

## Attaining OpEx is crucial for maintaining sustainability and competitiveness

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**The pharmaceutical industry in India is at a critical juncture, full of enormous promise and substantial responsibilities. The stakes are great and the world stage is prepared. A continual improvement approach, supported by investments in talent, technology, and teamwork, is essential for success. Companies that want to prosper in this changing environment must address operational excellence (OpEx) issues, change supply chains, and promote an innovative culture.**



India's pharmaceutical sector, valued at approximately \$31 billion in 2023, holds immense promise, evolving rapidly to claim its place as a cornerstone of the global healthcare landscape. With a projected annual growth rate of 10-12 per cent, the industry aims to reach a market size of approx. \$33 billion by 2025. India supplies 31 per cent of US pharmaceutical imports and boasts a 15 per cent growth rate in exports, solidifying its position as a leader in affordable medicine.

These figures emphasise both opportunities and challenges that demand a sharp focus on operational excellence (OpEx). Reflecting on the industry's growth trajectory, one cannot overlook its resilience in addressing domestic demand while expanding its global footprint. Yet, the journey is fraught with systemic challenges. Achieving OpEx is imperative to ensure sustainability and competitiveness in a rapidly evolving market.

### **The Dual Challenge: Growth and Sustainability**

Cost management emerges as a critical priority. Rising expenses for raw materials, labour, and logistics put pressure on profitability. Adopting lean manufacturing principles, optimising asset utilisation, and minimising waste can significantly

improve margins. Tailored frameworks help organisations address inefficiencies, enhance asset availability, and streamline operations, transforming cost management from a challenge into a driver of innovation and efficiency.

Regulatory compliance is another labyrinth the industry must navigate with precision and care. Regulatory bodies like the Central Drugs Standard Control Organisation (CDSCO) and the US FDA impose stringent quality and safety requirements. Non-compliance can lead to bans or warning letters, eroding market trust. Investing in robust compliance mechanisms not only mitigates these risks but also enhances operational metrics, translating into better profitability and global credibility. A disciplined, system-driven approach can ensure readiness for inspections, setting Indian firms apart as reliable global suppliers.

The industry's heavy reliance on imported Active Pharmaceutical Ingredients (APIs), particularly from China, exposes its supply chains to geopolitical risks and disruptions. The pandemic amplified these vulnerabilities, highlighting the urgent need for resilient supply chains. Strategies like backward integration—building domestic API manufacturing capabilities—and leveraging technology for real-time supply chain monitoring are gaining traction. These measures can reduce dependencies and bolster operational resilience.

### **Innovation and Technology: Driving the Future**

Innovation, particularly in biosimilars and specialty drugs, is a vital growth driver. The pharmaceutical sector invests 15-20 per cent of its revenue in research and development (R&D). However, this commitment strains resources, especially for smaller firms. Collaboration between R&D and operations teams, coupled with the adoption of advanced technologies like artificial intelligence (AI) and data analytics, can accelerate drug discovery, optimise clinical trials, and anticipate market demands. Such innovations enable firms to remain competitive in high-value segments while meeting the growing complexity of global healthcare needs.

The cost structures of major pharmaceutical companies reveal critical insights into the industry's priorities and challenges. Manufacturing expenses typically account for 30-40 per cent of total costs, influenced by factors such as production scale and the adoption of advanced technologies. Marketing and sales activities represent another 20-25 per cent, highlighting the intense competition for market share that drives companies to invest heavily in promotional efforts. Administrative expenses, which include governance and compliance overheads, generally account for 10-15 per cent of total costs. However, it is the substantial allocation to R&D—around 15-20 per cent—that underscores the industry's commitment to innovation.

These figures illustrate the balancing act companies must perform to achieve operational efficiency while simultaneously investing in growth-oriented initiatives. The emphasis on R&D reflects a strategic focus on developing new therapies and maintaining a competitive edge in a rapidly evolving market landscape.

The Indian pharmaceutical industry is poised for growth, not just in terms of volume but through sustainable, value-driven expansion. India remains a dominant global supplier of affordable medicines, with exports reaching \$27.85 billion in FY 2023-24, targeting markets like the US, Europe, and emerging economies. At the same time, domestic demand is increasing due to rising healthcare awareness and the prevalence of chronic diseases such as diabetes, cancer, and cardiovascular conditions.

The industry is evolving beyond drug discovery, with Indian firms expanding into biotechnology, biosimilars, and niche areas like orphan drugs. Strategic collaborations with global pharmaceutical giants, particularly in fields like gene therapy and precision medicine, are enhancing access to advanced technologies and new markets. This shift from volume-driven to value-driven growth reflects an industry that is maturing and ready to address global healthcare challenges.

### **Embracing Digital Evolution**

While many companies are exploring AI, data analytics, and end-to-end digital solutions, significant gaps remain in adoption. These technologies can do more than just streamline operations; they can redefine supply chain management and decision-making processes.

Digital transformation is pivotal for the industry's future. Many companies are only beginning to explore the potential of AI, data analytics, and end-to-end digital solutions. These technologies can optimise operations, improve supply chain visibility, and facilitate real-time decision-making. At dss+, we've partnered with clients to deploy digital tools that enhance operational efficiency and regulatory compliance. For instance, automating documentation and monitoring quality parameters in real time can streamline processes while ensuring adherence to global standards.

Government initiatives further bolster the sector's growth potential. Programmes like the production-linked incentive (PLI) scheme aim to enhance domestic manufacturing capabilities and reduce dependency on imports. Investments in greenfield pharmaceutical plants and incentives for upgrading manufacturing facilities reflect a concerted effort to strengthen the industry's infrastructure and global competitiveness.

India's pharmaceutical sector stands at a pivotal juncture, marked by tremendous promise and significant responsibility. The global stage is ready, and the stakes are high. Success demands a mindset of continuous improvement, underpinned by investments in technology, talent, and collaboration. Addressing OpEx challenges, transforming supply chains, and fostering a culture of innovation are critical imperatives for companies looking to thrive in this dynamic landscape.

The path forward is clear. By aligning their strengths in manufacturing with an unwavering commitment to quality and compliance, Indian pharmaceutical firms can redefine their role in global healthcare. More importantly, this sector can make a profound difference—not just to India's economy but to global health outcomes. Accessible, life-saving medicines remain a cornerstone of humanity's collective progress, and India is uniquely positioned to lead this charge.

This journey isn't just about industry growth; it's a testament to human ingenuity, collaboration, and perseverance. It's about leveraging every challenge as an opportunity to innovate and excel. This is a narrative worth celebrating and championing—a story of resilience, ambition, and a vision to create a healthier, more equitable world.

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