CPHI China
PMEC China
ARAB PHARMA Manufacturers' EXPO

INDIAN PHARMA COMPENDIUM 2026

Click here to download this edition...

Vol. 2, Issue. 3 International Edition

News AT A GLANCE

APME 2026 spotlights Arab drive for...

Page No. 11

From India to the world - The future of pharma...

Page No. 14

Risk sharing finance and policy reform key...

Page No. 18

India pharma amid US–Iran tensions

Page No. 35

From APIs to biotech: China's dual strength powers CPHI & PMEC 2026

OUR BUREAU, MUMBAI

CPHI & PMEC China 2026 is set to take place from 16 to 18 June 2026 at the Shanghai New International Expo Centre (SNIEC), building on its extremely successful run over the last few years.

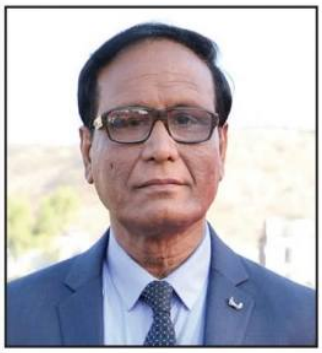
As the world's premier destination for pharmaceutical ingredients and manufacturing solutions, this year's edition is set to bring together over 110,000 attendees, and more than 3,600 local and international exhibitors. This comfortably makes CPHI & PMEC China Asia's largest pharma event, offering unparalleled opportunities to source, supply and innovate within China's pharmaceutical powerhouse.

China as Global Pharma Hub

The extraordinary growth of CPHI & PMEC China speaks to the country's reputation as the global hub for pharmaceutical building blocks. The event has become the essential marketplace for global products and solutions that power modern medicine worldwide, from APIs and natural extracts, machinery, laboratory instruments and packaging, to biotech and Traditional Chinese Medicine (TCM).

CONTINUED ON p2▶

Reimagining pharma manufacturing: India and China lead the green transition



DR SANJAY AGRAWAL

THE pharmaceutical industry is standing at the threshold of a structural transformation. For decades, global competitiveness in pharma was measured by manufacturing scale, cost efficiency, and speed of supply. Today, however, a new benchmark is redefining industrial leadership- sustainability.

From stricter environmental regulations and ESG mandates to climate-conscious procurement policies and cleaner production technologies, the sector is undergoing a major shift toward environmentally responsible manufacturing. In this transition, India and China are emerging not only as pharmaceutical powerhouses but also as critical players in shaping the future of green chemistry.

Traditionally, the pharmaceutical relationship between the two nations revolved around supply-chain interdependence. China dominated the production of intermediates, key starting materials (KSMs), and APIs, while India excelled in formulations, generics, vaccine manufacturing, and exports to regulated markets. Together, the two countries built one of the most influential pharmaceutical ecosystems in the world.

But the dynamics are changing rapidly

As sustainability becomes central to industrial policy and healthcare economics, the India-China pharmaceutical relationship is gradually evolving beyond APIs into a broader strategic framework focused on green chemistry, cleaner manufacturing systems, advanced process engineering, and environmentally sustainable pharmaceutical production.

This emerging transition has the potential to reshape not only Asian manufacturing but the global pharmaceutical landscape itself.

The Sustainability Imperative in Global Pharma

The pharmaceutical industry has long faced criticism for its environmental footprint. Conventional drug manufacturing processes consume large quantities of water, solvents, chemicals, and energy, while generating hazardous waste and industrial emissions.

According to several environmental studies, pharmaceutical manufacturing can contribute significantly to:

- Water contamination
- Chemical waste accumulation
- Air pollution
- Carbon emissions
- Soil toxicity
- Antimicrobial resistance through untreated discharge

As global environmental concerns intensify, regulators across major healthcare markets are tightening sustainability expectations.

The European Union's Green Deal, stricter US environmental standards, carbon disclosure requirements, and ESG-driven investment strategies are increasingly influencing pharmaceutical sourcing and procurement decisions. Buyers and investors are now examining how medicines are manufactured- not just how effectively they perform.

