THE NEXT FRONTIER
GLOBAL LEADERSHIP IN BIOPHARMA

Cutting-edge research, future-ready talent, next-gen infrastructure, judicious investments and strategic collaborations are crucial to fuel India's ascent as a biopharma powerhouse

By **Lakshmipriya Nair**

India has traced a journey of grit and glory to emerge as a major supplier of generic drugs and vaccines globally. Today, it is a key player in the global pharma landscape. However, as healthcare demands and the life sciences landscape evolves, it is now time to conquer new frontiers and expand its horizons far beyond generics.

With advancements in biotechnology, robust scientific capabilities, cost-effective manufacturing processes, a large workforce and a shift towards more complex biologic drugs, India is at the cusp of a huge opportunity to emerge as a leader in biopharma.

Brimming with potential

As per an Invest India report of 2023, the Indian Bioeconomy, valued at $137 billion in 2023, is targeted to reach $150 billion by 2025 and $300 billion by 2030.

IBER Report 2023 divulges, "The biopharma vaccines (non-COVID alone) market makes a significant daily contribution of approximately $38 million. On a monthly basis, this market adds around $1.16 billion." It adds, "India notably leads global vaccine supply by volume, producing nearly two billion doses annually."

The same report informs that "The biopharma therapeutics segment commands an annual value of $16.8 billion, On a daily basis, this sector generates approximately $46.03 million and contributes around $1.4 billion monthly."

The Invest India report reveals, "The rise in domestic demand is fuelled by initiatives such as Aatmanirbhar Bharat and Make In India, while overseas demand for Indian vaccines and biopharma is due to the globally competitive efficacy of Indian products. India has about three per cent share in the global biotechnology industry."

Thus, industry experts and analysts alike are bullish on India's biopharma sector. They point out the country's competitive advantages, including cost-effective production, skilled workforce, and a growing pipeline of new therapies.

However, despite the promise and potential, it won't be all plain sailing for India Biopharma Inc. To achieve true global leadership, the sector will have to address several critical challenges and capitalise on its unique strengths.

As Sibaji Biswas, ED and CFO, Syngene International cautions, "Several essential areas for improvement in the current ecosystem need addressing to unlock its full potential."

So, what are the challenges and complexities faced by India Biopharma Inc?

◆ **Limited investments in R&D and innovation is a major one.** Dr Arun Anand, COO and Board Director, Immuneel Therapeutics explains that risk aversion, longer timelines for ROI, lack of adequate early-stage funding, absence of an ecosystem that does not reward innovation hamper investments in biopharma R&D in India.

Sasmitha Sahu, Managing Consultant, GlobalData states, "While India has demonstrated success in generic drug production, the same is not true for novel and biosimilar biopharma products." He explains that there is limited interest in biopharma product research and development due to process-intensive and cost-intensive production associated with biopharma therapies, coupled with a complex regulatory environment and weaker IP framework that could translate to higher risks in this space."

Dr Cyrus Karkaria, President – Biotech, Lupin concurs, "India has a good network of research labs and well-developed base industries, a large pool of qualified scientific talent, several research labs and R&D institutions. Despite these factors, there are hurdles facing biotech innovation in India. Indian academia,

We have traditionally spent a lot of time on process engineering to make medicines affordable and accessible. However, now we need to strengthen our quality systems. We need to harmonise quality across the industry and with international standards

Dr Arun Anand (Immuneel)
COO and Board Director, Immuneel Therapeutics

It is imperative for Indian biotech players to understand the needs of their potential partners and global competitors. Meticulously tracking the changing global landscape, adapting quickly to change, and reinventing business models will require significant creativity and flexibility

Dr Cyrus Karkaria
President – Biotech, Lupin

Indian companies can leverage the latest biopharma innovation happening in academia and invest in R&D for novel biologics. Building public-private partnerships can aid in capability building, while favourable policies and financial aid by the government can foster industry growth

Sasmitha Sahu
Managing Consultant, GlobalData

Emphasising R&D, incentivising innovation through tax breaks and venture capital funding, along with investing in STEM education and research facilities will build a skilled workforce and a thriving ecosystem that can make India a successful global biopharma hub

Sibaji Biswas
ED & CFO, Syngene International

industry and research labs lack a strong patenting culture, and the academia-industry linkages are weak."

