iPHEX
PHARMA MachTech Expo 2026
LABNEXT EXPO 2026

INDIAN PHARMA COMPENDIUM 2026

Vol. 2, Issue. 6

News AT A GLANCE

From generics to innovation: Indian...

Page No. 6

Scientific infrastructure, supply-chain capability...

Page No. 22

India's pharma future hinges on balancing...

Page No. 25

Innovation, trust and preventive healthcare ...

Page No. 36

iPHEX 2026: Indian pharma industry eyes $1.4 bn export opportunities

OUR BUREAU, MUMBAI

THE Pharmaceuticals Export Promotion Council of India (Pharmexcil) has set an ambitious target of unlocking approximately USD 1.4 billion in export business opportunities through the upcoming 12th edition of iPHEX 2026, scheduled from September 7–9 at Bharat Mandapam, New Delhi. The three day exhibition and conference arrives at a pivotal moment for India's pharmaceutical sector, which recorded a 6.8% growth in exports in Q1 FY27 compared to the same period last year.

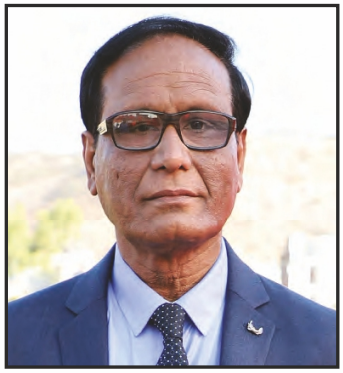
This growth underscores India's resilience in a complex global trade environment, where supply chain disruptions, pricing pressures, and regulatory challenges continue to test exporters. Against this backdrop, iPHEX 2026 is being positioned not merely as a trade fair but as a strategic platform to connect Indian manufacturers with international buyers, strengthen trust, and convert conversations into concrete business deals.

Scale and Scope of iPHEX 2026

The event promises to be one of the largest gatherings of pharmaceutical stakeholders in Asia. With 800+ exhibitors, 600 overseas companies, and

CONTINUED ON p2▶

Strategies to build India's pharma regulatory and compliance ecosystem with global markets



DR. SANJAY AGRAWAL

INDIA has emerged as one of the world's most important pharmaceutical hubs, supplying medicines, vaccines, active pharmaceutical ingredients (APIs), and generic formulations to markets across the globe. Its cost competitiveness, manufacturing capabilities, scientific talent, and expanding research ecosystem have created significant opportunities for further growth. However, as pharmaceutical markets become increasingly regulated and interconnected, India's future competitiveness will depend not only on manufacturing capacity but also on the strength, consistency, and international alignment of its regulatory and compliance ecosystem.

Building a globally compatible regulatory framework requires a coordinated approach involving regulators, pharmaceutical companies, research institutions, testing laboratories, healthcare professionals, and policymakers. The objective should be to create an ecosystem where Indian pharmaceutical products can meet stringent international requirements while maintaining affordability, quality, safety, and timely access.

Strengthening Regulatory Harmonisation

One of the most important strategies is greater harmonisation of Indian pharmaceutical regulations with internationally accepted standards. Regulatory expectations differ across markets such as the United States, European Union, United Kingdom, Japan, and emerging markets. Companies operating globally must therefore navigate multiple regulatory frameworks, documentation requirements, inspection systems, and product standards.

India can reduce this complexity by strengthening alignment with global frameworks such as those established by the International Council for Harmonisation (ICH), World Health Organization (WHO), and other recognised regulatory bodies. Greater harmonisation of technical requirements, clinical documentation, quality standards, pharmacovigilance systems, and manufacturing expectations can make Indian approvals more compatible with international submissions.

At the same time, harmonisation should not simply mean copying foreign regulations. India needs a risk-based regulatory framework that reflects its own healthcare requirements while maintaining global credibility.

Building Stronger Quality and Manufacturing Compliance

Quality assurance must remain at the centre of India's global pharmaceutical strategy. International markets increasingly expect manufacturers to demonstrate robust Good Manufacturing Practices (GMP), data integrity, process validation, quality control, traceability, and effective corrective and preventive action systems.

Indian manufacturers should move beyond compliance as a checklist and develop a culture of continuous quality improvement. Digital quality management systems, automated monitoring, electronic batch records, real-time process analytics, and advanced laboratory technologies can strengthen manufacturing oversight.

Regulators can support this transition by expanding risk-based inspections and using data-driven approaches to identify potential quality risks. Consistent enforcement is equally important. A regulatory ecosystem gains international credibility when compliance expectations are transparent, predictable, and applied uniformly across manufacturers.

Improving Regulatory Capacity and Expertise

A globally competitive pharmaceutical ecosystem requires regulators with strong technical and scientific capabilities. Pharmaceutical regulation today extends beyond conventional manufacturing controls into areas such as biologics, biosimilars, gene therapies, cell therapies, artificial intelligence, digital health, personalised medicine, and advanced drug-delivery systems.

India should therefore invest continuously in regulatory education and specialised training. Regulatory professionals need exposure to international standards, emerging technologies, clinical research methodologies, statistical assessment, pharmacovigilance, and global inspection practices.

Collaboration between Indian regulators and international regulatory agencies can further strengthen expertise. Joint training programmes, technical exchanges, regulatory workshops, and participation in international working groups can help Indian authorities stay aligned with evolving global expectations.

