BioSpectrum
the business of Bio & Health Sciences

BioPharma’s Transformative & Strategic Outlook 2025

01 December 2024 | Features | By Shivani Thakar

The Indian biopharma industry witnessed notable transformative developments and announcements, marked by innovation, regulatory advancements, and market expansion this year. From achieving global recognition in biosimilars to advancing biomanufacturing capabilities and precision therapeutics, the sector has solidified its role as a key player in the global pharmaceutical landscape. This progress underscores India’s strategic focus on leveraging its robust infrastructure, skilled talent pool, and government support to meet the evolving demands of the healthcare industry. Key developments in 2024 include an increase in biosimilar approvals, enhanced collaborations for biologics and vaccines, and a focus on potential investments in cutting-edge technologies like Artificial Intelligence (AI), continuous manufacturing, and automation through biofoundries. Looking ahead, the industry is well-positioned to align with emerging trends that are shaping the global biopharma landscape for 2025 and beyond. These include the growing emphasis on precision medicine, a shift towards sustainable biomanufacturing practices, and an increase in demand for advanced therapies such as cell and gene therapies. With over $200 billion worth of biologic patents set to expire by 2030, Indian companies are poised to play a pivotal role in driving the next wave of innovation and accessibility in biologics and biosimilars. Let’s explore further.

The Government of India has introduced several Production Linked Incentive (PLI) Schemes aimed at enhancing domestic manufacturing and attracting significant investments in the life sciences-related sectors. Additionally, initiatives like ‘Make-in-India’, the National Biopharma Mission (NBM), as well as new provisions from the Anusandhan National Research Foundation (ANRF), to name a few, are set to boost innovation and technological prowess. Key highlights of 2024 included the approval of the BioE3 (Biotechnology for Economy, Environment and Employment) Policy for biomanufacturing, the Bio-RIDE scheme, Vigyan Dhara scheme. The Union Budget 2024 also focussed on ramping up HPV vaccination efforts and announcing new provisions for the biopharma and healthcare sectors through initiatives like the ANRF. The biopharma sector also saw an influx of startups, SMEs, and international companies in 2024, focusing on precision medicine, biosimilars, and biotherapeutics.

Integration of advanced technologies like bioinformatics, data analytics, and artificial intelligence in bioresearch services is poised to accelerate, enhancing research capabilities and driving growth in BioIT/Research Services. A report by WNS, a leading Business Transformation company, states that the transformation of the pharma sector, globally, in 2025 will rely on technologies such as Artificial Intelligence (AI), Machine Learning (ML), Internet of Things (IoT), data-driven platforms and blockchain. Innovation in the future will take place on the back of digital investments in supply chains, clinical trials, and

drug development. Personalised patient-centric healthcare will also become the norm.

Other key upcoming trends include the global biosimilars market, therapeutics innovation and sustainable bio-industrial practices. Tech integration in the bio IT/research services will also be a major driver in the coming years. Expanding global acceptance of Indian-made biosimilars presents a lucrative opportunity for the biopharma sector to capture a larger market share in developed countries. Continued advancements in biopharmaceuticals, personalised medicine, and precision treatments are expected to propel the therapeutics segment forward.

Considering the digital healthcare perspective, ***Arvind Vaishnav, Head, Philips Innovation Campus and Innovation Partnerships – Growth region, Philips, Bengaluru says, "****The emphasis on automation across healthcare is likely to increase as globally, there is a concerted effort towards addressing staff shortages and at the same time relieving staff of repetitive tasks and processes. Needless to say, this will also save healthcare professionals time, allowing them to spend more time with what's more critical, spending time with patients. We are already witnessing this with generative AI functioning as a virtual assistant, organising clinical notes and simplifying ways patient information is communicated across teams. It is also now apparent that AI will be adopted beyond automation. It is proven that AI can help simplify complex diagnostics, enabling less experienced professionals to provide high-quality care with confidence. Imagine, AI embedded in ultrasound systems. It allows physicians to detect, diagnose and monitor cardiac conditions more confidently and efficiently.*

From a technology perspective, it is also interesting to see how introduction of new technologies in interventional care, minimally invasive procedures are becoming more advanced and hence more common. Having said that, this implies the need for Physicians to collect and analyze data from a wide range of sources, such as live X-ray images, 3D ultrasound, Intravascular Ultrasound (IVUS), to name a few all the while closely monitoring the patient. Hence, integration of systems, software and devices will become increasingly important. This integration allows interventional physicians to treat patients with greater control and confidence during every stage of minimally invasive cardiac procedures.

