BIOTECHNOLOGY

INDUSTRY REPORT

CURRENT & FUTURE TRENDS

SPR & CO.

September 2023

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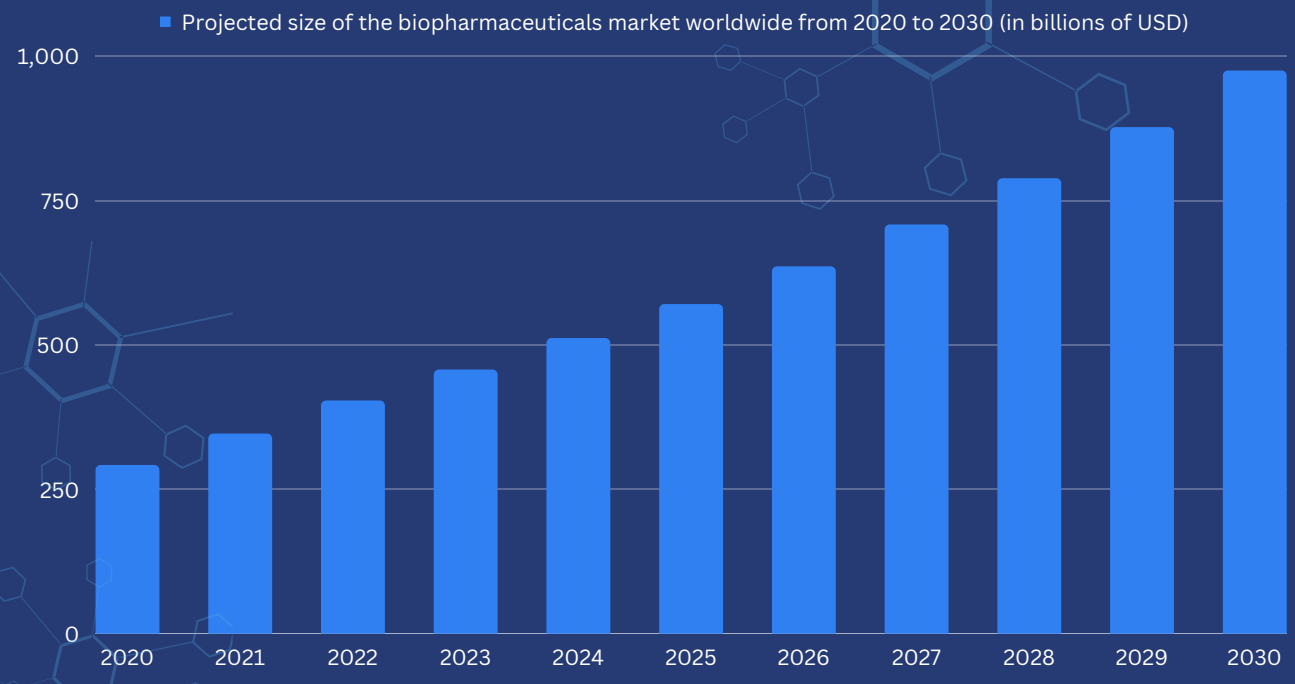
Overview

Biotechnology is a branch of science that creates or manufactures products from biological systems, living beings, or materials derived from them. Biotechnology today encompasses many disciplines, including biochemistry, genetics, and molecular biology. Every year, new technologies and products in fields such as medicine, agriculture, and industrial biotechnology are developed. The global biotechnology industry is estimated to be worth USD 1.37 trillion in 2022, with a compound annual growth rate (CAGR) of 13.96% from 2023 to 2030. The industry is propelled by significant government support in the form of efforts aiming at modernising the regulatory environment, improving approval processes and reimbursement policies, and standardising clinical research. The industry is being driven by favourable government initiatives as the biotechnology sector grows in developing countries such as China, Japan, and India. Efforts are targeted at streamlining the drug regulatory pathway, standardising clinical research, improving reimbursement rules, and speeding product approval, all of which will provide the industry with attractive development opportunities.



The above graph depicts that the market size of the biotechnology industry is projected to steadily grow till 2030; this consistent upward trend is facilitated by a congruence of factors such as increasing importance given to R&D and the ever-present need for further advancement in the field of pharmaceuticals.

