regenerative medicine is due to its personalized treatment approach, offering more effective disease management compared to conventional methods. This encompasses a variety of medical techniques including artificial organs, cellular therapies, and tissue engineering. Tissue engineering and biomaterials use implanted scaffolds to facilitate the creation of new tissue, attracting stem cells to foster tissue development with

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desired characteristics. Cellular therapies employ stem cells from various sources to repair damaged tissues. Moreover, medical devices and artificial organs provide support to ailing organs.

Key Market Drivers

Increasing Investments in Research and Development (R&D) Activities

Growing investments in R&D have driven market expansion by fostering innovative product launches. This uptick in investment has led to comprehensive R&D initiatives, with numerous start-up companies securing funding for novel therapies and products. This has facilitated substantial collaborations, mergers, and partnerships geared towards optimizing the benefits of R&D activities. In June 2022, Belgian biotech company Galapagos acquired Cell Point and Abound Bib, a strategic move aimed at accelerating the development and commercialization of advanced cell therapies. By integrating Cell Point and Abound Bio, Galapagos gains access to innovative, scalable, decentralized, and automated point-of-care cell therapy supply models, along with a cutting-edge fully human antibody-based therapeutics platform. These advancements position Galapagos as an integrated biopharmaceutical firm with the potential to disrupt the CAR-T treatment paradigm. Beyond private entities, various governments and government-funded research institutions are actively investing in this industry to introduce effective treatment options for chronic diseases like cancer, Parkinson's disease, diabetes, renal diseases, cardiovascular diseases, and others. In January 2022, the Royal College of Surgeons in Ireland secured USD 226,000 in funding from the European Commission for the development of antioxidant-ion substituted nanoparticles for osteoporotic bone treatment.

Increasing Prevalence of Chronic Conditions

The rising occurrence of chronic conditions like heart disease, diabetes, and cancer is expected to propel market growth. For example, data from the Centers for Disease Control and Prevention reveals that 37.3 million individuals in the United States are living with diabetes. Contributing factors to the diabetes surge include changing lifestyles, an aging population, and insufficient physical activity. Stem cell biology offers promising avenues for diabetes treatment, employing various stem cell types including embryonic, germline, mesenchymal, and induced pluripotent cells.

Growing Incidence of Genetic Disorders and Trauma Emergencies

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The increasing prevalence of diseases such as congestive heart failure, myocardial infarction, Parkinson’s disease, various forms of bone loss, and Duchenne muscular dystrophy (DMD) is driving the demand for cell therapy in the regenerative medicine market. Additionally, reliance on autologous grafts for bladder, ureter, and urethra reconstruction fuels market growth. Numerous companies are pushing forward with cell therapy through collaborations. For instance, Eli Lilly partnered with Sigilon Therapeutics in April 2018 to develop encapsulated cell therapies for type I diabetes treatment. The introduction of such cutting-edge products is poised to drive demand for cell therapies and boost the regenerative medicine market. While autologous, allogenic, and xenogenic cell therapies are widely used in the regenerative medicine market, only a limited number of products have received FDA approval for commercialization. For instance, Laviv from Fibrocell Science, Inc. is approved for treating moderate-to-severe nasolabial fold wrinkles in adults, while Carticel from Genzyme Corporation is used for symptomatic cartilage defect repair in the knees. The prevalence of trauma injuries has contributed to increased adoption of regenerative medicine and organ transplantation. The rise in accidents, burn injuries, and other trauma cases has significantly bolstered the regenerative medicine market. According to the Center for Disease Control and Prevention, Traumatic Brain Injury (TBI)-related hospitalizations reached approximately 223,135 in 2019, with 69,473 TBI-related deaths in 2021. These figures equate to over 611 TBI-related hospitalizations and 176 TBI-related deaths per day in the United States. This surge in accident trauma cases has driven global demand for regenerative medicines. While many companies have expanded into the regenerative medicine market for trauma injuries, this segment is still primarily used in organ transplantation. However, advancements in accident care technologies are expected to lead to rapid growth in the regenerative medicine market during the forecast period.

Emergence of New Technologies

The emergence of novel technologies such as 3D printing is expected to drive the adoption of autologous cell therapies for life-threatening conditions. Notable products like Apligraf, developed by Organogenesis, Inc., utilize allogenic cells for treating ulcers. Regenerative technologies' progress fuels stem cell applications in the market. Innovations in organs like heart arteries, engineered bladders, and other internal structures contribute to this advancement. Numerous stem cell-based therapies are currently undergoing clinical trials, demonstrating substantial potential for tissue regeneration. Market players have introduced several technologies to enhance stem cell research efficiency and commercial applications, thereby stimulating the growth of the regenerative medicine market. Government and private agency R&D programs and investments are expected to support market growth in the forecast period. However, the

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high costs associated with regenerative medicine treatments could pose a barrier to market expansion. GlaxoSmithKline's product for adenosine deaminase, which causes severe combined immunodeficiency (ADA-SCID), and other companies' gene additive therapies research, including GE Healthcare and Mayo Clinic, employ nucleases like zinc finger nucleases (ZFNs), CRISPR/Cas9, and mega nucleases (MNs) to modify the human genome. However, gene correction can have unintended effects on cell development and proliferation. Additionally, the efficiency of gene correction treatment varies depending on the targeted cells' genome, limiting its application.

Key Market Challenges

Insufficient Vector Production for Cell and Gene Therapy

Current vector production methods often lack scalability. Meeting clinical trial and commercialization demands can be challenging, particularly for therapies targeting large patient populations. As regenerative medicine advances, therapeutic approaches diversify, necessitating reliable vector production methods for various vectors, including adeno-associated viruses (AAVs) and lentiviruses.

