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**DAY 1**

## News AT A GLANCE



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► Page No. 6



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► Page No. 8



Streamlining regulatory processes for drug approvals...

► Page No. 12

# 10<sup>th</sup> edition of iPHEX kicks off in grand way

LAXMI Yadav

**T**HE 10th edition of the International Exhibition for Pharma and Healthcare (iPHEX)-2024 kicked off in a big way on August 28 at the India Exposition Mart Limited (IEMML) in Knowledge Park II, Greater Noida, Delhi-NCR.

The inauguration of the three-day India's largest pharma exhibition and business-to-business event was graced by Nitin Kumar Yadav, IAS, Joint Secretary (Export Products-Pharma), Department of Commerce, Ministry of Commerce and Industry, and Dr. Rajeev Singh Raghuvanshi, Drugs Controller General of India (DCGI), Ministry of Health and Family Welfare who were Guests of Honour. Lena Nanun-

Continued from Page 1

CONTINUED PAGE On 2 ►






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# Indian Drug Industry Set for Volume-to-Value Leadership Journey in 2024



DR. SANJAY AGRAWAL

a leadership role characterized by value creation. This shift is driven by several factors, including evolving market dynamics, technological advancements, regulatory changes, and increasing global competition. This article explores the key elements of this transition, the challenges and opportunities involved, and how Indian pharmaceutical companies can navigate this transformative journey.

ing affordable medications to a global market. However, the industry's growth trajectory is now shifting towards a value-oriented approach. This involves focusing on high-value innovations, premium products, and enhanced patient outcomes rather than just sheer volume.

that meet these emerging needs.

**A**s the Indian pharmaceutical industry enters 2024, it stands at a pivotal juncture, poised to transition from a focus on high-volume production to

## 1. The Shift from Volume to Value

The Indian drug industry has traditionally been known for its high-volume production capabilities, particularly in generic drugs. This has established India as the "pharmacy of the world," supply-

## a. Changing Market Dynamics:

The global pharmaceutical landscape is evolving, with increasing demand for personalized medicine, advanced therapeutics, and innovative drug delivery systems. Indian pharmaceutical companies are recognizing the need to shift from producing generic drugs to investing in research and development (R&D) and creating value-added products

## b. Technological Advancements:

Innovations such as artificial intelligence (AI), machine learning, and blockchain are revolutionizing the pharmaceutical industry. These technologies enable better drug discovery, more efficient clinical trials, and enhanced supply chain management. By embracing these advancements, Indian pharmaceutical companies can move beyond high-volume production and focus on high-value innovation.

## c. Regulatory Changes:

Regulatory bodies are increasingly emphasizing drug quality, safety, and efficacy. The Indian pharmaceutical industry must adapt to these evolving standards by

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# Indian Drug Industry Set for Volume...

CONTINUED PAGE FROM 25 ▶

investing in quality assurance, compliance, and advanced manufacturing practices. This shift towards higher standards will support the transition from volume to value.

## 2. Key Trends Driving the Transition

Several key trends are shaping the Indian drug industry's transition from volume to value. These trends highlight the industry's evolving focus and the strategies being employed to achieve this transformation.

**a. Investment in Research and Development:** Indian pharmaceutical companies are ramping up their investments in R&D to develop innovative drugs and therapies. This includes exploring new drug delivery systems, advanced biologics, and personalized medicine. Companies are also collaborating with global research institutions and biotech firms to accelerate drug discovery and development.

**b. Focus on Specialty and Niche Markets:** There is a growing emphasis on specialty drugs and niche markets that offer higher profit margins and address unmet medical needs. Indian pharmaceutical companies are increasingly investing in areas such as oncology, immunology, and rare diseases, where there is significant potential for value creation.

**c. Adoption of Digital Technologies:** Digital transformation is a key driver of the volume-to-value shift. Technologies such as AI, big data analytics, and digital therapeutics are being used to enhance drug development, optimize clinical trials, and improve patient outcomes. Indian pharmaceutical companies are leveraging these technologies to create value beyond traditional high-volume production.