GROWTH FACTORS

- The **COVID-19 pandemic** has had a favourable impact on the biotechnology business by expanding possibilities and breakthroughs in medicine discovery and vaccine manufacture. For example, about 11 billion doses of COVID-19 vaccine were produced globally in 2021, resulting in the vaccination of approximately half of the world's population within a year. Furthermore, the success of mRNA vaccines and expedited approval processes have resulted in a boom in vaccine-related revenues, with Moderna, Pfizer/BioNTech, and Johnson & Johnson vaccines generating a combined revenue of roughly USD 31 billion in 2021.

- Expanding demand for biotechnology techniques for **agricultural applications** such as micro-propagation, molecular breeding, tissue culturing, traditional plant breeding, and genetically modified crop production, among others, has bolstered market growth. Furthermore, genetically engineered crops and herbicide-tolerant and insect-resistant seeds are gaining popularity and contributing to market expansion. Adoption of tissue culture technology for the production of novel rice variants and disease- and pest-free banana varieties in South Asia and Africa, as well as the use of the technology for the cloning of disease-free and nutritious plant varieties, has propelled agricultural biotechnology applications.

- **Rising incidences of target diseases and genetic disorders**, as well as continuous technological advancements in Polymerase Chain Reaction (PCR) technologies, the development of miniaturised portable instruments, and the incorporation of robotics, as well as increased investments, funds, and grants for research activities, also contribute to the biotechnology market growth in the coming years.

- The **increasing prevalence of infectious and chronic diseases**, as well as increased R&D spending to develop breakthrough genomic techniques such as cell-based assays and polymerase chain reaction (PCR), are expected to generate considerable development in developing countries. The growth of the biotechnology market in developing nations will be assisted by an increase in healthcare spending, the expansion of healthcare infrastructure, and decreasing procedural costs of illness diagnosis techniques.

- The fast expansion of healthcare infrastructure in emerging countries is accompanied by **rapid growth and upgrading of healthcare institutions**. This factor is contributing to the growing demand for clinical diagnostic procedures in diagnostic laboratories, resulting in higher sales and revenue growth for biotechnology products in the market.

Biotechnology In India

India is one of the top 12 biotechnology destinations in the world, and the third largest in Asia Pacific. By 2023, India's biotechnology industry is expected to be worth $92 billion, up 15% from the previous year. In the last eleven years, the Indian bio-economy has seen a multifold increase in worth, with COVID-19 providing the industry with a much-needed boost. India is currently positioned as one of the leading destinations for bioinnovation and biomanufacturing, and is thus designated as a sunrise sector and an important component of India's aim of reaching a $5 trillion economy by 2024. The biotechnology sector in India is divided into four categories: biopharmaceuticals, bioagriculture, bioinformation technology, and bioservices.

74+	18%	8000+	32000+
Bio-incubators	**Expected CAGR (2022-2025)**	**Products/ Technologies Supported By DBT-BIRAC**	**Employment Generated**

Biopharmaceuticals: India is one of the world's largest suppliers of low-cost medications and vaccines. India is also a market leader in biosimilars, with the most biosimilars approved in the local market.

Bio-agriculture: With approximately 55% of Indian land dedicated to agriculture and related activities, India is one of the leading producers of Bt-Cotton and has the world's fifth largest area of organic agriculture land.

Bio-industrial: The application of biotechnology in industrial processes is revolutionising industry and waste disposal across the country.

Bio IT & Services: India has a significant capability in contract manufacturing, research, and clinical trials, and it has the most US FDA-approved plants outside of the US.

- With a 17% CAGR, the market is expected to reach USD 150 billion by 2025 and USD 300 billion by 2030.
- 5300+ biotech startups, with a projected 10000 by 2025
- 760+ Biotech Firms
- 750+ Biotech Products on the Market 1 Million+ Skilled Biotech Workers

INDUSTRY SCENARIO

Rising domestic and international demand is propelling the Indian biotechnology sector forward. Domestic demand is increasing as a result of initiatives such as Aatmanirbhar Bharat and Make in India, whereas worldwide demand for Indian vaccines and biopharmaceuticals is driven by the medicines' globally competitive efficacy. India distributes vaccines to more than 150 countries and is a popular location for contract manufacture and clinical trials. Companies are exploiting generics and biosimilars to reduce healthcare costs, and India has positioned itself as a hub to provide inexpensive access to innovative and inclusive healthcare solutions. India is the seventh most popular site for clinical trials in the world.