He adds, "Most academic and research institutions are not well equipped to undertake innovative and translational research. India needs support in setting up an ecosystem, in terms of scientific expertise and incubation centers with seed funding to help develop innovative ideas leading to sustainable growth."

◆ **Manufacturing and supply chain gaps also pose significant hurdles.** As India's biopharma sector tries to keep pace with evolving market demands and patient needs, modernising existing biopharma manufacturing facilities and building future-ready facilities are crucial for India's emergence as a biopharma global leader. This will be pivotal for ensuring quality compliance, managing cost pressures, and adapting to evolving regulatory standards too.

Dr Karkaria elucidates, "Manufacturing and end-to-end supply chain are pivotal components within the biopharma industry. Over the past few years, several emerging trends such as pricing and inflation, technology implementation, focus on sustainability practices, transition toward personalised and next generation therapeutics, and innovative healthcare delivery models, are compounding the complexities within manufacturing and supply chain operations. These trends serve as crucial catalysts, necessitating a shift in priorities and a much-needed transformation of the manufacturing sector."

He adds, "To sustain innovation and leapfrog to the next level, Indian players will have to focus more on preserving, optimising and investing capital, along with raising capital. Improving operating efficiency and building top-class infrastructure will be required to efficiently utilise capital amid funding constraints."

◆ **Lack of clarity in the IPR framework causes complexities.** A robust IP framework is essential for fostering innovation in the biopharma sector. India has made strides in improving its IP regime, but further reforms are needed to align with international standards.

The IP protection framework in India is perceived as weak, with concerns over patent infringement and compulsory licensing. This hinders innovation and foreign investment.

As Sahu highlights, "With India recognising patents on pharmaceutical products, there is an existing IP ecosystem in the country but a robust system with clear guidelines is still lacking to address

potential patent conflicts."

Slow and bureaucratic regulatory approval processes also often lead to delays in drug approvals and market access. Inconsistent enforcement of standards, lengthy approval timelines, and a lack of harmonisation with international regulatory practices are affecting India's growth trajectory in biopharma.

◆ **Plugging the skill gaps and retaining top talent is challenging.** While India has a large workforce, there's a need for more specialised skills in advanced biopharma technologies.

Pointing this out, Sahu says, "Biopharma sector is still in nascent stages in India. As with any sector, creation of ample training, career and growth opportunities will be pivotal to develop and retain top talent in the biopharma sector as well."

She underscores, "Changing advancements in digital innovations and a greater focus on data analytics means the skills employers need are shifting, changing the makeup of workforces across the sector. This also means employers are constantly in a state of assessing needs and hiring to ensure they have the right people in place to meet demand — the people who will create, develop and bring their solutions to market. Finding and retaining talent, however, has gotten more challenging due to a range of factors: skills gaps, greater competition within and outside the industry, and rising inflation.

SWOT ANALYSIS OF INDIA'S BIOPHARMA SECTOR

STRENGTHS

- Second-highest number of USFDA-approved facilities outside the US
- Large pool of skilled STEM graduates and scientists
- Strong position in generic drug production and vaccine manufacturing
- Cost-effective manufacturing capabilities
- Growing research base and increasing adoption of advanced technologies
- Established IT and data analytics expertise
- Experience in handling complex biologic projects with short turnaround times

WEAKNESSES

- Relatively low R&D investment compared to global standards
- Gaps in infrastructure and manufacturing facilities for advanced biopharma production
- Regulatory complexity and lack of clarity, especially around CRDMO businesses
- Limited focus on novel drug development and biosimilars
- Weaker intellectual property framework compared to some global leaders
- Skill gaps in cutting-edge biotechnology domains
- Need for modernisation of many existing facilities

OPPORTUNITIES

- Growing global demand for biopharma products and vaccines
- Increasing interest in India as an alternative to China (China plus one strategy)
- Potential for leadership in emerging areas like cell therapy and personalised medicine
- Scope for increased collaborations and partnerships with global pharma companies
- Leverage IT strengths to advance biopharma R&D and manufacturing processes
- Government initiatives supporting the sector (e.g., PLI scheme, PRIP, BIRAC grants)
- Growing domestic market for biopharma products

THREATS

- Intense global competition in the biopharma sector
- Rapidly evolving regulatory landscape and quality standards
- Potential brain drain of top talent to other countries
- Geopolitical tensions affecting global supply chains
- Rising costs of R&D and manufacturing in advanced biopharma areas
- Pressure on drug pricing affecting profitability
- Challenges in balancing innovation with affordability of medicines

Strategising for progress

So, what can be done to mitigate these risks and challenges? Let's take a look at the strategies and measures recommended by experts to make India a prominent biopharma hub.