**d. Enhanced Quality and Compliance:** To meet global standards and regulatory requirements, Indian pharmaceutical companies are focusing on enhancing quality and compliance. This includes investing in advanced manufacturing processes, implementing robust quality control measures, and adhering to Good Manufacturing Practices (GMP). These efforts are crucial for transitioning to a value-oriented approach.

**e. Global Expansion and Strategic Partnerships:** Indian pharmaceutical companies are expanding their global footprint and forming strategic partnerships to access new markets and technologies. This includes entering high-value markets in the

United States and Europe, as well as collaborating with international firms for joint R&D and commercialization efforts.

## 3. Challenges in the Transition

While the shift from volume to value presents numerous opportunities, it also comes with its own set of challenges. Indian pharmaceutical companies must navigate these challenges to successfully complete their transformation journey.

**a. High R&D Costs:** Investing in R&D and developing innovative drugs requires substantial financial resources. Indian pharmaceutical companies need to allocate significant budgets for research and development while managing costs and maintaining profitability.

**b. Regulatory Hurdles:** Adhering to stringent regulatory standards and obtaining approvals for new drugs can be a complex and time-consuming process. Indian pharmaceutical companies must stay abreast of global regulatory requirements and ensure compliance to avoid delays and penalties.

**c. Competitive Landscape:** The pharmaceutical industry is highly competitive, with global players vying for market share in specialty and niche segments. Indian pharmaceutical companies must differentiate themselves through innovation, quality, and strategic partnerships to stay ahead of the competition.

**d. Talent Acquisition and Retention:** The transition to a value-oriented approach requires skilled talent in areas such as R&D, data analytics, and regulatory affairs. Indian pharmaceutical companies must invest in talent acquisition, training, and retention to build a capable workforce for driving innovation.

**e. Infrastructure and Investment Needs:** Upgrading manufacturing facilities, implementing advanced technologies, and enhancing quality control processes require significant infrastructure investments. Indian pharmaceutical companies must invest in modernizing their facilities and adopting cutting-edge technologies to support their value-oriented strategy.

## 4. Strategies for Successful Transition

To successfully navigate the volume-to-value transition, Indian pharmaceutical companies can adopt several key strategies. These strategies

focus on leveraging their strengths, addressing challenges, and positioning themselves for long-term success.

**a. Prioritize Innovation and R&D:** Investing in R&D and innovation is crucial for creating high-value products and therapies. Indian pharmaceutical companies should focus on developing new drug delivery systems, exploring advanced biologics, and pursuing personalized medicine. Collaborating with global research institutions and biotech firms can also accelerate innovation and enhance R&D capabilities.

**b. Embrace Digital Transformation:** Leveraging digital technologies is essential for driving efficiency and value creation. Indian pharmaceutical companies should invest in AI, big data analytics, and digital therapeutics to optimize drug development, improve clinical trial outcomes, and enhance patient engagement. Implementing digital tools can also streamline supply chain management and operational processes.

**c. Strengthen Quality and Compliance:** Adhering to global quality standards and regulatory requirements is critical for gaining market access and building trust with stakeholders. Indian pharmaceutical companies should focus on enhancing their quality assurance processes, investing in advanced manufacturing technologies, and ensuring compliance with GMP. This will support their transition to a value-oriented approach and facilitate global expansion.

**d. Expand Global Reach:** Expanding into new markets and forming strategic partnerships can provide access to high-value opportunities and technologies. Indian pharmaceutical companies should explore partnerships with international firms for joint R&D and commercialization efforts. Additionally, targeting high-value markets in the United States and Europe can drive revenue growth and enhance global presence.

**e. Invest in Talent Development:** Building a skilled workforce is essential for driving innovation and managing complex R&D and regulatory processes. Indian pharmaceutical companies should invest in talent acquisition, training, and retention to develop a capable team. This includes hiring experts in R&D, data analytics, and regulatory affairs to support the transition to a value-oriented strategy.

