Emerging Frontier of Medical Biotechnology: A Comparative Study of India and South Korea

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Abstract: **A phenomenon such as a pandemic does not emerge with prior notice, meaning biotechnology requires more than studying a disease, or depending on complementary disciplines. Despite the accessibility of conventional methods, modern healthcare requires precision, scalability, safety, and molecular control capabilities as the most reliable and effective solutions. Existing research studies have already emphasized the necessity of medical biotechnology for engineering biological systems to prevent, diagnose, or treat diseases at the molecular level. Medical biotechnology is the applied branch of modern biology dedicated to healthcare, to develop products, tools, and therapies to address medical, diagnostic, and therapeutic challenges arising from complex health problems. Modern healthcare has been receiving the most transformative advancements in medicine for decades, including therapeutic biologics, advanced biopharmaceuticals, molecular and cellular technologies, and an improved regulatory framework for biologics. Recent advances, such as CRISPR, Biochips, and AI in medical biotechnology, are simpler, more efficient, and with improved predictability of the outcomes. This review highlights the key applications of medical biotechnology, including recombinant proteins, monoclonal antibodies (Hybridoma technology), vaccines, gene and stem cell therapies. It also discusses the leading biopharma and biotech companies and the regulatory frameworks for biologics in India and South Korea.**

Index Terms: **Medical Biotechnology; Biologics; Regulatory Framework; India; South Korea**

I. Introduction

The term biotechnology was first introduced by Karl Ereky in 1917 as the means by which products are obtained from living organisms as their raw material, using biological processes [1]. In the past, the initial applications of biotechnology were mainly in food production, animal breeding, and crop yield enhancement. With the foundation laid by Watson and Crick in 1953 [2], by discovering the double-helix structure of DNA, the invention of recombinant DNA technology in 1973, and the commercialization of the first recombinant insulin by Genentech in 1982 [3], medical biotechnology started to be recognized as a distinct discipline. In addition, the innovations also influenced the pharmaceutical industry to conduct research and development across a wider range of therapeutics and seize the burgeoning opportunities in biomedical sciences [4]. Later, medical biotechnology became necessary to modify DNA, produce proteins safely, design targeted therapies, and create advanced diagnostics as further advances. In recent years, indeed, there have been various advancements in the field, such as genome editing, stem cell research, and molecular therapies, which are fulfilling the increasing demand of modern healthcare, making it the most prioritized sector worldwide.

Moreover, the sequencing of the human genome made it possible to study the genetic makeup, and with the advancements in DNA sequencing technologies, it has become faster and affordable to decipher an individual's entire genetic code [5]. This information opens the door for personalized and precision medicine, so that the treatments and the preventive measures can be designed based on an individual's generic profile, which not only increases the effectiveness but also minimizes adverse side effects. Regenerative medicines, on the other hand, are a hope for patients with degenerative conditions and injuries, such as Alzheimer's, Parkinson's, and spinal cord injuries. Additionally, Stem cell therapies, as a biotechnological product, carries a potential to regenerate damaged tissues and organs. This successful application holds the ability to extend human lifespan and improve its quality as well [6]. Medical biotechnology holds significant promise for not only combating complex health problems but also for managing infectious diseases, with faster diagnostic tests and pathogen detection, to combat even the early stages of an outbreak [7].

Medical biotechnology has witnessed various domains, most of which might not even have been expected in the past days of the biotechnological era, such as Bioprinting, a technology combining 3D printing with biology. By creating living tissues and organs, this holds a prominent aspect to address the shortage of organ transplants, risk of organ rejection, need for immunosuppressants, and advancements in regenerative medicine [8]. Nanobiotechnology, a convergence with nanotechnology to engineer nanoscale devices and materials for biomedical purposes, including targeted drug delivery systems, nanoscale imaging techniques, and diagnostic sensors, which ultimately improves the accuracy and efficacy of medical treatments [9]. Furthermore, AI is offering a huge potential, with the aspects of machine learning, particularly in analyzing vast datasets generated by genomics, proteomics, and other "omics" technologies [10].

Biopharmaceuticals are another major sector, with therapeutic drugs using biological organisms to treat a wide range of diseases, and are often referred to as biologics or biological drugs, including vaccines, gene therapies, and recombinant proteins. Although the production of biologics is a highly complex and regulated process, it has witnessed a remarkable growth in recent years and has ushered in a new era of medicine [11]. This review delves into the many ways biotechnology is shaping healthcare, highlighting some of the leading biopharmaceutical and biotechnological companies in India and South Korea, and compares how each nation approaches the regulatory landscape for biologics.