◆ **Collaborate to conquer:** Experts emphasise collaborations are key to build and sustain a robust ecosystem for the biopharma sector. They recommend different kinds of partnerships such as fostering international tie-ups with leading biopharma companies and research institutions, encouraging PPPs to bridge the gap between academic research and commercialisation, developing consortia to tackle complex diseases and promote knowledge sharing etc.

For instance, according to Biswas, "Collaboration stands as a prerequisite in building a sustainable and scalable ecosystem within India's pharma sector, particularly through partnerships among raw materials manufacturers and the pharma product companies and the Contract Research Development Manufacturing Organizations (CRDMOs)."

He points out that to overcome the historical trend of sourcing from China due to cost advantages, we need to share knowledge and work cohesively with the thousands of local manufacturers to build capability and scale in the ecosystem. This approach will help overcome existing challenges and build on the opportunities shaped by the current geopolitical landscape.

Sahu recommends, "Indian companies can leverage the latest biopharma innovation happening in academia and invest in R&D for novel biologics. Building public-private partnerships can aid in capability building, while favourable policies and financial aid by the Government can foster industry growth."

She also suggests, "India can foster collaboration between the IT and the biopharma companies through government or private initiated collaborative channels - these can help facilitate discussions around latest technological advancements available that could help in overcoming challenges in biopharma drug development and advancement."

◆ **Embrace technology to transform:** Experts and observers also believe that technology will be the true gamechanger. With the immense potential of emerging technologies such as AI/ML, automation and data analytics, India can boost its strengths, mitigate risks and overcome its shortcomings across functions and processes in biopharma, like accelerating drug discovery and development, optimising clinical trial design, enhancing manufacturing processes through predictive maintenance and enabling supply chain efficiencies. They strongly urge the industry to leverage the huge potential of technology to catapult their growth.

Biswas outlines, "Adopting advanced manufacturing technologies, including continuous processing, digitally programmed manufacturing systems (MES) and deep learning based continuous process improvements are factors that hold immense promise for transforming biopharma production. Unlike traditional batch processing, continuous processing involves maintaining steady-state operations over extended periods, potentially increasing productivity manifold and reducing costs significantly. This shift is

facilitated by the need for smaller facilities, improved process control, enhanced product quality consistency, and more efficient facility utilisation. Regulatory bodies like the US FDA and EMA are supportive of this transition, encouraging manufacturers to embrace these innovations."

He adds, "Robust automation and digitisation for effective controls, and continuous manufacturing are likely to lead to productivity enhancements that far outweigh the initial investment costs. Like any other segment there is also an opportunity to build a layer of artificial intelligence that can continuously learn and improve the input parameters to enhance dependability and throughput of the manufacturing process. Indian pharmaceutical companies stand to significantly enhance their global competitiveness by aggressively pursuing these technologies, thereby positioning themselves as leaders in novel biopharma production."

Dr Karkaria highlights, "Digital technology, data analytics, and artificial intelligence (AI)/machine learning (ML) hold the potential to transform the entire R&D value chain, from the intricate stages of drug discovery to the complexities of clinical development. This transformation can enhance efficiency and productivity, reduce costs and timelines, and improve patient access and diversity. Leveraging its robust IT capabilities, India has the potential to spearhead advancements in this field globally, and propel the innovation trajectory of the country's pharma industry."

◆ **Reward research, incentivise innovation:** Biswas says, "Emphasising R&D, incentivising innovation through tax breaks and venture capital funding, along with investing in STEM education and research facilities will build a skilled workforce and a thriving ecosystem that can make India a successful global biopharma hub."

He also recommends, "Enhancing STEM education and aligning curriculum with industry needs can bolster the pool of skilled professionals. Collaboration between academia and industry is crucial to bridge the gap between academic research and commercialisation."