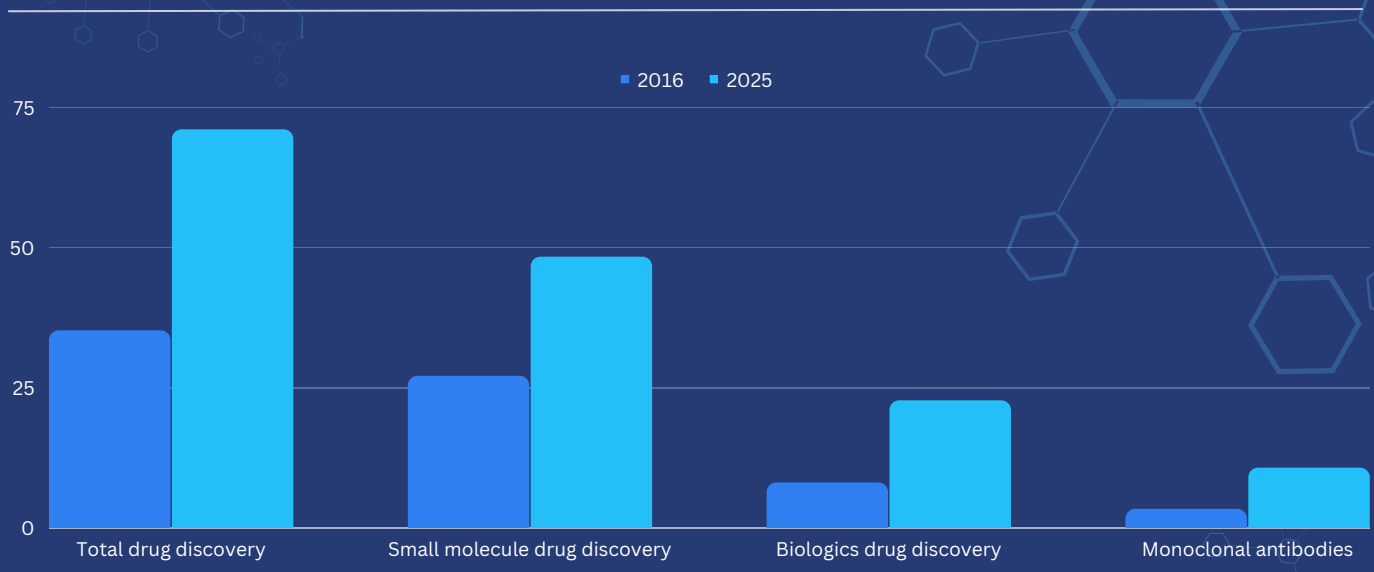
India has the fifth largest amount of organic agricultural land in the world. The Department of Biotechnology has funded 51 Biotech-KISAN (Biotech Krishi Innovation Science Application Network) hubs to connect Indian farmers with best scientists and institutions, empowering farmers (particularly women farmers) with information on soil health, irrigation, and new agri-technologies. Forty four centres have been established in the country's 15 agro-climatic zones, with activities being implementing in 169 districts.

The Government of India proposed 500 new 'waste to wealth' plants under GOBARdhan (Galvanising Organic Bio-Agro Resources Dhan) scheme to be established for promoting circular economy, under the Union Budget 2023. At a total investment of INR 10,000 crore, these will include 200 compressed biogas (CBG) facilities, 75 of which will be in urban areas, and 300 community or cluster-based plants. From 2018 to 2022, a total of 22 mergers and acquisitions (M&A) transactions in India's life sciences sector happened, with a total value of $4.6 billion.

- Favourable government policies like Draft R&D Policy 2021, PLI Schemes and Clinical trial rules have propelled India to be the 'pharmacy of the world'. India has invested $1 Bn in biotechnology R&D in 2022.
- Increasing population and lifestyle changes in India have also contributed to a booming biotechnology sector.

Drug Research

As a result of advances in smart technology, drug development is one of the most promising biotech fields. Traditionally, drug research has faced difficulties in recruiting enough volunteers for trials, as well as extensive production delays that can last years. Machine learning technology has enormous potential for drug research, as well as techniques to improve and assess medicine diagnosis and treatment. Just as telehealth bridges time and space to expedite triaging without requiring patients to physically visit a doctor, biotechnology increases medication production timelines without requiring drugmakers to recruit thousands of volunteers to complete clinical studies. The following graph depicts the drug discovery market worldwide by segment in 2016 and 2025 (projected), in billions of USD. As the graph depicts, the industry is expected to experience a sizeable boom in terms of drug research in the coming years, across the three major fields of research in this arena.