II. Status of Medical Biotechnology

Since the development of the first genetically engineered biomedicine by Genentech in the 1980s, medical biotechnology has evolved into one of the fastest-growing branches of modern biotechnology. Its advancement is greatly influenced by the aging society, shifting disease patterns, and changing healthcare financing systems [12]. The global biotechnology market was valued at USD 1.38 trillion in 2023, with the highest segmented compound annual growth rate (CAGR) and 44.55% from the health sector [13]. The market is further expected to reach USD 4.26 trillion by 2033, with the Asia-Pacific being the fastest-growing region at a CAGR of 14.8%, driven by advanced healthcare infrastructure, increased clinical labs, and supportive laws and regulations [14].

The Bioeconomy of India was valued at USD 150 billion in 2023, forecasted to double to USD 300 billion by 2030, with 49% of the value held by Biopharmaceuticals. India currently has 665 FDA-approved manufacturing facilities, after the United States [15,16,17]. Over 50% of global vaccine demand and 65% of the WHO's requirements are met by India, including 60% of global Diphtheria, Pertussis, and Tetanus (DPT), Bacillus Calmette-Guérin (BCG), and measles vaccines [18,19].

The bioeconomy of South Korea is mainly driven by biotechnology research and development (R&D), which is organized and implemented by the Korean government [20]. Recently, in 2025, the Presidential Bio Committee was also established to coordinate strategy, expand production capacity, and scale R&D [21]. The national biotechnology revenue of South Korea reached USD 25.64 billion in 2023, which was forecasted to reach USD 81.63 billion by 2030 [22]. Additionally, Songdo District, South Korea, is recognized as one of the world's largest biologics manufacturing capacities [23].

III. Products and Applications of Medical Biotechnology

3.1. Recombinant Proteins

The human body has the capacity to produce thousands of proteins and enzymes naturally, controlling a wide range of basic to complex functions. However, due to aging or impairment of organs, a deficiency of these proteins may arise, which often results in severe pathological conditions, including mental disorders, diabetes, and impaired blood clotting [24]. To treat such conditions and diseases, artificial proteins using genetic engineering techniques were produced [25]. These recombinant proteins became the fastest-growing medicines in the pharmacological industry, with more than 170 proteins currently in use worldwide [26]. Among the hosts used to create recombinant proteins, *Escherichia coli* remained the best choice because of its low-cost availability, rapid growth, and genetic tractability [27]. Moreover, other methods, such as yeast-based recombinant protein production for vaccine production, are also being simultaneously explored [28]. The market share of these protein-based products is continuously escalating due to an increase in chronic diseases, and the global execution against viral infections like SARS-CoV-2 [29].

3.2. Hybridoma and Monoclonal Antibodies

In 1975, Georges Kohler and Cesar Milstein discovered the Hybridoma technology [30]. The technology is capable of creating an immortal cell line for the secretion of uniform, monospecific antibodies that recognize even a single epitope with high affinity [31]. Monoclonal antibodies (mAbs) have high specificity for target antigens, making them a crucial tool in modern biomedical research and therapeutic development [32]. Through Hybridoma technology, indefinite monoclonal antibodies producing hybridomas can be produced by fusing antibody-producing B cells and immortal myeloma cells [33]. These monoclonal antibodies are widely used in diagnostics to detect minimal residual disease and metastatic cancer [34]. Moreover, the isolation of a single monoclonal antibody (mAb) against any particular antigen was only possible with this hybridoma technology [35]. Recently, the Electric pulse-based fusion has also been introduced, which can increase the efficiency of hybridoma formation [36].