In his opinion, "Fostering a robust innovation ecosystem through policies supporting R&D, technology transfer, and faster regulatory approvals is essential. Strengthening regulatory frameworks and bringing in much required clarity and support will ensure compliance and accelerate biopharma advancements. These measures collectively can aim to elevate India's biopharma sector to global leadership by fostering innovation,

enhancing production capabilities, and nurturing a skilled workforce."

Dr Anand also opines that we need better synergies between biopharma players and investors. He adds that funding innovation requires a mindset that supports long-term growth and a scientific approach. He states that building a conducive ecosystem, improving R&D skills, fostering industry-academia collaborations, and developing an academic curriculum that rewards innovation are essential.

Dr Karkaria adds, "India must work to create such a favorable climate for attracting and managing investments, which in turn, fuel innovation. These have been facilitated by a climate of sizeable public funding, surpluses from traditional businesses of large corporations, protection for intellectual capital, vibrant venture capital participation, a competitive marketplace and a demanding environment for academic researchers."

He emphasises, "To bridge the industry – academia gap, Indian education should focus on providing expertise in the areas of novel drug development, bulk drug production technology, regulatory practices, latest techniques in testing and quality control, IPRs, among others. Soon, there would be a need for such specialisations as more research and manufacturing clusters are set up in India."

◆ **Improve IP framework, make regulations robust:** Strong intellectual property (IP) framework, empowered policies and effective regulations will be vital to fulfill India's ambitions to become a powerhouse in biopharma. A robust IP framework is crucial for India's biopharma sector to thrive globally since it encourages investment in high-risk, high-reward research, attracts MNCs to conduct R&D in India and protects innovations by Indian companies and researchers. While India has made some progress in strengthening its IP laws, further initiatives such as measures to reduce patent application backlogs, improve enforcement of IP rights and awareness programmes about IP protection among researchers and entrepreneurs.

Sahu recommends, "Fostering a robust innovation ecosystem through policies supporting R&D, technology transfer, and faster regulatory approvals is essential."

According to Dr Anand, our IP framework has been getting streamlined since 2005. However, our processes need to be faster and more transparent to foster innovation. He also roots for more focus on emerging areas like cell and gene therapies and says that we need an ecosystem and policies that support small companies in biopharma.

Thus the importance of a robust, clear, and supportive regulatory environment in fostering India's growth as a biopharma hub cannot be overstated.

◆ **Top notch talent is an imperative :** Building and retaining top talent in emerging biopharma areas require concerted and targeted measures like creating educational programs in advanced biotechnologies, offering competitive salaries and career development opportunities, fostering a culture of innovation and entrepreneurship within organisations, and providing incentives for researchers and scientists to return to India after gaining experience abroad.

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> *- IBER Report 2023*

Our experts concur with these points.

Biswas highlights, "India has over a long period exported talent to advanced economies of the world, especially the US. To build a robust Indian industry around innovation and latest scientific pursuits, it's important we leverage this vast talent pool and invite them back to India. There must be proactive efforts from the government through incentivisation and creation of an enabling environment for these talent pools to flourish and foster innovation in India."

Sahu recommends, "Strategic investments can be used to fund biopharma research and development (R&D) activities, build state-of-the-art facilities required for biopharma drug development and manufacturing, and to attract and retain top talent in the sector.

Dr Karkaria suggests, "Looking at current staff and providing appropriate training and career engagement to help them advance internally can help ensure that the company has the skills it needs to innovate ahead of the competition."

◆ **Quality should be the cornerstone :** "As global companies continue to face new challenges, it is imperative for Indian biotech players to understand the needs of their potential partners and global competitors. Meticulously tracking the changing global landscape, adapting quickly to change, and reinventing business models will require significant creativity and flexibility," underscores Dr Karkaria.

Dr Anand emphasises that we have traditionally spent a lot of time on process engineering to make medicines affordable and accessible. However, now we need to strengthen our quality systems. We need to harmonise quality across the industry and with international standards.

He also recommends that India should develop capabilities for manufacturing complex biologics and cell and gene therapies.

Sahu points out, "Notably, India has the most USFDA-approved plants outside of the US. Scaling up in terms of quality is a natural progression for the industry."

