

# **The Indian Bulk Drug Industry Holds Strategic Importance in Strengthening Global Supply Chain Resilience**

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Foreign manufacturers dominated submissions of API Drug Master Files (Type II DMF) to the largest pharmaceutical market, the US, in 2023, with only 4% from US based bulk drug manufacturing facilities. India accounted for half of all filings, followed by China (32%) and the EU (10%) [1]. This landscape shifted slightly in 2024 as Chinese facilities rose in US DMF submissions [2]. China's bulk drug manufacturing sector consistently have high capacity utilization rates, suggesting their expertise in industrial operations. As the largest manufacturing base, China accounts for almost 28% of the global manufacturing output which is equivalent to an annual value of US \$ 4 trillion [3]. This dominance is driven by robust infrastructure, a highly skilled workforce, cutting-edge technological adoption, and proactive government policies prioritizing industrial growth and innovation. Rising labor costs of about US \$6.5 per hour on average [4] in manufacturing and strict environmental regulations are challenging for China. The US Department of Commerce study determined that 97% of all antibiotics in the US came from China [5], which was a cause of anxiety. Ongoing tariff uncertainties [6] have worsened the scenario, with a potential to reverse small molecule drug substance volumes from China. The ongoing trade tensions have prompted many multinational companies to consider

multipronged plans for securing their supply chains.

China's well-advanced logistics networks and port locations continue to offer faster production and shipping lead times, making shipments to the US and Europe typically faster than those from India. India's shipping lead times are generally longer, impacted by infrastructure limitations and longer routes. The recent commissioning of India's first deep-water transshipment port in Vizhinjam allows major motherships to access India directly, cutting delays and costs [7]. In addition, the new world-class air cargo service can quickly address the current logistical challenges. To augment, the ongoing development of a strategic logistical route [8] may allow a more efficient and timely flow of goods. India has a high global output and maintains a lower labor cost of US \$2.13 per hour [9]. The country boasts the largest number of English-speaking graduates in science, technology, engineering, and math (STEM) with a low dependency ratio of 31.2 percent. This combination ensures a steady and abundant labor supply. It is estimated [10] that India's working-age population will peak at 68.9 percent by 2030. This is expected to be the highest working-age population in the country's history.

India has developed a mature and vibrant bulk drug manufacturing industry, supplying the domestic and global pharmaceutical markets. The demand is expected to be sustained with the proliferation of domestically anchored global generic formulation site volumes. The production linked incentive (PLI) scheme [11] associated with drug substance self-reliance and ongoing trade negotiations, continues to boost the sector. India's bulk drug manufacturing sector is well-positioned for substantial growth, supported by rapid infrastructure development, favourable government policies, and a large, skilled workforce. As supply chain diversification is planned, India tops as a reliable source. The prospects create a solid foundation for expansion for Indian bulk drug manufacturers in the evolving global pharmaceutical landscape.

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