3.3. Vaccines

Vaccines are the most effective biologic in preventing and combating severe infectious diseases [37]. Early vaccines were simpler in composition, using live, attenuated viruses such as those for rabies and smallpox [38], or inactivated bacteria like *Bordetella pertussis*. With the advancement in biomedical sciences, safer and more refined formulations have emerged, including toxoid vaccines for tetanus and virus-like particles (VLPs) for hepatitis B [39]. Vaccines are saving at least 2 to 3 million lives worldwide per year [40]. Through historical events, such as the COVID-19 pandemic, the importance of vaccines for future progress is readily apparent [41]. The potential of vaccines to combat and prevent severe diseases is exceptional, and the rapid development of these vaccines, similar to that of the COVID-19 vaccine, particularly mRNA-based vaccines, is another notable achievement [42]. For rapid and inexpensive mass production, new manufacturing methodologies and delivery materials are focused on next-generation mRNA vaccines [43]. Moreover, Amplified vaccines use "amplifiers" in addition to antigens and adjuvants, unlike classic vaccines, and are being preferred as an approach to increase efficiency [40]. Recently, reverse vaccination (RV) has also been studied as a new approach for vaccine development [44].

3.4. Genome Editing and Gene Therapy

In genetic engineering, genome editing is a widely used technique for site-specific modifications to DNA using the cellular repair mechanism [45]. It began with transgenesis, the deliberate transfer of genetic material between organisms as demonstrated by Rudolf Jaenisch in 1974 [46]. Currently, there are four genome-editing technologies mainly in use, including meganucleases, zinc-finger nucleases (ZFNs), transcription activator-like effector nucleases (TALENs), and Clustered Regularly Interspaced Short Palindromic Repeats- Cas (CRISPR-Cas) systems [47,48].

Gene therapy is an application of genome editing. In the 1990s, the first gene therapy was initiated for a hereditary health condition by inserting the protein-encoding gene into the person's cells [49]. Over the years, various targeted treatments have been approved, including therapies for melanoma [50], lipoprotein lipase deficiency [51], and Duchenne muscular dystrophy [52].

3.5. Stem Cell Therapy

Stem cell therapy brought a revolution in modern medicine for treating a wide range of debilitating diseases and injuries. It also serves as a therapeutic tool for severe conditions like cardiovascular disorders, cancer, and even hepatic and pulmonary diseases. (Mirzaei et al., 2016c; Mirzaei et al., 2016f). Since the 1960s, multipotent stem cells, another principal class of stem cells, have been sourced from bone marrow due to their self-renewal and differentiation capabilities, as well as their capacity to produce lymphocytes, megakaryocytes, and erythrocytes, which are significant in therapeutic applications [53,54]. There is a huge scope for stem cell therapies in the future as well, marking a new era of personalized regenerative healing through the integration of precision medicine, immune modulation, genome editing, and bioengineering collaborations [55]. Recently, the potential for stem cell therapy without stem cells has also been studied to address the limitations posed by the use of stem cells in cell-based therapy, including the use of adipose-derived stem cells (ASCs) [56].

3.6. Biochips

Biochips are integrated circuit microchips, having biosensors with transducers [57], also called chips. These are miniature digital technologies that collect and analyze data, such as blood or urine, primarily from living organisms and cells [58]. These chips help in early diagnosis and screening of various chronic and infectious diseases [57]. Through these chips, not only immediate point-of-

care diagnosis of diseases but also continuous sampling and real-time testing for biochemical toxins and pathogens is possible [59]. Moreover, wearable and implantable Lab-on-Chip (LOC) devices are a big revolution for monitoring physiological and biochemical parameters in non-clinical settings [60]. These days, there are even various types of wearable biosensors available, including skin-based patches [61], smart textiles [62], and even wearable wristbands and watches [63]. There are several micro-/nanofabrication methods for the production of biochips, especially for paper-based biochips, including screen printing, inkjet printing, dip coating, and thermal evaporation [64].

3.7. Bio-nanotechnology

Nanomedicines and diagnostic devices are examples of nanoscale manufacturing technologies integrated with biology, termed bionanotechnology or nano-biotechnology [65]. Advances in technology are bringing an unexplored approach addressing adverse challenges, such as aiding advances to combat cancer metastasis [66], or holding promise for an effective drug delivery system [67], even addressing biocontamination of medical devices and implants [68]. Apart from these, bionanotechnology has a wide range of applications, including gene delivery, DNA nanotechnology, tissue engineering, molecular imaging, and even biosensors and biomarkers [69]. Bionanotechnology as a field holds great promise as it has the capacity to integrate with various fields of medical sciences, providing a wide range of cutting-edge technologies with improved outcomes [65].