Advantage India

It is opportune that these measures are being implemented in India's biopharma sector to some extent. Industry stakeholders highlight some of them:

◆ **Government initiatives:** Biswas mentions, "Government initiatives like the Promotion of Research and Innovation in Pharma MedTech Sector (PRIP) scheme, Biotechnology Industry Research Assistance Council (BIRAC) grants, and the PLI scheme for APIs, along with the 'Make in India' program, promote domestic drug production and foster targeted research."

Sahu states, "Notably, government initiatives like Make in India, Atmanirbhar Bharat, and the National Biotechnology Strategy (2021- 25) are encouraging the growth of India's technological and product development capabilities in biopharma.

◆ **International collaborations:** Sahu informs, "India and the US are collaborating to establish the first-ever National Science Foundation and Department of Biotechnology joint funding opportunity that will support collaborative research proposals to promote biotechnology innovation and advance the bioeconomy. The latest launch of the Bio-5 Biopharmaceutical Supply Chain Consortium and the announcement by India and the US to initiate development of a joint strategic framework for building biopharma supply chain optimisation envisages a significant step in this direction."

◆ **IP framework:** Sahu mentions, "India has recently notified the DBT IP Guidelines in September 2023 to ensure seamless transfer of IP from academia towards commercialisation for the development of novel products."

◆ **Talent development:** Dr Karkaria notes, "In their efforts to engage and nurture future talent, organisations are creating specific talent communities and content plans. They are investing in technologies to improve engagement, such as platforms to facilitate learning and development, peer-to-peer recognition or collaboration."

He adds, "Majority of Indian biopharma companies are investing in diversity, equity and inclusion (DEI) to enhance the talent experience during the talent acquisition process."

◆ **R&D breakthroughs:** Sahu

highlights, "Recently, there have been some breakthrough developments by Indian biopharma including the development of the first indigenous chimeric antigen receptor (CAR) T-cell therapy in India for the treatment of r/r B-cell lymphomas and leukaemia."

◆ **Global interest:** Dr Karkaria states, "India has become a chosen destination for collaborative R&D, contract research and manufacturing and clinical research as a result of growing compliance with internationally harmonised standards such as Good Laboratory Practices (GLP), current Good Manufacturing Practice (cGMP) and Good Clinical Practices (GCP)."

He adds, "The Indian biopharma industry is on the brink of becoming a major global force in terms of manufacturing and research capabilities. We are witnessing dynamic changing trends such as large acquisitions by multinational companies in India, increasing investments, deeper penetration into the rural markets, growth and availability of healthcare and incentives for setting up special economic zones (SEZs)."

◆ **Start-up ecosystem:** He informs, "Over the last couple of years, India has emerged as a leader in the startup arena which reflects new, innovative entrepreneurial talent. This culture needs to be nurtured, which is possible only if we reward this talent and create a business environment in which commercial exploitation of new ideas are realised with ease. Only then can tomorrow's giant businesses emerge from today's unicorns."

As per IBER Report 2023, in 2022, 1390 new biotech startups joined the ecosystem, bringing the 10-year total to 6,755, at a CAGR of 29.8 per cent. The cumulative base grew to 6,755 from 732 startups in 2015—a multiple of almost 9.2 times in seven years."

◆ **Geopolitical factors:** Biswas elaborates, "The pandemic highlighted the vulnerabilities of global supply chains, making diversification a strategic imperative. The BioSecure Act, which mandates a phased reduction in Chinese dependencies by 2032, underscores the need for the global pharma companies to recalibrate their global supply chain strategies. Over the past few quarters, we have seen a steady shift, presenting significant opportunities for Indian CRDMOs to leverage the evolving pharma ecosystem and the large skilled workforce to attract global pharma companies. This positions India as a viable and resilient alternative to China. By capitalising on these strengths and navigating the evolving global landscape, we can solidify our position as a leader in the biopharma sector."

An ongoing quest

Thus, India's biopharma industry stands at a pivotal juncture. To grow and progress, the industry stakeholders will have to align with international standards for drug quality, minimise manufacturing failures, and expedite market delivery, which, in turn, demands a multifaceted approach to usher significant improvements in operations, quality compliance, and control strategies.

By addressing current gaps, leveraging its strengths in IT and manufacturing, and implementing strategic initiatives, India has the potential to emerge as a global leader in biopharma innovation. Success will require coordinated efforts from government, industry, and academia, but the rewards – in terms of growth, job creation, and improved global health outcomes – make it a worthy pursuit.

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