Biotech firms can swiftly analyse data from ongoing studies as well as data from previous trials. This analysis and capacity to combine large datasets provides the information required to make a more accurate diagnosis and, ultimately, to develop improved medicines and treatment paths for patients. Acuranumab, a drug that many hope may cure Alzheimer's disease, is a prime example of the same. After a setback in March 2021, Biogen stated that 'a larger dataset for the EMERGE trial had become available, and that analysis of this dataset had shown a significant reduction in clinical decline." MRI scans and other in-patient monitoring equipment provide more objective data to medical professionals, allowing them to develop better treatment options for patients. Considering that biotechnology advancements have made clinical trials less of a manual procedure, drug firms can lower costs by recruiting fewer in-person patients for trials. Biotech businesses may employ clinical trial digitalization to combine genetic and biometric data to discover the underlying causes of illnesses like as heart disease.

AI In Biotechnology

Artificial intelligence (AI) is already being utilised extensively in biotechnology to solve a wide range of challenges. Drug discovery, drug safety, functional and structural genomics, proteomics, metabolomics, pharmacology, pharmacogenetics, and pharmacogenomics are just a few examples of the widespread application of AI and machine learning (ML) in this sector. Future advancements are vitally dependent on biotechnology researchers' capacity to successfully deploy advanced AI technologies. Currently, the biotechnology business is significantly reliant on data storage, filtering, analysis, and sharing. Biotechnology businesses and healthcare organisations all across the world already have massive datasets. To move faster and decrease manual errors, drug manufacture, chemical analysis of various chemicals, RNA and DNA sequencing, enzyme investigations, and other related biological operations all require a significant boost from AI software solutions.

DIGITAL TRANSFORMATION

AI development and application are reliant on digital technology, with digital computers serving as the foundation. The use of digital technologies to profoundly change the way businesses, organisations, research institutes, and universities work is referred to as digital transformation. In the context of biotechnology, digital transformation could involve the adoption of new technologies and procedures to increase the efficiency, accuracy, and speed of research and development, as well as the creation of wholly new and disruptive goods and services. By offering access to big data and automating some operations, digital transformation can assist speed the development and usage of AI in biotechnology, improving the efficiency and accuracy of research and development.

AI IN AGRICULTURAL BIOTECHNOLOGY

Biotechnology companies are already employing AI/ML solutions to create autonomous robots capable of doing key agricultural activities such as crop harvesting at a far faster rate than humans. Drone data is processed and analysed using computer vision and deep learning techniques. This aids in crop and soil health monitoring. ML algorithms aid in the tracking and prediction of numerous environmental changes, such as weather changes that affect crop productivity. Digital transformation is also having a significant impact on smart agriculture. One application is the assessment of ecological and economic sustainability using the nutrient cycle. The farmer can acquire information about current nutrient balance and hence identify potential issue areas by showing the nutrient cycle in the form of a digital chart.

By adapting agricultural management to a changing climate, AI in agriculture can help to ensure food security. This includes identifying resistant crops that are more resistant to environmental changes and extremes such as drought. This would allow crop yields to be maintained in the face of abiotic challenges, which can have a significant impact on crop productivity. The immense potential of big data has raised the importance of AI in agricultural fields. With technologies that are already widely used in agriculture, such as image-based phenotyping platforms in greenhouses, unmanned aircraft systems (UAS) at the field scale, and satellite-based remote sensing up to the landscape and global scale, data availability grows exponentially. Advances in computer vision algorithms are crucial for making use of the information, while also providing new chances to increase system understanding.

AI IN MEDICAL BIOTECHNOLOGY

The European In Vitro Diagnostics Regulation (IVDR) stipulates explicitly that software, and hence AI algorithms, are required for its operations, which presents substantial hurdles for IVD organisations that use AI for data analysis and decision support. However, if the ethical and legal challenges are addressed, AI can to revolutionise medical biotechnology by enabling faster, more accurate, and cost-effective identification and development of new medications. Specific applications of AI in medical biotechnology include:

- **Drug target identification**: AI can be used to analyse data from multiple sources, such as genetic data and protein-protein interaction data, to identify new therapeutic targets for disease treatment. This includes using ML algorithms to uncover patterns and correlations that humans may not see.