Creating a Stronger Digital Regulatory Infrastructure

Digital transformation can significantly improve the efficiency and transparency of pharmaceutical regulation. India should develop integrated digital platforms through which companies can submit applications, track regulatory processes, manage compliance documentation, report adverse events, and communicate with regulatory authorities.

Electronic submissions can reduce paperwork, improve traceability, and accelerate regulatory reviews. Artificial intelligence and advanced analytics could eventually support regulators in identifying unusual safety signals, manufacturing trends, inspection risks, and inconsistencies in submitted data.

However, digitalisation must be accompanied by strong cybersecurity, data governance, access controls, and data-integrity standards. Pharmaceutical regulatory information is highly sensitive, and the credibility of a digital ecosystem depends on maintaining the integrity and confidentiality of regulatory data.

Strengthening Clinical Research and Pharmacovigilance

India's global pharmaceutical ambitions also require stronger clinical research and post-market safety systems. Regulatory approval is only one stage of a medicine's lifecycle. Continuous monitoring is necessary to understand how products perform once they are used across diverse patient populations.

India should strengthen pharmacovigilance networks involving manufacturers, hospitals, healthcare professionals, research institutions, and regulators. Faster reporting and analysis of adverse drug reactions can help identify safety signals earlier.

Clinical research standards should also remain aligned with international ethical and scientific expectations. Improving clinical trial infrastructure, patient recruitment systems, research transparency, data quality, and institutional review mechanisms can make India a more attractive destination for global pharmaceutical research and development.

Enhancing Supply Chain Traceability

Global pharmaceutical supply chains are becoming increasingly complex. Counterfeit medicines, falsified products, API shortages, quality deviations, and supply disruptions can affect patient safety as well as India's international reputation.

A stronger traceability ecosystem can help address these risks. Technologies such as barcoding, serialization, blockchain-based verification, and integrated supply-chain platforms can improve visibility from manufacturing through distribution.

India should encourage interoper-

CONTINUED ON p17▶

Strategies to build India's pharma...

CONTINUED FROM p16▶

able traceability standards that can connect domestic systems with international supply chains. Such systems would help regulators and companies identify products rapidly during recalls, investigate quality issues, and protect patients.

Supporting Small and Medium Pharmaceutical Companies

While large Indian pharmaceutical companies generally possess significant regulatory capabilities, smaller manufacturers may face challenges in meeting increasingly sophisticated global compliance requirements. High costs associated with laboratory infrastructure, digital systems, validation, regulatory expertise, and international certifications can create barriers for smaller businesses.

A stronger ecosystem should therefore provide technical guidance, training, shared testing infrastructure, regulatory support programmes, and access to compliance expertise for smaller manufacturers. Industry associations and specialised institutions can play an important role in helping these companies understand international requirements.

Supporting SMEs is particularly important because India's pharmaceutical ecosystem is broad and geographically distributed. Raising compliance standards across the entire industry will strengthen India's reputation as a reliable global supplier.

Promoting Regulatory Cooperation and Mutual Recognition

India can further strengthen its position by expanding regulatory cooperation with major pharmaceutical markets. Mutual recognition arrangements, information-sharing agreements, joint inspections, and reliance mechanisms can reduce duplication and improve regulatory efficiency where appropriate.

Greater cooperation does not mean lowering standards. Instead, it allows trusted regulatory authorities to rely on assessments or inspections already conducted by another competent authority, reducing unnecessary duplication while maintaining patient-safety safeguards.

Such mechanisms could be particularly valuable for Indian manufacturers seeking simultaneous access to multiple international markets.

CONTINUED ON p19▶

Strategies to build India's pharma...

CONTINUED FROM p17▶

Creating a Culture of Compliance

Ultimately, regulations are effective only when compliance becomes embedded within organisational culture. Pharmaceutical companies need to view regulatory compliance not as a cost or administrative requirement but as a fundamental component of product quality and patient safety.

Boards and senior management should establish clear accountability for quality and compliance. Employees across manufacturing, research, supply chain, sales, and quality functions should receive regular training. Internal audits, whistleblower mechanisms, data-integrity controls, and transparent reporting systems can further strengthen organisational accountability.

A proactive compliance culture also reduces the risk of costly regulatory observations, product recalls, export restrictions, and reputational damage.

Conclusion

India's pharmaceutical industry has the scale and capabilities to remain a major force in global healthcare. The next phase of growth, however, will depend increasingly on regulatory credibility rather than manufacturing capacity alone. India needs an ecosystem that combines globally harmonised standards, strong regulatory institutions, digital infrastructure, advanced quality systems, robust pharmacovigilance, supply-chain traceability, and a culture of continuous compliance.

The goal should be to make regulatory excellence a competitive advantage for Indian pharmaceuticals. By strengthening collaboration between government, regulators, industry, academia, healthcare institutions, and international partners, India can build a regulatory ecosystem that supports innovation while protecting patient safety.

A globally aligned regulatory framework will not only help Indian pharmaceutical companies enter and sustain their presence in international markets; it will also strengthen trust in the quality, safety, and reliability of medicines manufactured in India. In the long term, regulatory excellence can become one of the strongest foundations for India's ambition to be a trusted global pharmaceutical leader.

(The author is a Leading Pharmaceutical Consultant and Editor- in Chief of IJMToday. Email- www.drsanjayagrawal.in)