This is creating urgent pressure for pharmaceutical companies worldwide to transition toward greener and cleaner manufacturing models.

Understanding Green Chemistry in Pharma

Green chemistry refers to the design of chemical products and manufacturing processes that minimize or eliminate the use and generation of hazardous substances.

Unlike traditional approaches that manage pollution after production, green chemistry focuses on preventing environmental damage at the source.

In the pharmaceutical industry, green chemistry includes:

- Safer synthesis pathways
- Reduced solvent usage
- Biocatalysis and enzyme-based reactions
- Renewable feedstocks
- Energy-efficient production systems
- Continuous manufacturing technologies
- Waste minimization techniques
- Solvent recovery and recycling
- Reduced process toxicity
- Improved atom economy

The concept also aligns closely with circular economy principles, where resources are reused, recycled, and optimized to minimize environmental impact.

Importantly, green chemistry is not solely about environmental responsibility. It also delivers operational and economic advantages such as:

- Lower production costs
- Reduced waste treatment expenses
- Improved process efficiency
- Better regulatory compliance
- Enhanced worker safety
- Stronger long-term profitability

For India and China, integrating green chemistry into pharmaceutical manufacturing is becoming both a strategic necessity and a competitive opportunity.

India and China: Two Pillars of the Global Pharma Ecosystem

India and China collectively hold enormous influence over global pharmaceutical supply chains.

China remains one of the world's largest producers of APIs, intermediates, fine chemicals, and industrial chemical inputs. Its strength lies in large-scale manufacturing infrastructure, advanced chemical engineering capabilities, and

CONTINUED ON p16▶

Reimagining pharma manufacturing...

CONTINUED FROM p15▶

industrial process optimization.

India, meanwhile, has earned global recognition as the "Pharmacy of the World" due to its leadership in:

- Generic medicines
- Vaccine manufacturing
- Affordable healthcare solutions
- Regulatory-approved manufacturing facilities
- Formulation development
- Contract research and manufacturing services

Indian pharmaceutical companies supply medicines to more than 200 countries, including major regulated markets such as the US, UK, and Europe.

Historically, this relationship was often described in terms of dependency, especially India's reliance on Chinese raw materials. However, the future narrative is becoming far more collaborative and innovation-driven.

Both nations now recognize that sustainability, resilience, and technological advancement will define the next phase of pharmaceutical growth.

Why Green Collaboration Makes Strategic Sense

The transition toward sustainable pharmaceutical manufacturing requires extensive expertise, capital investment, technological innovation, and scalable industrial capabilities.

This is where India and China possess highly complementary strengths.

China's advantages include:

- Advanced chemical manufacturing ecosystems
- Strong industrial infrastructure
- Process scale and automation
- Chemical engineering expertise
- High-volume production capabilities

India contributes:

- Regulatory expertise
- Global pharmaceutical market access
- Cost-efficient innovation
- Biotechnology growth
- Strong formulation and R&D capabilities

Together, these capabilities create opportunities for collaboration in several key areas.

Sustainable API Manufacturing

API production remains one of the most environmentally intensive segments of the pharmaceutical value chain.

By integrating cleaner synthesis routes, solvent recovery systems, and energy-efficient processes, India and China can significantly reduce environmental impact while maintaining manufacturing competitiveness.

Continuous Manufacturing Technologies

Traditional batch manufacturing often leads to higher waste generation and energy consumption.

Continuous manufacturing systems improve:

- Process efficiency
- Product consistency
- Resource utilization
- Waste reduction
- Energy savings

China's industrial infrastructure combined with India's pharmaceutical process expertise can accelerate adoption of such technologies.

Green Solvent Technologies

Solvents account for a major portion of pharmaceutical waste.

Research collaborations focused on bio-based solvents, recyclable solvent systems, and low-toxicity alternatives could dramatically improve sustainability performance across the sector.

Biotechnology and Fermentation-Based Production

Biotechnology-driven pharmaceutical manufacturing is emerging as a cleaner alternative to conventional chemical synthesis.