High Treatment Costs

The high costs associated with treatments employing these products, coupled with the absence of reimbursement policies, hinder market growth. Most stem cell therapies are categorized as experimental or investigational treatments, leading to limited Medicare insurance coverage and significant out-of-pocket expenses. Medicare exclusively covers expenses for FDA-approved therapies such as allogeneic transplantation. Stem cell therapy costs vary widely, ranging from USD 5,000 to USD 50,000, influenced by factors such as cell type, quantity, quality, and source. For instance, Novartis' Zolgensma, a one-time gene therapy for spinal muscular atrophy, carries a price tag of USD 2.12 million. The lack of insurance coverage leaves patients to cover treatment costs out-of-pocket or resort to crowdfunding, delaying treatment and impeding market growth. Additionally, the availability of approved therapies for various genetic disorders is limited, often accompanied by significant expenses and potential side effects, further constraining their adoption and market growth.

Key Market Trends

Growing Potential in Emerging Economies

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Developing economies present substantial potential in the regenerative medicine market, driven by the increasing incidence of traumatic injuries and organ transplants worldwide. Key industry players strategically recognize opportunities in tissue engineering and regenerative medicine within these economies, leveraging tactics such as product launches, approvals, agreements, partnerships, and mergers. Despite ethical challenges due to unfavorable norms, developing economies are anticipated to embrace tissue engineering and regeneration technology.

Rising Demand for Regenerative Medicine in Organ Transplantation

Kidney transplants are in high demand, with 80% of the waiting list comprising kidney patients. Despite government efforts to increase donor numbers, the demand for organ transplants continues to rise. Tissue engineering and regenerative medicine hold significant potential to address this global demand for transplants. Challenges like vascularization and tissue signaling must be overcome to replicate original organ functions successfully. Progress is evident in the development of complex tissues and even whole organs using tissue engineering, regeneration, and bioprinting technologies. Commercializing regenerative medicine products holds promise, given numerous products in various clinical trial phases, poised for future commercial availability.

Segment Insights

Therapeutic Trends

Tissue engineering dominated the global regenerative medicine market in 2022, claiming the largest market share. Advantages such as the ability to replace faulty structures with functional living counterparts and the potential to treat previously untreatable conditions contribute to this dominance. Significant R&D investments and ongoing innovative product launches are expected to drive demand in the tissue engineering segment.

Application Insights

Oncology led the regenerative medicine market in 2022 due to the growing global cancer burden. Government and private sector investments in cancer research and advanced cell therapy development played a pivotal role. In January 2023, Calidi Biotherapeutics (CBT) and First Light Acquisition Group (FLAG) joined forces to revolutionize oncolytic virotherapies using stem cell-based platforms. The cardiovascular segment is projected to experience notable growth, fueled by

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advancements in cell-based therapies and regenerative medicine. Key players actively develop regenerative therapies for repairing, restoring, and revascularizing damaged heart tissues. The adoption of autologous and allogeneic single and mixed cells for studying their effects on cardiovascular diseases is on the rise. Additionally, biologics, small molecules, and gene therapy are investigated for regenerating heart cells, further driving market growth.

Regional Insights

Geographically, North America dominates the regenerative medicine market due to the high prevalence of chronic diseases and advanced healthcare infrastructure. In contrast, the Asia-Pacific region is poised for rapid growth, driven by increased healthcare spending and significant investments by major manufacturers in introducing new products. North America's regenerative medicine market is in a growth phase with potential for the future, as therapies advance to the third phase of clinical trials. This indicates active commercialization efforts. Favorable regulatory and reimbursement policies for tissue engineering demonstrate government interest in supporting regenerative product growth. However, strict regulatory policies related to stem cell technologies, primarily due to ethical concerns, hamper the adoption of embryonic stem cells, posing challenges to market growth.

Key Market Players

Stryker Corporation

Athersys, Inc.

Integra Lifesciences Corporation

Isto Biologics (Isto Biologics Medical Systems, Inc.)

Organogenesis Inc.

CryoLife, Inc.

Medtronic plc

U.S. Stem Cell, Inc.

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Zimmer Biomet Holdings, Inc.

3M Company

Report Scope:

In this report, the Global Regenerative Medicine Market has been segmented into the following categories, in addition to the industry trends which have also been detailed below:

Regenerative Medicine Market, By Therapy:

Stem Cell Therapy

Gene Therapy

Tissue Engineering

Small Molecule & Biologic

Regenerative Medicine Market, By Material:

Synthetic Material

Biologically Derived Material

Genetically Engineered Material

Pharmaceuticals

Regenerative Medicine Market, By Application:

Cardiovascular

Oncology

Musculoskeletal

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Wound Healing

Ophthalmology

Others

Regenerative Medicine Market, By End User:

Hospitals

Specialty Centres

Academic & Research Institutes

Regenerative Medicine Market, By Region:

North America

- United States
- Canada
- Mexico

Europe

- France
- United Kingdom
- Italy
- Germany
- Spain

Asia-Pacific

- China

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- India
- Japan
- Australia
- South Korea

South America

- Brazil
- Argentina
- Colombia

Middle East & Africa

- South Africa
- Saudi Arabia
- UAE
- Kuwait
- Turkey
- Egypt

Competitive Landscape

Company Profiles: Detailed analysis of the major companies present in the Global Regenerative Medicine Market.

Available Customizations:

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Global Regenerative Medicine market report with the given market data, Tech Sci Research offers customizations according to a company's specific needs. The following customization options are available for the report:

Company Information

Detailed analysis and profiling of additional market players (up to five).

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