IV. Regulatory Framework Required for Biologics

India defines biologics as medical, therapeutic, diagnostic, or preventive products derived from living organisms. Biologics are termed as similar biologics under the Central Drug Standard Control Organisation (CDSCO) and the Department of Biotechnology (DBT)'s 2016 guidelines, which have similar quality, safety, and efficacy to approved reference biological products [70]. India's regulatory framework for biologics is operated through a multilayered structure, which contains the Institutional Biosafety Committee (IBSC) [71], Review Committee on Genetic Manipulation (RCGM) [72], the Genetic Engineering Appraisal Committee (GEAC)[73], and the Central Drug Standard Control Organisation (CDSCO) [74,75]. The major acts governing these biologics are the Drug and Cosmetic Act of 1940, the Drug and Cosmetic Rules of 1945, the Environment Protection Act of 1986 [76,77], and various guidelines, such as recombinant DNA Safety Guidelines of 1990 [78].

South Korea defines biologics as complex therapeutic products derived from living organisms or their components, such as cells, proteins, nucleic acids, or tissues. The Ministry of Food and Drug Safety (MFDS), formerly known as Korea Food and Drug Administration (KFDA), is the main regulatory body, releases notifications on the regulations for review and authorization of biologics and biosimilar products [79,80]. Additionally, the Institute of Drug Safety and Risk Management (KIDS), as a regulatory science centre, was designed for advanced biological products [81,82]. The MFDS has its central headquarters, the National Institute of Food and Drug Safety Evaluation (NIFDS), and six regional offices [83]. Mainly, the regulations come under the Pharmaceutical Affairs Act (PAA), which governs the approval of drug and biological products [84]. The regulatory structure of South Korea has seven regulations and eight guidelines [85]. Overall, South Korea's biosimilar framework has a three-tiered system with the Pharmaceutical Affairs Act, Notification on Review and Authorization of Biological Products, and Guidelines on Evaluation of Biosimilar Products [79].

Both India and South Korea have specific regulatory requirements for the approval of biologics, which are further compared in Table 1.

Table 1. Comparative analysis of regulatory and developmental framework for approval of biologics in India and South Korea [86].

Category	Country	
	India	***South Korea***
Regulatory Body	Central Drugs Standard Control Organization (CDSCO)	Ministry of Food and Drug Safety (MFDS)
Manufacturing Landscape	Over 70 biologic/biosimilar products on the market	25 biosimilar manufacturers
Eligibility for Clinical Trial Initiation	Clinical trial begins after CDSCO approval	Only IND approval required; no separate trial notification
Approval Review Organizations	CDSCO and DCGI	MFDS and NIFDS
Approval Timeline	12–15 months	10–15 months
Clinical Summary Requirement	Yes, in English	Yes, in Korean
Clinical Study Report Requirements	Yes (English)	Yes (Module M5 of CTD, English acceptable)
Packaging Label Requirements	English; Rule 96 & Schedule D2 (D&C Rules 1945)	Korean; Pharmaceutical Affairs Act (Article 56)
Local Subject Requirement	>100 subjects required in Phase 3	Significant number of subjects
Investigators	Large national pool across therapy areas	Institution-based availability
IRB/IEC System	IEC & Institutional Ethics Committee	Institutional IRB

V. Leading Biotech and Biologics Manufacturing Companies

5.1. India's leading companies

- Biocon Limited: A global biopharmaceutical company with a main focus on affordable medications for diabetes, cancer, and autoimmune diseases [87].

- Serum Institute of India (SII): A multinational biotechnology and biopharmaceutical company, manufacturing vaccines and immuno-biologicals [88].
- Bharat Biotech: An international limited, leading in vaccines, as well as bio-therapeutics, such as Rotavirus, Hepatitis-B, and Typhoid [89].
- Dr. Reddy's Laboratories: A multinational pharmaceutical company focusing on affordable and innovative medicines, mainly in gastrointestinal, cardiovascular, oncology, and dermatology [90].
- Titan Biotech Limited: A leading manufacturer and exporter of high-quality raw material biotechnology ingredients, including microbiological products [91].
- Lupin Limited: A multinational pharmaceutical company and a global leader in therapeutics, such as anti-infective drugs, and one of the world's largest generic pharmaceutical companies [92].
- Enzene Biosciences: A global company of biologics and biosimilars development, manufacturing, and supply, especially EnzeneX^{TM} [93].
- Zydus Lifesciences: A multinational pharmaceutical company, with a main focus on Biosimilars, Vaccines, therapeutics, and R&D for new therapies [94].