Areas such as:

- Biologics
- Enzyme catalysis
- Fermentation technologies
- Bio-based APIs offer promising pathways toward low-emission drug manufacturing.

India's growing biotech ecosystem and China's manufacturing scale position both countries advantageously in this space.

ESG and the New Economics of Pharma

Environmental, Social, and Governance (ESG) frameworks are rapidly influencing pharmaceutical investment decisions and global supply-chain partnerships.

Investors increasingly favor companies with:

- Sustainable manufacturing practices
- Carbon reduction commitments
- Transparent environmental reporting
- Ethical sourcing systems
- Circular economy initiatives

At the same time, multinational pharmaceutical buyers are incorporating sustainability criteria into supplier evaluations.

This means environmental responsibility is becoming directly linked to commercial competitiveness.

For Indian and Chinese pharmaceutical manufacturers, adopting green chemistry is no longer simply about compliance. It is becoming essential for:

- Export competitiveness
- International partnerships
- Investor confidence
- Regulatory approvals
- Long-term market sustainability

Companies that fail to modernize risk losing relevance in a rapidly evolving global healthcare ecosystem.

Government Initiatives Driving the Transition

Both India and China are increasingly aligning industrial policy with sustainability goals.

India's Sustainability Push

India has introduced multiple initiatives aimed at strengthening domestic pharmaceutical manufacturing while encouraging modernization.

These include:

- Production Linked Incentive (PLI) schemes
- Bulk drug park initiatives
- Investments in green industrial corridors
- Renewable energy integration
- Sustainable chemical manufacturing policies

Indian pharmaceutical companies are also investing in:

- Zero-liquid discharge systems
- Solar-powered facilities
- Wastewater recycling
- Green building certifications
- Carbon footprint reduction programs

China's Green Industrial Transformation

China has aggressively expanded environmental regulation across manufacturing sectors.

The country has implemented:

- Stricter emission controls
- Cleaner production standards
- Industrial decarbonization targets
- Circular manufacturing initiatives
- Eco-industrial parks

Chinese pharmaceutical and chemical manufacturers are increasingly investing in cleaner technologies to align with both domestic regulations and international market expectations.

Digitalization and Smart Manufacturing

The future of green chemistry will be deeply connected with digital transformation.

Artificial intelligence, machine learning, industrial automation, and predictive analytics are enabling pharmaceutical companies to optimize manufacturing processes with unprecedented precision.

Smart manufacturing technologies help:

- Reduce process waste
- Improve yield efficiency
- Lower energy consumption
- Predict equipment failures
- Optimize chemical reactions
- Improve quality consistency

AI-driven process chemistry is expected to play a major role in developing sustainable pharmaceutical manufacturing systems over the next decade.

India's rapidly expanding digital innovation ecosystem combined with China's industrial automation capabilities could create a strong foundation for next-generation pharmaceutical production.

Challenges on the Road Ahead

Despite significant opportunities, several barriers remain.

Geopolitical and Trade Concerns

Political tensions and supply-chain diversification efforts continue to influence India-China business relations. Strategic trust and policy stability will be essential for deeper long-term collaboration.

High Transition Costs

Green transformation requires substantial capital investment, particularly for small and medium-sized pharmaceutical manufacturers.

Facility modernization, clean technology adoption, and sustainability compliance can be financially demanding.

Regulatory Complexity

Different environmental regulations across regions create operational challenges for globally integrated pharmaceutical supply chains.

Greater harmonization and international cooperation will be necessary to streamline sustainable manufacturing practices.

CONTINUED ON p17▶

Compliance, innovation, scale: India–China pharma contest

KRISHNANATH MUNDE, MITALI DALVI


Krishnanath Munde


Mitali Dalvi

INDIA and China are reshaping global pharma through distinct but complementary strengths in compliance, innovation, and scale. India is strengthening its position by tightening regulatory standards (e.g., revised Schedule M), improving quality, trust, and driving industry consolidation. China is advancing a state-led model, rapidly aligning with global norms and shifting toward high-value, innovation led exports.