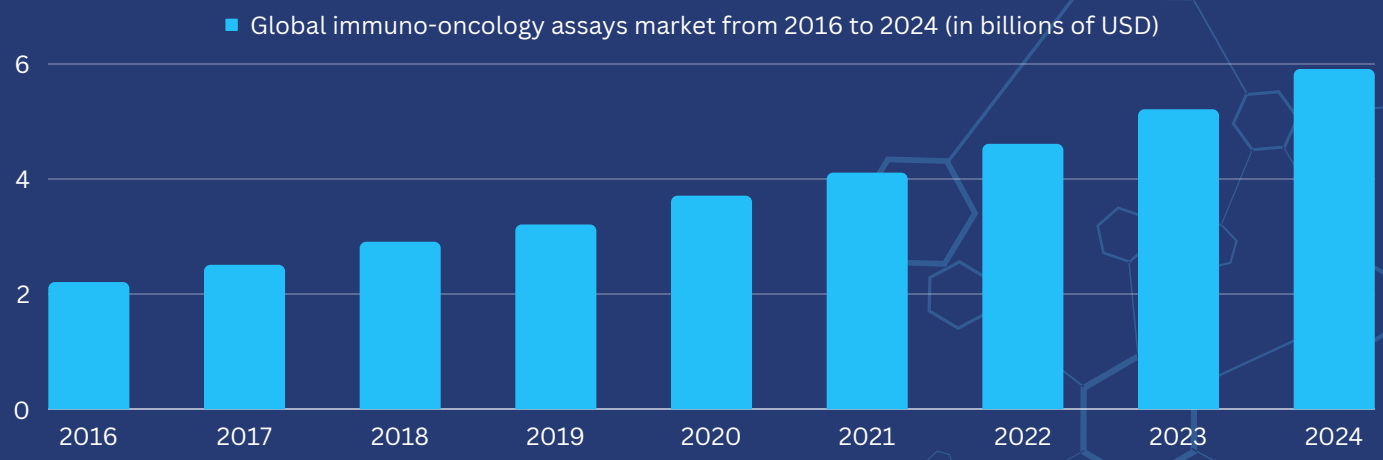
- **Drug screening**: AI can be used to analyse data on possible medications' action against various targets in order to find those that are most likely to be effective. This may entail using ML algorithms to forecast the likelihood of a specific drug's effectiveness based on its properties and the qualities of the target.

- **Image screening**: Artificial intelligence can be used to analyse medical images such as CT scans and MRI images to detect abnormalities and diagnose diseases. This could entail using deep learning algorithms to automatically split and categorise components in medical photos.

- **Predictive modelling**: AI can be used to analyse data from multiple sources, such as electronic health records and wearable devices, to produce health predictions. This can include using machine learning algorithms to forecast the chance of an individual having a specific ailment or the effectiveness of a specific treatment.

Efforts In Oncology

The global oncology ecosystem continues to discover, develop, and deliver significant innovative medicines with the goal of improving outcomes for a growing number of patients. While this is a powerful monument to the stakeholders' intellect and innovative ability, worldwide oncology is experiencing complex problems, as evidenced by current trends.



CURRENT FINDINGS

- In 2022, oncology trial starts maintained at historically high levels, up 22% from 2018.
- Over the last five years, the global number of treated patients has climbed by an average of 5% per year.
- Cancer drug spending is predicted to reach USD 375 billion globally by 2027, up from USD 196 billion in 2022.
- Oncology clinical trial representation for Black/African American and Hispanic patients was 80% and 61% lower, respectively, than the 2019 US cancer incidence.
- Emerging biopharma businesses led cancer innovation in 2022, accounting for 71% of the pipeline.
- Over the past decade or so, the number of cancer drugs in development has increased substantially, with over 2,000 products currently in development.
- Emerging biopharma businesses are responsible for 71% of cancer treatments now in development, up from 51% in 2017.

THE INDIAN CONTEXT

The expected cancer burden in India for 2021 is 26.7 million, with a rise to 29.8 million by 2025. Cancer patients have traditionally been subjected to treatments such as chemotherapy, surgery, and radiation, which fight their malignancies but frequently harm healthy tissues and have major limitations. For instance, surgery may be impossible in cases of massive, inoperable tumours. In order to overcome these issues, immunologists and oncologists have concentrated their efforts on determining how to use a patient's immune system to attack cancer cells. These concerted efforts have resulted in the development of immuno-oncology (IO) drugs, which stimulate the patient's immune system with the goal of achieving long-term and durable responses in a variety of difficult-to-treat cancers, offering long-term survival, reduced treatment toxicity, and improved quality of life.