While we focus on technology trends in healthcare, it would not be complete without the mention of what is likely to gain traction in 2025: transition towards managing health outside of the hospital. Advances in technology solutions is expected to support remote detection of patient health risks based on vital signs and other data. According to our 2024 Future Health Index report, remote patient monitoring will be the biggest area of planned AI implementation over the next three years, with 41% of healthcare leaders intending to invest in it. This will not only help prevent complications and hospitalisations with timely interventions, but also improve quality of life for patients.''

Increased Focus on Biomanufacturing

The government introduced the BioE3 policy, a strategic framework designed to propel India into the next era of industrialisation through high-performance biomanufacturing. The BioE3 Policy, approved on August 24, 2024, chalks a strategic roadmap to making India a global biomanufacturing hub by promoting high-performance biomanufacturing through innovation for the development of bio-based products and building an infrastructure that enables scale-up and commercialisation. The six thematic areas of focus highlighted in the BioE3 Policy include bio-based chemicals and enzymes, functional foods and smart proteins, climate-resistant agriculture, carbon capture and utilisation, futuristic marine and space research, and precision biotherapeutics. The policy draws attention to biologics/biotherapies like cell and gene therapy, mRNA therapeutics, monoclonal antibodies, immunotherapy, as well as next-generation vaccines.

In line with these, with a growing portfolio of biosimilars, India has the potential to become a global leader in biotherapeutics. This trend includes precision therapies targeting specific disease markers, such as cancer and autoimmune diseases, highlighting India's ambition to meet rising global demand.

Catalyst to the reaction setup, India's interest in biofoundries is growing, with biofoundries being positioned as a critical infrastructure for the high-throughput design and testing of genetically engineered organisms. To integrate digital automation and robotic systems to scale up the production of cell lines, proteins, and other biologics, this focus aligns with the government's biomanufacturing push, signalling a shift toward advanced, automated production capabilities.

Biofoundries hold the potential to emerge as the backbone of biomanufacturing and synthetic biology, offering integrated infrastructure to streamline the design, construction, and testing of genetically engineered organisms. Biofoundry is a place where biomanufacturing meets automation. The highly modular structure of a biofoundry helps accelerate the design-build-test-learn (DBTL) workflow to deliver products fast and in a streamlined fashion. Advanced platforms to enable rapid, high-throughput experimentation, and automating processes that were once labour-intensive and time-consuming is a central theme.

Innovation-driven biomanufacturing - to develop new biologics, vaccines, gene therapies, and diagnostics - is underway across the globe. Biofoundries are instrumental in revolutionising biotechnology for healthcare, agriculture, and environmental sustainability - from personalised therapies and advanced biologics in healthcare to synthetic fertilisers and sustainable bio-based materials in agriculture. India, too, has come up with multiple initiatives to support and set up biofoundries, such as the BioE3 Policy, the Bio-RIDE scheme, and the Vigyan Dhara scheme. The BioE3 Policy lays out plans for accelerating the transition to biomanufacturing by promoting integrated use of Artificial Intelligence (AI), digitalisation with ‘omics’, and upstream biotechnology innovations through bio-AI hubs, biofoundries, and biomanufacturing hubs across the country.

With the new BioE3 Policy in place, coming years will provide insight into how biofoundries will play a role in boosting innovation, scale-up and commercialisation of bio-based products. In addition, with a Global Biofoundry Alliance now established to coordinate biofoundry activities and innovations worldwide, India is positioning itself in this rapidly evolving field, through the establishment of biofoundries infrastructure to advance India’s biomanufacturing goals.

A May 2024 report by Frost & Sullivan, exploring the topic of Contract Development and Manufacturing Organisations (CDMOs) empowering the large-scale production of biologics, reveals that CDMOs are advancing the biopharmaceutical industry with superior biomanufacturing capabilities. The biopharmaceutical industry is expanding rapidly. More biologics programmes have entered late clinical and commercialisation stages globally. The number of FDA-approved biologics and cell/gene therapies rose from 11 in 2019 to 24 in 2023. In 2023, more than half of the top 10 best-selling drugs were biologics with five monoclonal antibodies, one polypeptide, one vaccine, and three chemical drugs. This demand calls for scaling up commercial production, and efficiency has become essential to enterprises. Due to the trend of specialisation and especially contract development, the global biopharmaceutical landscape is increasingly shaped by CDMOs undertaking commissioned productions and offering unique solutions with higher added value.

Production expansion for a more complex category of biologics is facilitated by the flourishing industry, accelerated drug approvals, and booming global demand for biosimilars. This is an opportunity for biologics CDMOs who can address the high costs of self-built production lines, limited experiences in R&D and production, and other challenges faced by traditional pharmaceutical companies. The global market size of biologics CDMOs has grown significantly from $13.3 billion in 2018 to $29.3 billion in 2022 and is projected to reach $58.1 billion by 2026 and $100.4 billion by 2030.

