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Biopharma Industry in India: Trends in Technology

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A Report by Cactus Communications, written by Dr H. S. Sudhira, Director, Gubbi Labs

The biopharma industry in India has been growing at a considerable rate with the constant development of new and emerging technologies. The transformation of Indian pharmaceuticals industry into biopharmaceutical industry stands as a testimony to this change. The growth was fuelled by changes in policy, the rise in third-party manufacturing and outsourcing activities, the strategic acquisition and partnerships with foreign entities, India's proficiency in reverse-engineering patented drugs, and its efforts to adhere to the World Trade Organization's (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPs) commitments and complimented by adopting to latest technological trends. Before India entered the WTO in 1995, its pharmaceutical exports were below $600 million in value. A decade later, in 2005, export values soared to $3.7 billion, making up over 61 percent of the pharmaceutical industry's revenue[1]. This shift towards more complex and high-value biological drugs began over the past two decades as outcome of the above changes.

In recent years, biologics and biosimilars have emerged as crucial components of the healthcare sector, offering novel treatment options for various diseases. Vaccines also play a vital role in public health by preventing the spread of infectious diseases and saving countless lives worldwide. In addition, certain emerging technologies like cell and gene therapies are ushering a new era for biopharma industry in addressing the global healthcare challenges.

Over the past decade, biologics and biosimilars have taken centre stage in medical advancements. Their potential in treating diseases previously considered untreatable, such as certain types of cancer, autoimmune disorders, and rare genetic conditions, has changed the face of healthcare. India, with its robust biotechnology and information technology sectors, has embraced this shift and is making significant strides in the development and manufacturing of biological drugs. Some of the significant trends in development of biopharma industry in India are predominantly bio-contract development and manufacturing organisations (CDMOs), harnessing artificial intelligence and data analytics, and regulatory reforms. The key trends that are shaping this exciting and transformative niche in India's biopharma sector are explored in these chapters.

Emergence of Bio Contract Development and Manufacturing Organisations

Over the years, India has made a significant place for itself on a global scale in the production of generic drugs. The transition has been marked by the emergence of bio–Contract Development and Manufacturing Organisations (CDMOs), mirroring trends in China and South Korea. These organisations play a crucial role in helping companies develop and commercialise their products, offering comprehensive services from drug formulation and development to manufacturing and regulatory

submissions, thus playing a pivotal role in biologics, biosimilars and vaccine production and supply chain.

CDMOs play an indispensable role in biologics and biosimilars production and their supply chain in India. Indeed, the country is transitioning from being primarily a generics powerhouse towards becoming a hub for high-value drugs. This transition from being predominantly generic to focusing on advanced biologics is significantly altering the market dynamics. The increased use of CDMOs can impact the speed of biologics and vaccine development, as these organisations can provide a multitude of services at one location, from initial development to full-scale manufacturing. As such, they are shaping a new era in biologics and vaccine development in the region.

Growth and contribution of Indian bio-CDMOs

The Biologics CDMO Market size is expected to grow from $13.58 billion in 2023 to $24.77 billion by 2028, at a CAGR of 12.78% during the forecast period (2023-2028)[2]. This growth is driven by an increasing number of companies within the pharmaceutical sector considering outsourcing services. In India, domestic formulations by CDMOs are projected to grow at a CAGR of 14% by FY25[3].

Indian CDMOs have built world-class facilities to cater to global business requirements[4]. They have been helping develop innovative therapies and have asserted themselves as world-class chemistry-service providers[5]. They play a critical role in the biopharmaceutical ecosystem and are already contributing to the development of novel biopharmaceuticals[6]. They also play a significant role in the production of small-scale clinical batches to large-scale commercial production.

Harnessing the Power of Artificial Intelligence and Data Analytics

The integration of artificial intelligence (AI) and machine learning (ML) in enhancing our understanding of diseases and vaccine development is another transformative trend observed in the Indian biopharma industry. Leveraging India's IT prowess, AI-driven pharmaceutical innovations are expected to lead the way forward. India's vast clinical trial data can be analysed using innovative AI techniques for secondary data analysis, accelerating the drug discovery process.

AI and ML can collate and analyse massive amounts of data to predict antigenic shifts, thereby accelerating vaccine development. AI technology was notably deployed in the development of the COVID-19 vaccines, where it played a crucial role in rapidly identifying the coronavirus genome structure, enabling scientists to develop vaccines in record time.

Moreover, AI algorithms have the potential to enhance patient stratification, tailoring treatments in an unprecedented manner, thereby providing personalised medicine opportunities. Incorporating AI into biologics, biosimilars and vaccine development is revolutionising the way the industry operates, enhancing efficiency and productivity, and fostering innovative breakthroughs. Additionally, the wealth of clinical trial data available in India provides an invaluable resource for advanced data analysis, offering potential for breakthrough insights and innovations.

Furthermore, AI and ML algorithms have expanded the capabilities of R&D in biopharma by easing the identification of disease targets, optimising drug development processes, improving efficiencies, reducing production errors, and contributing to predictive and preventative healthcare.

Regulatory Reforms: Fuelling Innovation

Regulatory reforms are a key enabler of innovations. Recognising this, the Indian government has streamlined its processes to facilitate faster approvals of biologics and biosimilars, accelerating the speed-to-market of these critical drugs. Key initiatives, such as the New Drugs and Clinical Trials Rules, have been launched to hasten development and approval processes. A simplified and expedited regulatory process can potentially lead to quicker market access for innovative treatments, benefiting both the industry and patients. The Indian regulatory authority, the Central Drugs Standard Control Organisation (CDSCO)[7], in collaboration with the Department of Biotechnology (DBT), developed “Guidelines on Similar Biologics; Regulatory Requirements for Marketing Authorisation in India” in 2012, which were revised in 2016. This has

implemented guidelines for the approval and regulation of biologics including similar biologics (biosimilars)[8], ensuring safety, efficacy, and quality.

[1] The Emergence of India's Pharmaceutical Industry and Implications for the U.S. Generic Drug Market - U.S. International Trade Commission (usitc.gov)

[2] Biologics CDMO Companies - Market Size, Share & Growth (mordorintelligence.com)

[3] The Future of Pharma: Are CDMOs shaping up a more holistic industry (indiatimes.com)

[4] The Rise of Biopharmaceutical Outsourcing to Indian CDMOs - BioProcess InternationalBioProcess International (bioprocessintl.com)

[5] Big ambitions for India's contract research firms (acs.org)

[6] Frontiers | CDMOs Play a Critical Role in the Biopharmaceutical Ecosystem (frontiersin.org)

[7] CDSCO (cdsco.gov.in)

[8] Guidelines_on_Similar_Biologics_06_10_2017.pdf (birac.nic.in)

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About Gubbi Labs
Gubbi Labs is a private research collective that works on various domains ranging from sustainable ecosystems to liveable settlements. As part of its science communication initiative, it runs Research Matters, a multilingual science news portal.

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Cactus Communications is a science communication and technology company, accelerating scientific advancement by making science globally accessible.

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