5.2. South Korea's leading companies

- Samsung Biologics: One of the world's largest contract and manufacturing organizations (CDMO), handling a wide range of products, like monoclonal antibodies and Recombinant proteins [95].
- Samsung Bioepics: A biosimilar and biopharmaceutical company, focusing on high-quality, lower-cost biological drugs [96].
- Cellitron: A biopharmaceutical company with a primary focus on R&D, manufacturing, marketing, and sales of innovative therapeutic products [97].
- CKD Bio: A biopharmaceutical company, with fermentation-based specialized products, such as antibiotics, immunosuppressants, intermediary, and β-lactamase inhibitors [98].
- LG Chem: A global pharmaceutical company, focusing on innovative drugs and production with eco-friendly materials [99].
- Cha Biotech: A Biotechnology company with a main focus on R&D, as innovative cell and gene therapies for rare cancers and incurable diseases [100].
- LigaChem Biosciences: A clinical-stage biotechnology company, focusing on novel therapeutics with marketed technologies [101].
- Medipost: A biotechnology company that focuses on regenerative medicines, such as stem-cell therapeutics for degenerative diseases [102].

VI. Future Prospects

With the continuous advancements in medical biotechnology, a better lifestyle and extended life expectancy can be anticipated. The field holds potential in regenerative therapeutics, along with precision and personalized medicines, which will become more favourable in the future. Technologies like CRISPR will become the most preferred and favorable options for dealing with genetic or hereditary conditions, with further advancements. Additionally, biosensors and biochips will become an integral part of daily life, tracking body activities to enhance productivity, irrespective of the health condition or requirements. Furthermore, AI and robotics will be a huge part of the future biotechnology industry, including diagnostics, analysis, and data interpretation. However, the old-school machine learning methods will reach their limit, with all those piles of chemical and biological data that the pharmaceutical industry currently holds. Due to such advances, the issues related to bioethics and safety will become more severe, which involves the misuse of these technologies beyond medical applications. With increased dependency, the chances of risks also increase. For example, AI-assisted data analysis and interpretation must be monitored frequently, as it can give false interpretations based on history and can become a major issue on a large scale or even a threat to privacy. Techniques like genome editing and DNA sequencing also raise major ethical concerns, including legal, moral, and social aspects, which can lead to over-the-line editing and alterations. Addressing these prospective issues is essential for moving into a new era of modern biotechnology, or medical biotechnology. By keeping frequent checks on ethical considerations, updating regulations and guidelines, improving the data validation process, and spreading awareness among the public, we can mitigate these risks and harness the potential of such innovative medicines, therapies, and technological advances to drive innovations in the field of medical biotechnology.

VII. Conclusion

Medical Biotechnology has evolved significantly over the past few decades, with the increasing demand for professional and advanced healthcare. With technologies such as genome editing and precision medicine, it holds potential to become one of the most valuable fields in biomedical sciences. It emerges as an interdisciplinary field, with interventions in other disciplines, such as nanotechnology and AI, promising beneficial upgrades in the healthcare industry. Building on its primary focus, it is further enhancing its progress and innovation.

In this global landscape, India and South Korea are both excelling and emerging as vital powers in the Asia-Pacific with strong bioeconomies. The strengths of both countries, however, do not completely overlap, making any future collaboration a meaningful execution. India's biopharma and biotech industry has its main focus on a wide range of manufacturing and affordable production, whereas South Korea's market is largely dominated by biopharmaceutical companies for innovatives and structured R&D. With India's strength in mass manufacturing at a lower cost, and South Korea's R&D infrastructure and tech quality, we can reach even the most remote parts of the world with innovative yet affordable medications.

Moreover, further advancements in the field are still required, especially with the use of AI and robotics, and the effectiveness of therapeutic drugs, for instance, to deal with Antibiotic resistance, which people are currently facing in huge amounts, due to their excessive use. Although this study has explored several significant applications and technologies in medical biotechnology, it represents just a fraction of the field's vast potential, which has much more to offer in the future. With the advances in technologies and their commercialization, the requirement for more frequent updates of rules and regulations related to ethical and social concerns

will also increase. Overall, Medical biotechnology holds an enormous potential in shaping the upcoming generations; however, it must be regulated and handled with care and precision to minimise malpractices and bioethical issues.

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