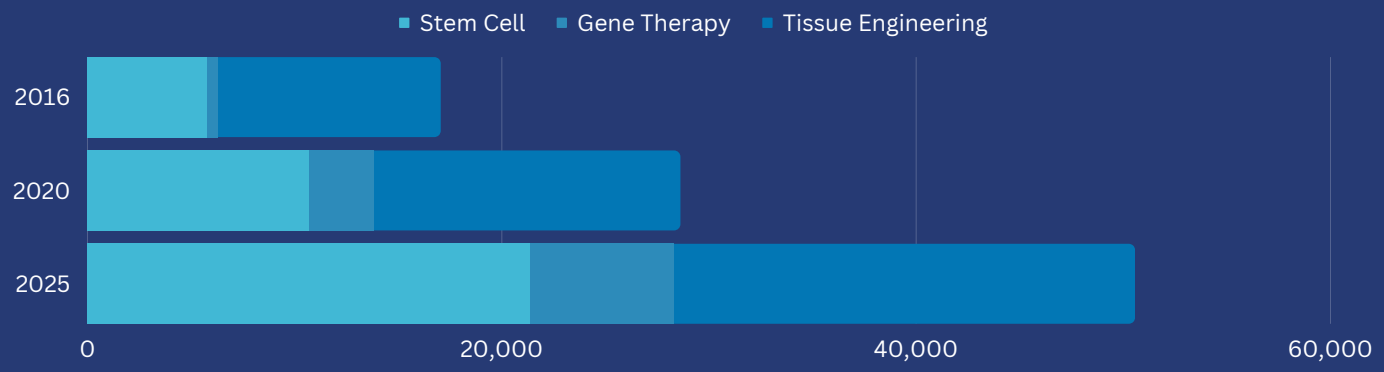
There are various kinds of IO treatment options, each with its own technique for strengthening the patient's immune system against cancer. Several recent developments in cancer immunotherapy research and treatment have occurred in India. Cancer vaccine development has been one of the most significant advancements. Cancer vaccines that activate the immune system to combat cancer cells are being developed by researchers in India. These vaccines are still in the early stages of research, although preclinical tests have showed encouraging outcomes. The use of immuno-modulatory medicines is another field of research that is gaining traction in India. These medications are intended to eliminate the "brakes" that cancer cells place on the immune system, allowing it to attack cancer more effectively.

In 2020, the Indian government approved the first immunotherapy medicine in India, Nivolumab and it is now available as a first-line treatment for a specific kind of lung cancer. A few Indian firms and hospitals are also researching immunotherapies such as chimeric antigenic receptor (CAR) - T cell therapy, natural killer (NK) therapy, and tumor-infiltrating lymphocytes (TIL) therapy, with several in phase 2 clinical trials with commendable early results. The application of personalised medicine in immuno-oncology is another area of innovation in India. This method involves analysing genetic information about a patient's cancer to determine the best IO treatment for that individual.

Some of these game-changing breakthroughs are heavily reliant on artificial intelligence AI/ML. AI is also being used to evaluate novel and improved combination medicines, which involve combining more than one form of existing treatment with immunotherapy for improved outcomes. India possesses all of the required experience, research skills, regulatory framework, and diversified patient populations. It is worth noting that clinical data obtained in Indian sites has been used to support drug approvals in the United States and Europe over the last decade. India is committed to becoming a key centre for oncology clinical trials. Recently, India is hailed as having an improved and streamlined regulatory environment and is considered as the next hub for global clinical trials.

Growth In Gene Therapy

Gene therapy is a cutting-edge treatment for cancer, chronic illness, infectious disease, and blood problems. Gene therapy entails replacing faulty genes in a patient's body with good ones in order to treat or prevent disease progression. Somatic gene therapy and germline gene therapy are the two types of gene therapy based on the location of the target gene on a chromosome. It has the potential to cure a variety of disorders, including Parkinson's, haemophilia, cystic fibrosis, Alzheimer's, brain tumours, cancer, AIDS, SCID, and others. The global gene therapy market was valued at USD 6.0 billion in 2020 and is expected to increase at a CAGR of 22.8% from 2021 to 2030, reaching USD 46.5 billion by 2030. The following graph showcases the global regenerative medicines market by therapy type in 2016, and a forecast for 2020 and 2025 (in millions of USD); the graph depicts that while gene therapy forms the smallest market in comparison to the others, it has consistently multiplied in size, with advancements in technology in biotechnology.