**f. Enhance Operational Efficiency:** Improving operational efficiency

can help reduce costs and enhance profitability. Indian pharmaceutical companies should focus on optimizing their manufacturing processes, adopting lean practices, and implementing advanced technologies for production and quality control. Streamlining operations will support their value-oriented approach and drive long-term success.

## Case Studies and Success Stories

Several Indian pharmaceutical companies have successfully embarked on the volume-to-value journey, serving as examples for others in the industry.

### 1. Sun Pharmaceutical Industries

**Overview:** Sun Pharma, one of India's largest pharmaceutical companies, is shifting focus from generics to specialty drugs and biologics.

#### Key Moves:

- **Specialty Focus:** Emphasis on oncology, dermatology, and complex generics.
- **R&D Investment:** Significant resources dedicated to new drug delivery systems and biologics.
- **Global Expansion:** Strategic acquisitions and partnerships to enhance its global presence.

**Impact:** Sun Pharma's shift to high-value therapeutics has strengthened its market position and reduced reliance on traditional generics.

### 2. Dr. Reddy's Laboratories

**Overview:** Dr. Reddy's is investing in digital technologies and specialty therapeutics to drive growth.

#### Key Moves:

- **Digital Transformation:** Use of AI and data analytics for drug discovery and clinical trials.
- **Specialty Therapies:** Focus on oncology, dermatology, and biosimilars.
- **Strategic Partnerships:** Alliances with global firms to access advanced technologies.

**Impact:** Dr. Reddy's emphasis on innovation and specialty products has enhanced its competitive edge and global reach.

### 3. Cipla

**Overview:** Cipla is focusing on specialty drugs and expanding its global market presence.

CONTINUED PAGE On 27 ▶

# Indian Drug Industry Set for Volume...

CONTINUED PAGE FROM 26

**Key Moves:**

- **Specialty Products:** Investments in respiratory and oncology therapies.
- **R&D Efforts:** Development of complex generics and biosimilars.
- **Global Expansion:** Strategic acquisitions and market expansion in the U.S., Europe, and Africa.

**Impact:** Cipla's transition to high-value products and global presence has reinforced its leadership in the industry.

**4. Lupin Pharmaceuticals**

**Overview:** Lupin is shifting towards specialty products and biologics.

**Key Moves:**

- Specialty Focus: Emphasis on on-

colony, cardiology, and respiratory diseases.

- **R&D Investment:** Significant resources for high-value therapeutics and drug delivery systems.
- **Global Expansion:** Strategic acquisitions and partnerships to enhance global reach.

**Impact:** Lupin's focus on specialty drugs and biologics has solidified its position in high-value therapeutic areas.

**5. Aurobindo Pharma**

**Overview:** Aurobindo Pharma is investing in specialty drugs and digital technologies.

**Key Moves:**

- Specialty Products: Focus on oncology and dermatology, along with biosimilars.
- Digital Initiatives: Use of data analytics and automation in drug

development.

- **Strategic Acquisitions:** Expansion through acquisitions like Apotex's generics business.

**Impact:** Aurobindo's shift towards high-value products and digital technologies has strengthened its competitive position and global presence.

These case studies illustrate how Indian pharmaceutical companies are effectively transitioning from high-volume production to a focus on high-value innovations and global expansion.

**Conclusion**

As the Indian pharmaceutical industry navigates through 2024, the shift from volume to value represents a significant transformation. This transition is driven by changing market dynamics, technological ad-

vancements, regulatory changes, and the need for higher-value innovations. While the journey presents challenges, Indian pharmaceutical companies have the opportunity to lead in areas such as R&D, digital transformation, and global expansion.

By prioritizing innovation, embracing digital technologies, enhancing quality and compliance, and investing in talent development, Indian pharmaceutical companies can successfully navigate the volume-to-value transition. The industry's ability to adapt and innovate will determine its future success and leadership in the global pharmaceutical market.

*(Author is the Leading Pharmaceutical Consultant and Editor-in Chief of IJMToday)*



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