In innovation, China leads in biologics and advanced therapies due to strong biotech ecosystems, while India focuses on cost-efficient generics, process chemistry, and scalable production. We highlight here that China dominates APIs and intermediates at scale, while India leads in formulations and biosimilars. Globally, China is seen as a manufacturing hub with strong supply chain control, while India is a trusted partner known for regulatory credibility and quality.

As regulations tighten, pharma supply chains are becoming more consolidated and focused, where success depends on regulatory trust, innovation, and resilience where both countries remain key players.

Regulatory compliance: India and China are adapting to stricter USFDA and EMA standards, but through different approaches that influence their export competitiveness. In India, companies are investing in quality systems, improving compliance, and moving toward complex generics and now specialty side. The revised Schedule M has raised industry standards. These changes improve product quality, traceability, and global credibility, but also increase costs and consolidation in the industry.

China is taking a coordinated, state-driven approach. It is aligning with global regulations, accelerating approvals, and moving from API-focused exports to finished dosage/biologics and innovation led products. This enables China to move up the value chain and compete globally in niche segments.

Tighter USFDA and EMA standards are also reshaping global supply chains. The trend is shifting from fragmented, cost driven networks to more consolidated, quality focused ecosystems. Buyers in the US and EU now prefer fewer, reliable suppliers with strong compliance records.

Innovation pipelines: China's innovation pipeline is driven by translational medicine and integrated biotech ecosystems. Strong state funding and links between academia and industry support rapid development in biologics, cell, and gene therapies. India's strength lies in a chemistry driven model built on process expertise, generics manufacturing, and cost efficient development. While China focuses on new molecule discovery and advanced platforms, India leverages scale, regulatory agility, and efficient small molecule production.

Overall, China leads in innovation driven discovery, while India focuses on affordable, high-quality drug production, creating a complementary global role.

Manufacturing scale: China leads in APIs with large, integrated manufacturing hubs, cost efficient bulk production, and strong backward linkages. It acts as a global supply base for many key materials. India's strength is in generics, supported by largest USFDA approved plants (combined for API and formulations), largest ANDA pipeline (for formulations; 35-40% market share globally), leader in DMF filing (for API; 50% market share globally), strong compliance, and export focus. In biologics, China has rapidly expanded capacity through heavy investment, while India focuses more on biosimilars and affordable vaccines. In summary, China leads upstream (APIs/intermediates), while India leads downstream (formulations).

Global competitiveness: China's strength lies in supply chain integration and control, enabling speed, scale, and cost efficiency. However, it faces pressure from buyers seeking diversification away from single country dependence. India benefits from stronger trust in regulated markets due to its compliance track record and large base of approved plants. While less integrated than China, its supply chain is becoming more resilient with diversification and policy support (PLI). In maturity, China leads in scale and efficiency, while India leads in regulatory credibility and quality systems.

Technology adoption: China focuses on AI-driven manufacturing and smart factories to improve scale and operational control. India focuses on digital quality systems and compliance analytics to strengthen regulatory trust. Across both, AI and analytics are improving data integrity, accelerating audits, and supporting continuous improvement. China leads in production efficiency, while India uses technology to enhance quality and transparency.

Investment and infrastructure: China leads in funding, with state backed industrial parks and strong RCD and clinical infrastructure. This enables fast capacity expansion and large-scale innovation. India operates with lower funding but benefits from cost efficient RCD, strong CRO networks, and a globally accepted clinical trial ecosystem. China's advantage is capital and infrastructure depth, while India's strength is cost effective innovation and global integration.

Talent and training: China has a large engineering focused workforce aligned with manufacturing and automation but continues to develop a stronger global compliance culture. India has a deep pool of pharma scientists and regulatory expertise aligned with global standards, though gaps remain in advanced manufacturing and digital skills. Both countries need to upskill in AI, data, and biologics while strengthening quality and innovation culture.

