

Biopharma Industry in India: Vaccines

30 August 2024 | Features

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Vaccine manufacturing is a critical aspect of the health sector that has received significant attention over recent years, primarily exacerbated by the global health crisis. With the increasing demand and urgency of vaccine production, several significant revolutions, particularly centred on technology, have transformed the operation and efficiency of vaccine production.

India, being one of the largest vaccine manufacturers globally, plays a pivotal role in this realm.

Indian pharmaceutical companies such as Serum Institute of India and Bharat Biotech have widely used these technological innovations to upscale their production capabilities, thus contributing to the much-needed requirement of vaccine doses globally. Flowing with the wave of technology, India has rolled out vaccines for COVID-19 in record time, further demonstrating the country's prowess.

During the pandemic, India demonstrated its agility by scaling up vaccine production rapidly. Equitable access to vaccines was ensured through resilient supply chains and logistics. India's commitment to global health equity is exemplified by its participation in international vaccine initiatives. The country has played a significant role in initiatives like Gavi, the Vaccine Alliance, and the Global Polio Eradication Initiative, aiming to provide affordable vaccines to vulnerable populations and

eradicate diseases. India, supplied 242 million low-cost and high-quality vaccines to 101 countries, embodying the spirit of **Vasudhaiva Kutumbakam** (the world is one family)[1].

Over the last two decades, Indian pharmaceutical companies invested heavily in vaccine manufacturing. India dominates the production of vaccines for diseases like measles, BCG, and DPT. Approximately 90% of the global demand for measles vaccines is met by India. India supplies around 60% of the world's vaccine demand. The World Health Organisation (WHO) sources 65-70% of its vaccine requirements from India.

Several factors have contributed to India's prominence. This strategic position can be attributed to a robust enterprise ecosystem, favourable government policies, and the increasing adoption of emerging technologies aiding vaccine development. The country has become a global hub to produce vaccines, supplying low-cost, high-quality products worldwide as an outcome of these multiple enabling factors.

India has embraced technology trends in vaccine manufacturing and focused on capacity building. This includes advancements in cGMP (Current Good Manufacturing Practices), implementation of quality assurance processes, and collaboration with international organisations. As a result, Indian vaccine manufacturers have been able to comply with stringent regulatory standards and export vaccines to countries worldwide.

Indian vaccine manufacturers have forged strategic alliances and research collaborations with global pharmaceutical companies, research institutions, and international organisations. Such partnerships have helped in technology transfer, knowledge sharing, and research collaborations, enhancing India's vaccine manufacturing capabilities.

Technology trends in Vaccine Development

Technological advancement in the biopharmaceutical sector is a driving force propelling vaccine development to unprecedented heights. Amid this backdrop, India, often referred to as the 'Pharmacy of the World,' harnesses its robust vaccine manufacturing capabilities to address global public health problems. With the advent and proliferation of biotechnology, the last decade has witnessed an array of technological trends transforming the vaccine development landscape in India.

Investment in research and development is another key aspect bolstering these technological advancements. The industry focuses not just on enhancing the current platforms, but also on the discovery and development of novel technologies. For example, Indian firms are researching the development of mRNA vaccines, a cutting-edge technology harnessed in the COVID-19 vaccines developed by Pfizer-BioNTech and Moderna. These trends have revolutionised not just the research and development processes, but also production, quality assurance, and distribution. Some of the technological trends that shape vaccine development in India are explored in the following sections.

Molecular Techniques and Advancements

In traditional vaccine development, pathogens are typically grown in labs, and then weakened or killed to stimulate an immune response. However, recent technological advancements have allowed for more targeted and efficient vaccine development. Molecular techniques like DNA recombination and protein engineering are significant technological trends that have driven the development of recombinant vaccines such as those against Hepatitis B and HPV in India.

Cell Culture Technology

Cell Culture Technology has offered novel methods to develop vaccines. Traditional vaccine manufacturing often involved growing viruses or bacteria in eggs or animals. However, modern techniques using cell culture and recombinant DNA technologies have been developed. This technology allows for more controlled and scalable vaccine production, addressing the urgent need for volume production of vaccines during outbreaks such as COVID-19. This approach enables efficient vaccine production by growing cells in culture, eliminating the need for eggs or animals as hosts. This method facilitates a more flexible and cost-effective process with higher production yields. Several leading biopharmaceutical entities in India like Stells Biopharma, Sartorius, Lupin, Jubilant Biosys, Syngene, among others have adopted this approach, leading to more

efficient vaccine production processes.

High-Throughput Screening Techniques

High-throughput screening (HTS) techniques have emerged as a powerful tool enabling the rapid identification of candidate vaccine antigens. These techniques allow researchers to screen thousands of drug candidates simultaneously. HTS has the potential to streamline the extensive and at times uncertain process of vaccine development, thereby increasing the efficiency and output of the biopharma industry in India.

Nanotechnology

The application of nanotechnology in vaccine development is another technological trend in India's biopharma industry. Nanoparticles can be engineered to mimic viruses, thereby safely inducing a strong immune response. This technology enables the targeted delivery of vaccines, reducing potential side effects, and enhancing the efficacy of the immune response. Indian biopharma industries have shown a keen interest in exploiting these benefits in their vaccine development efforts.

Continuous Flow Processing

Batch processing was traditionally employed in vaccine manufacturing, with each batch being subjected to independent testing and validation. However, there is a perceptible move towards continuous flow processing. Unlike batch processing, continuous flow systems allow raw materials to enter the system without stoppages. This real-time operation significantly enhances efficiency and reduces production times. With the ability to monitor and adjust the production process instantaneously, this technology is paramount for ramping up vaccine production to meet the escalating demand during emergencies such as the ongoing COVID-19 pandemic.

Integrative Manufacturing

The traditional vaccine manufacturing process is often segmented into various stages like cell culture, downstream processing, purification, and formulation. The move towards integrative manufacturing highlights a trend in vaccine production where different stages are interconnected and streamlined. This manufacturing model, propelled by automation, seeks to reduce human errors, enhance efficiency, and expedite the output.

The Future of Vaccine Development in India

While these technological trends have undeniably boosted vaccine development in India, support from the GOI has been immense. The GOI actively fortifies its biopharma sector with schemes aiming at strengthening the pharmaceutical industry and encouraging innovation. The Production-Linked Incentives (PLIs) scheme fosters vaccine development using emerging technologies with financial overlays planned to spur capacity expansion. Furthermore, global partners such as the USA, Japan, and Australia are also collaborating and aiding India in enhancing its vaccine manufacturing capacities.

Additionally, the accessibility and affordability of these technologically advanced vaccines for the vast Indian population are matters of concern. Nonetheless, with continuous technology advancements, strong investment, strategic policies, and collaboration amongst stakeholders, India's biopharma industry is set to revolutionise vaccine production and distribution. As evident in the handling of the COVID-19 pandemic, techno-scientific advancements have robust potential in addressing global health crises, thereby strengthening India's position on the global health map.

The intersectionality of technology and vaccine manufacturing is evident in India's biopharma industry. This fusion is propelling an unprecedented pace of innovation in vaccine development. The continuous investment in research and adoption of novel technologies coupled with the government's supportive initiatives makes India a beacon in global vaccine manufacturing. As the future unfolds, India's prowess will impact the worldwide effort against infectious diseases and assure a healthier future for all.

[1] [India's vaccine manufacturing prowess \(investindia.gov.in\)](http://investindia.gov.in)



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