MARKET SCENARIO

The gene therapy market is segmented on the basis of vector type, gene type, application, and region. On the basis of vector type, it is bifurcated into viral and non-viral vectors. Retroviruses, lentiviruses, adenoviruses, adeno-associated viruses, herpes simplex viruses, poxviruses, vaccinia viruses, and others comprise the viral vector section. Naked/plasmid vectors, gene gun, electroporation, lipofection, and other techniques are included in the non-viral vector sector. The rise in the prevalence of chronic diseases such as cancer, rare illness genetic disorders, and others is a major driver driving the gene therapy market growth. Furthermore, increased government funding, ethical acceptance of gene therapy for cancer treatment, and an increase in cancer prevalence promote market expansion. Furthermore, an increase in healthcare spending, the development of improved healthcare infrastructure, and the availability of reimbursements all contribute to the plethora of opportunities in gene therapy. However, the high cost of gene treatments is projected to limit market growth during the forecast period.

Scaling Up Synthetic Biology

Synthetic biology is applied across a multitude of industries, such as manufacturing, electronics, medicine and pharmaceuticals. Biofabricated electrical film, cell engineering for therapy, and automated coronavirus testing using sequencing are all examples of synthetic biology. It provides novel ways for creating new biological systems or redesigning existing ones for practical applications, and has been defined as a revolutionary technology at the centre of the so called "bioeconomy", capable of providing innovative answers to global healthcare, agriculture, industry, and environmental concerns.

11.4
Market size in 2022
(in billions of USD)

CAGR of 25.6%
during the forecast period

35.7
Market size in 2027
(in billions of USD)

TRANSFORMING ASPECTS OF DAILY LIFE

- **Healthcare**: New medicines and therapies are being developed using synthetic biology. Scientists, for example, are using method to create new kinds of medications, vaccines, and cell therapies that can treat and cure rare diseases.
- **Agriculture**: Synthetic biology is being utilised to boost agriculture production and develop crops that are resistant to pests, diseases, and changing environmental circumstances.
- **Energy**: Synthetic biology is being applied to develop new, more sustainable energy sources. For instance, synthetic biology is being utilised to design and develop microbes capable of producing biofuels such as ethanol and biodiesel from plant material.
- **Environment**: Synthetic biology is also being used to clean up environmental contaminants, such as oil spills, toxic waste, and heavy metals. Scientists are designing and building new microorganisms that can consume these pollutants and convert them into harmless substances.
- **Manufacturing**: Another application of synthetic biology involves producing a wide range of products, including chemicals, enzymes, and proteins, more efficiently and sustainably.

Risks & Solutions

Biotechnology's benefits are palpable and evident to the rest of the world. COVID-19 vaccinations have saved millions of lives, and CAR-T cell treatments are bringing personalised medicine to cancer treatment success. Aside from medical applications, biological enzymes are commonly applied in various fields, such as in laundry detergents for stain removal, plant-based "meats" in burgers that "bleed", and direct-to-consumer genetic testing genealogy services. These biotechnology advances are the result of not only long-term biological research and hard work by scientists all over the world, but also of the convergence of advances in computing, machine learning, and the availability of powerful research tools that speed up discovery and allow important scientific questions to be asked and answered. However, there are risks to biotechnological advancement as well. Even in the early days of recombinant DNA technology, it was recognised that there were inherent hazards in learning more about biological pathways, as that knowledge may be utilised to inflict harm. For instance, accidents are also possible if a biotechnology product "escapes" from its containment, endangering people, animals, or the environment. The following are some pertinent risks experienced by firms in this industry, and some potential solutions to the same.

MANAGING PROMINENT RISKS

- **INVESTOR CAUTION:** Biotech production is prohibitively expensive., hence, research and development and FDA approval processes are also in flux. Biotech investment tends to be fraught with danger; failed development, approval, or commercialisation can devastate a small company while also putting a major strain on larger corporations. Moreover, private biotechs face difficulties in obtaining finance due of the dangers. It requires a special type of corporation to properly assess the risks and confidently invest millions of dollars in a business or product.

  However, without funding, biotechs struggle to obtain the necessary facilities, equipment, and personnel to ensure quality, efficient production processes. Not only is funding challenging to obtain, it also requires a significant amount of effort, meetings, and persuasion. Private investors devote a significant amount of time to analysing risks and discussing potential investments. The back-and-forth between the biotech firm and the investor might cause delays in R&D and production.

  One method for addressing these financial issues is to speed up contact with investors. Biotechs can use unified communications systems (UCS) instead of face-to-face meetings or as a means of intermittent talks. A UCS enables interactions that are rapid, dependable, and consistent across all prevalent means of engagement.