The report also states that manufacturing capacities are shifting towards the Asia-Pacific region. CDMO services are rising in the Asia-Pacific region because biopharmaceutical companies are seeking cost-effective and efficient R&D and manufacturing services to address the increasing demand. Global biopharmaceutical production capacity and consequently CDMOs are shifting towards this region as a result of continued efforts in improving infrastructure, industry chain supply, project management, quality management systems, and intellectual property protection. Establishing international production facilities and R&D centres are essential strategies for CDMOs in the Asia-Pacific region to enter the global market.

With India aiming to implement large-scale biomanufacturing initiatives, boosting talent and investments in biotech and biopharma, in addition to global developments like the US Biosecure Act, this trend in the biopharma industry holds significance for APAC’s leading biopharma hub.

Cell and gene therapy

In October 2023, the Central Drugs Standard Control Organisation (CDSCO) approved NexCAR19, India's domestically developed CAR-T cell therapy - the world's most affordable CAR-T cell therapy; and in 2024, the therapy has been made available to patients at several cancer centres/hospitals. In a recent success story from Bengaluru-based Eyestem Research, the company announced a positive outcome of the Drug Safety Monitoring Board (DSMB) review for the first cohort of its Phase one trial to treat Geographic Atrophy secondary to Dry Age-related Macular Degeneration. Eyestem's lead product, Eyecyte-RPE, is a patented suspension of retinal pigment epithelium cells aimed at combating geographic atrophy arising from Dry AMD. This pioneering treatment marks a major milestone in the global fight against vision loss, as it has the potential to replace damaged retinal cells.

With the BioE3 policy focussing on cell and gene therapy as part of the precision biotherapeutics space, this as-yet niche area is set to get a boost in the coming year. For example, larger, established companies like Miltenyi Biotech, and Intas Pharma are also entering into the cell and gene therapy space in India. Miltenyi Biotec, a global leader in biomedical solutions, has announced the signing of a Letter of Intent with the Translational Health Science and Technology Institute (THSTI), an autonomous institute of the Department of Biotechnology, Ministry of Science and Technology. With this partnership, both organisations aim to address the growing need for innovative treatments in the fight against cancer through cell and gene therapies. The purpose of this collaboration is to focus on leveraging the strengths of both organisations to enhance research and development in cell and gene therapy focusing on cancer and sickle cell disease. This collaboration would help in capacity building, technology transfer, training programmes, and joint research initiatives which would then be translated into medical therapies.

Vaccine Innovation

India's vaccine manufacturing is poised for further growth, supported by the Government of India's Production Linked Incentive (PLI) scheme, encouraging the use of new technologies to expand capacity. Additionally, international collaborations with countries such as the US, Japan, and Australia are aiding India in enhancing its capabilities. While challenges remain in making advanced, next-generation vaccines accessible and affordable for India's large population, continued investment, technological progress, and strategic policies position India as a key player in global vaccine innovation and production. India's current focus on interdisciplinary research, government support, and collaborations seems to be laying the groundwork for sustainable vaccine innovation.

Novel vaccine platforms are emerging worldwide. COVID-19 has resulted in an innovation surge in vaccine development globally. The advent of the COVID-19 pandemic brought the mRNA technology to the forefront. Beyond Pfizer and Moderna, who were pioneering leaders in bringing mRNA vaccine platform to the community, the indigenously developed 'GEMCOVAC-19' vaccine is the only third mRNA vaccine to be approved for COVID-19 in the world and is the very first mRNA vaccine developed in India in June 2023. Developed by Pune-based Gennova Biopharmaceuticals in collaboration with the Department of Biotechnology (DBT), this Omicron-specific mRNA (booster) vaccine 'GEMCOVAC-OM' is thermostable, which does not require ultra-cold chain infrastructure used for other approved mRNA-based vaccines, making it easy for deployment pan India. It is delivered intradermally using a needle-free injection device system.

In May 2024, biopharma companies Gennova and Emcure announced the resumption of their mRNA collaboration with US-based HDT. The long-term agreement will focus on developing mRNA vaccines against a broad range of infectious diseases, in India and several other countries. As part of their agreement, HDT has granted a license to Gennova to use HDT's patented mRNA vaccine technology in multiple fields. In September 2024, Hyderabad-based Bharat Biotech announced a collaboration with US-based Alopexx, Inc., for the co-development and commercialisation of Alopexx's proprietary broad-spectrum anti-microbial vaccine, AV0328, in India and other low-income and lower-middle-income countries. As part of the collaboration, the companies will co-develop and commercialise AV0328, a synthetic vaccine targeting poly N-acetyl glucosamine (PNAG), in India and other licensed territories. A phase I, first-in-human trial has been completed, demonstrating that AV0328 is well-tolerated with no serious adverse events observed. The vaccine-induced antibodies are capable of killing a wide range of PNAG-expressing pathogens, reaffirming its potential as a broad-spectrum antimicrobial solution.

