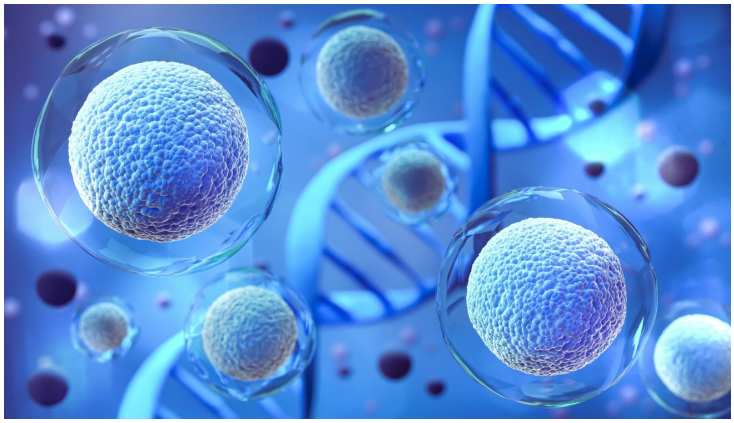
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Biopharma Industry in India: Emerging Technologies

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The rapidly evolving technological landscape has brought significant benefits to various sectors. In particular, the biopharma industry has experienced a plethora of advancements that have helped reshape its development and growth, especially in countries like India. Advances in areas such as gene editing, nanotechnology, stem cell research, and synthetic biology, among many others, have established a new framework for the biopharma industry in India. Emerging technologies, from artificial intelligence to genomics, are persistently reshaping India's biopharma industry, encouraging new research avenues, accelerating product development, improving supply chains, and enhancing the sector's global competitiveness.

Advancements in the field of genomics are revolutionising the Indian biopharma industry. Next-generation sequencing technologies have allowed researchers to gain in-depth insights into the genetic makeup of diseases. Some of the hereditary cancer syndromes, certain cardiovascular diseases (hypertrophic cardiomyopathy, long QT syndrome, familial hypercholesterolemia, and others), neurogenetic diseases, rare genetic diseases, are some of the diseases that the next generation sequencing can help in screening. This understanding has accelerated the development of targeted therapies, including personalised medicine. Genomics is empowering biopharma companies not only to understand diseases better but also to create effective and more personalised treatments. The Genomics for Understanding Rare Diseases India Alliance Network (GUaRDIAN) is one of the initiatives in India using genomics to understand the genetic origins of rare diseases.

In recent years, emerging technologies such as cell and gene therapy have become pivotal in shaping the paradigm of the biopharma industry, fostering revolutionary changes in the field of medical biotechnology. Unleashing promising potential for combating life-threatening diseases like cancer, Alzheimer's, and many genetic disorders, these new-age orchestrators are changing the conventional medical landscape of India.

Gene therapy and cell therapy are at the forefront of biomedical innovation, holding the potential to treat, and even cure, numerous lethal diseases. While cell therapy is an intervention technique where functional cells are introduced into a patient's body to replace or repair damaged tissues or cells, gene therapy aims to modify or manipulate the expression of a gene or to alter the biological properties of living cells for therapeutic use. Both interventions are enabling a transition from traditional pharmaceuticals to complex and innovative treatment methods, significantly impacting the biopharma industry.

An emerging way to treat cancer is immunotherapy, where the patient’s immune system is strengthened to attack cancer cells . It is less painful than surgery, chemotherapy, or radiation therapy, and is known to lower the relapse of cancer. Specialised killer cells, called 'T-cells' in the human immune system, protect our body from cancer and other diseases. They can recognise tumours and cancerous growths destroy them. In advanced stages, cancer cells can inactivate T-cells or modify themselves in a way that cannot detect them. A new approach in immunotherapy, known as CAR T-cell therapy, restores the ability of the T-cells to recognise the cancer cells and kill them.
Chimeric Antigen Receptors or CARs are proteins that assist T-cells in recognising and attaching to a specific protein or antigen, present on cancer cells. The interaction between these two proteins leads to the destruction of the cancer cell. First introduced in 2017, the CAR T-cell technology holds promise for the treatment of cancers, especially leukaemia.