- **STRINGENT REGULATIONS:** As federal rules and the FDA have severe criteria on how products are made and the end results, biotech production is prone to delays, inefficiency, and waste, and is typically slow for these reasons. This issue contributes to the aforementioned investor anxiety, as investors frequently demand faster payouts. Biotechs often have more aggressive quality control and quality assurance methods than corporations in other industries in order to meet FDA criteria and protect public safety. Quality assurance processes are preventative actions that aim to raise the rate of high-quality products; such procedures are used to identify products that do not meet standards. Biotech firms cannot and do not want to make corners on quality processes. However, there are methods that may be taken to increase manufacturing efficiency while maintaining quality:

  Automation: Many sectors' producers are focusing on automation to speed up various production and ancillary operations. Analytics programmes are used to uncover product flaws earlier in the manufacturing process. Adjustments are frequently automated to remove the requirement for manual involvement.

  Internal cooperation: Improved coordination among production managers, quality control experts, and quality assurance experts can shorten planning and response times. A unified communications system, once again, provides quick and flexible contacts among leaders in these domains, including planned meetings and unexpected exchanges.

  Collaboration: Biotech companies must be able to communicate effectively with FDA representatives in order to address any problems that arise during the approval and production procedures. Collaboration with industry partners is also essential.

- **SUPPLY CHAIN UNCERTAINTY:** One of the most major barriers to biotech production is something that is essentially outside their control. Biotechs rely largely on a reliable and adaptable supply of raw materials for production. However, there are numerous circumstances that can make it difficult for channel partners to achieve these expectations. The pandemic, for example, caused significant interruptions to several transportation systems that biotechs rely on to deliver raw materials on schedule. Delays in raw material availability cause interruptions in manufacturing operations.

  Rather than simply reacting to adversity, many biotech companies have gone on the offensive to acquire greater visibility into their supply networks. Artificial intelligence software is used to identify possible bottlenecks in the industry. The need for materials assessments among rivals also provide some information into anticipated supply shortages; early detection of potential disruptions to transportation methods also allows for faster adaptation to alternatives.

Producers can only do so much to plan for supply chain difficulties on their own, as an effective, collaborative strategy requires close ties with channel partners. Another relationship in which a UCS is crucial for agile and efficient interactions. When problems arise, suppliers must be able to swiftly and easily contact producers. Similarly, producers must be able to contact supplier representatives at the first hint of problems.

- **LIMITED INDUSTRY EXPERTS:** A paucity of industry specialists has crippled the overall life sciences business. A limited skill pool makes implementing any of the other options for fixing production challenges more difficult. Aside from issues regarding accessible personnel, employed professionals are so overburdened with work that it is difficult to stay up with industry changes. Producers also face the dilemma of having to invest in acquiring professionals from a restricted pool while simultaneously investing in training to keep current personnel current.

Increased dependence on automation can assist to alleviate the talent shortage; as a result, manufacturers must decide whether to increase investment in contemporary technology, including core communications infrastructure, or in additional personnel.

- **BIOSAFETY, BIOSECURITY, & ETHICAL CONCERNS:** The purposeful or unintended release of synthetic organisms into the environment during research and other uses is a major biosafety risk, particularly in synthetic biology. When synthetic bacteria are put into the environment, they can mutate or interact with other organisms, resulting in crossbreeding and bio errors. This has the potential to endanger the natural organisms' environment. Another major biosafety worry is the emergence of antibiotic-resistant superbugs. The European Union (EU) has recently financed various research projects on the environmental impact of intentionally released genetically altered microorganisms for plant growth or bioremediation. Such concerns may be alleviated with these steps:

Risk assessment: Any novel synthetic biology-based product or technology should be rigorously examined before it is developed or released into the environment to identify its potential risks and benefits.

Transparency: The development and application of biotechnology should be transparent, with public access to information about research initiatives and products.
3. Accountability: Researchers, institutions, and businesses that create synthetic biology-based products should be held accountable for the impact of their work, both in terms of possible advantages and risks.

Worldwide cooperation: Given the global nature of biotechnology and its potential influence on ecosystems and human health, worldwide cooperation and coordination are essential to ensuring that regulations and standards are uniform and effective.

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CONTACT US

ADITYA A. M.
Senior Partner
✉ aditya@spka.in

KARTHIK JEGANNATHAN
Chief Business Officer
✉ karthik@sprandco.com

TARUNESH CHETTY
Director, South Africa
✉ tarunesh.chetty@sprandco.co.za

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