Looking ahead, India's new government policies and the global scenario could start shaping the trend in the direction of vaccine innovation in the coming year - looking to expand its research and development of next-gen vaccines, bridging gaps with faster, more economical platforms to address both local and global health challenges.

Growth in Biosimilars

During September and October 2023, The Organisation of Pharmaceutical Producers of India (OPPI) and EY conducted primary research with the CXOs of the leading Indian and global multinational pharma companies, contract research development and manufacturing outsourcing organisations (CRDMOs), startups, patient advocacy groups, and other organisations to understand their perspective about the potential ambition for the pharma and healthcare sectors in the country for India@100. The report sheds light on some elements of the country's pharma/biopharma sector that we can expect to see growing in the coming year(s).

The report conveys that the research pointed out three goals for the industry: Become the innovation powerhouse of the world, become an integral part of the global pharma supply chain, and achieve sustainable and equitable healthcare access for all.

The report also states that as the competition and pricing challenges in the generics market continue to grow, some Indian companies have started venturing into the less crowded complex generics space. Biosimilars are increasingly becoming a focal point for India. Continued endeavours are underway in the realms of new chemical entities (NCEs) and new biological entities (NBEs).

India's position as an emerging leader in the global biosimilar market, emphasises the country's capabilities, growth trajectory, and strategies to address accessibility and affordability in healthcare. Valued at $349 million in 2022, the Indian biosimilars market is projected to grow to $2.1 billion by 2030. It represents nearly 20 per cent of the domestic pharmaceutical market, with sales expected to double from $6 billion in 2022 to $12 billion by 2025.

India approved its first biosimilar, a hepatitis B vaccine 2000, ahead of the US and Europe. Over 100 biosimilars have since been approved, covering vaccines, insulin, and monoclonal antibodies. Indian biosimilars are exported to highly regulated markets like North America, Europe, and Japan, fueled by the expiration of over 55 biologic patents globally between 2022 and 2032.

With advancements in technology and support from government initiatives, Indian companies are set to drive significant global impact, delivering affordable and high-quality biosimilar therapies to meet growing healthcare demands. To put this in perspective, this is a critical factor for an emerging and growing market like India as biologics worth over $200 billion are set to go off-patent by 2030, an opportunity in the waiting for Indian companies to grab.

Leading Indian firms in this space are expected to take advantage of the off-patent regime and further penetrate the global biosimilar markets by providing low-cost high-quality medicines. The pipeline for biosimilars in India is robust, fuelled by the government's initiative to offer subsidies to the local biosimilars manufacturers. This growth is also driven by the Central Drugs Standard Control Organisation (CDSCO)'s aligning guidelines closely with global regulators, including the United States Food and Drug Administration (USFDA) and the Medicines and Healthcare Products Regulatory Agency (MHRA).

Bengaluru-based Biocon Biologics has been a leader in this category. Over the last year, Biocon has further expanded its biosimilar portfolio with new product offerings and has deepened partnerships in the US and Europe to strengthen distribution channels. The company has also invested in its R&D pipeline for oncology and immunology treatments, reflecting a broader industry trend towards biosimilars.

A Forward-looking Strategy

Significant milestones in India's biopharma industry over the past year include advancements in biosimilars, novel biologics, and precision medicine, along with scaling manufacturing capabilities to meet international standards. Industry leaders have embraced cutting-edge technologies such as AI-driven drug development, continuous manufacturing, and biofoundry automation, driving innovation and efficiency. The growing pipeline of biosimilars and biologics, coupled with increasing regulatory approvals in global markets, reflects the sector's commitment to quality and compliance. This progress aligns seamlessly with emerging trends anticipated for the coming year.

As numerous Indian companies embark on their journeys into the realms of ADCs, DNA and RNA-based vaccines and therapies, and cell and gene therapy, India is poised to undergo a transformative shift, progressing toward its Discovery 1.0 phase. The global focus on personalised healthcare, rising demand for biologics, and increasing adoption of advanced biomanufacturing technologies will create opportunities for Indian biopharma to expand further. The industry's emphasis on affordability, accessibility, and innovation positions it to address the global demand for cost-effective therapies, particularly in regions facing healthcare inequities.

As India continues to leverage its strengths—such as a skilled workforce, robust infrastructure, and government support—2025 promises to be a year of greater collaboration, research breakthroughs, and market expansion. With a forward-looking strategy, the Indian biopharma sector is not only poised to sustain its growth trajectory but also to redefine its role as a global hub for biopharma innovation and excellence.

Shivani Thakar

shivani.thakar@biospectrumindia.com