Now, researchers at the Indian Institute of Technology Bombay (IIT Bombay) have developed a patented technology to leverage the patient’s immune system to cure cancer. Prof. Rahul Purwar and his team of scientists from the Department of Biosciences and Bioengineering, IIT Bombay, have used a combination of gene therapy and cell therapy to modify the immune cells to attack and kill cancer cells. They have secured a patent for their approach and in collaboration with Prof Gaurav Narula of the Tata Memorial Hospital. Taking this research to market, the researchers have incubated a company at IIT Bombay, called ImmunoACT to provide CAR-T cell therapy services commercially .

The Indian biopharma industry is steadily embracing the advancements in cell and gene technology. The Government's impetus through the Department of Biotechnology’s "National Biopharma Mission", launched in collaboration with the World Bank, has significantly contributed to the development and commercialisation of cell and gene therapies in India.

These therapies are becoming a focal point for investment, innovation, and commercialisation in the biopharma sector. Several startups and established pharmaceutical companies in India are focusing on these innovative technologies, leading to strategic alliances and collaborations between organisations and research institutions to expedite development and distribution.

The introduction of gene and cell therapies into the Indian pharma market is also challenging the traditional clinical pathway. Regulatory bodies are required to respond promptly and devise guidelines and policies that are fit for purpose for these novel therapy types. A collaborative effort between regulatory bodies, pharmaceutical companies, and stakeholders is poised to develop comprehensive protocols that ensure novel biopharmaceuticals' safety and efficacy.

Furthermore, entering the domain of cell and gene therapy also prompts the necessity for specialised manufacturing capabilities. The quality control checks and balances for these therapies vary significantly from the ordinary pharmaceutical

products – demanding high-purity manufacturing spaces, experienced workforce, and advanced analytical testing capabilities. Some of the Indian biopharma companies like ImmunnoACT, Immuneel and Biocon have already geared up to address these challenges.

The potential market for cell and gene therapies is vast. With the leap being made from generics to cell and gene therapies, Indian pharmaceutical enterprises will break new ground, ushering in a new era for the country's biopharma industry. With state-of-the-art research, sound clinical trials and data, and consistent regulatory efforts, gene and cell therapies stand to transform India's biopharma landscape, enhancing the healthcare sector's ability to treat chronic and life-threatening diseases.

Stem-cell technology is yet another game-changing technology that is influencing biopharma in India. Stem cells have shown potential in treating diseases which were previously considered incurable. Indian biotech companies such as Reliance Life Sciences and Lifecell have heavily invested in stem cell technology. Lifecell, a hallmark company in this niche, provides umbilical cord blood stem cell banking – a service that allows individuals to store stem cells at birth for potential future use.

Synthetic biology, described as the design and construction of novel artificial biological pathways, is a relatively new concept in India. However, it presents significant potential for the biosimilar and biopharmaceutical industry, offering avenues for the creation of high-value pharmaceutical products. Indian companies are leveraging synthetic biology in the production of ingredients for the pharmaceutical, nutraceutical, and cosmeceutical industries.

Another crucial emerging technology is the Internet of Things (IoT). IoT technologies are creating interconnections between tools, machines, and people, enabling data sharing in real-time. For instance, IoT has been instrumental in enhancing supply chain management in the biopharma industry, ensuring temperature control of sensitive drugs during transport, and offering real-time visibility and traceability, thus minimising risks associated with mishandling during transit. Indian pharma industry is increasingly implementing IoT to track and trace the supply chain logistics for pharmaceutical products, negating the threat of counterfeit drugs.

In addition, there are also ecosystem enabling players like the Centre for Cellular and Molecular Platforms (C-CAMP), Atal Innovation Centre at the Centre for Cellular and Molecular Biology (CCMB), and Bangalore Bioinnovation Centre, who are providing a host of support of services like analytical services, R&D services, incubation, seed funding and prototyping.

In summary, emerging technologies are driving significant advancements in the Indian biopharma industry, thereby positively influencing the global competitive landscape. Elements such as genomics, cell and gene therapy, stem-cell technology, synthetic biology, and IoT are not only improving operational efficiencies but also enhancing patient care through better diagnosis and treatment techniques. It is an exciting time for India's biopharma industry, as the fusion of biology and technology could serve as the springboard for exponential growth.





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