Policy outlook: India and China are aligning with global regulations, but in different ways. China has rapidly adopted global frameworks (e.g., ICH), streamlined approvals, and promoted innovation through strong state support. This creates a fast-moving environment for new drugs and therapies. India has built credibility through steady alignment with USFDA, EMA, and WHO standards and long experience in regulated markets. Its approach is more compliance driven and predictable, strengthening trust in generics and formulations. Strategically, China focuses on speed, scale, and innovation leadership, while India emphasizes consistency and reliability as a trusted global partner.

(Krishnanath Munde is Associate Director, Healthcare, India Ratings & Research- Fitch Group.)
(Mitali Dalvi is Senior Analyst, Healthcare, India Ratings & Research- Fitch Group.)

Reimagining pharma manufacturing...

CONTINUED FROM p16▶

Balancing Affordability and Sustainability

One of the industry's biggest challenges will be ensuring that greener manufacturing does not significantly increase medicine prices, especially for developing nations dependent on affordable pharmaceutical access.

Maintaining affordability while improving sustainability will require innovation, scale efficiencies, and supportive policy frameworks.

The Growing Importance of Industry Platforms

Global pharmaceutical exhibitions are increasingly becoming platforms for sustainability-driven collaboration.

Events such as CPHI & PMEC China 2026 and the 8th Arab Pharma Manufacturers' Expo 2026 are expected to spotlight:

- Green chemistry innovations
- Sustainable manufacturing technologies
- ESG-focused partnerships
- Clean energy integration
- Circular pharmaceutical supply chains
- Biotechnology advancements
- Smart manufacturing solutions

These forums are no longer limited to trade networking. They are evolving into strategic ecosystems where policymakers, manufacturers, technology providers, investors, and researchers collectively shape the future of pharmaceutical manufacturing.

The Middle East, particularly through platforms like the Arab Pharma Manufacturers' Expo, is also emerging as an increasingly important pharmaceutical hub connecting Asia, Africa, and Europe.

CONTINUED ON p19▶

Risk sharing finance and policy reform key to India's pharma growth: Bharat Shah

India's pharmaceutical industry is at a decisive turning point. The Revised Schedule M has elevated compliance to a system driven, risk management framework, while global competition intensifies through aggressive price cutting of APIs and Key Starting Materials. For India to sustain its role as the pharmacy of the world and evolve into a hub of biologics, biosimilars, and novel drug delivery systems, the sector must embrace a new triad: innovation, financing, and policy alignment.

In conversation with **LAXMI YADAV** of PharmaClick, **BHARAT SHAH** —National President of the Indian Drug Manufacturers' Association, stresses that India's leap forward requires risk sharing trade finance models, sovereign backed guarantees, and collaborative R&D consortia to de risk clinical trials. At the same time, green chemistry, continuous flow manufacturing, and advanced synthesis are vital to narrowing cost gaps and strengthening supply chain resilience.

Q1. While India's Tier 1 pharma giants can absorb the compliance costs of the Revised Schedule M, mid-market manufacturers operate on razor thin margins. As the industry's national voice, how does IDMA propose to prevent these upgraded quality benchmarks from entrenching a permanent economic divide—where MSMEs risk being priced out of global supply chains?

Bharat Shah: The Revised Schedule M is undoubtedly a pivotal milestone for Indian pharmaceuticals, shifting our regulatory framework from a traditional document-driven process to a system-driven, Quality Risk Management matrix. Large scale manufacturers possess the deep capital reserves to readily absorb these upgraded quality benchmarks, but our mid-market manufacturers, and medium enterprises operate on razor-thin margins. For these smaller units, the immediate capital expenditure required for infrastructure overhaul, sophisticated HVAC validation, and digital data-integrity systems can be incredibly daunting. IDMA's core position is that we wholeheartedly support the transition to world-class quality standards, but we staunchly oppose the economic exclusion of the small-scale sector that has long been the backbone of our domestic supply chain.

To prevent this upgraded benchmark from pricing smaller players out of the market, IDMA has actively implemented a multi-pronged advocacy and handholding framework. We have engaged with the Department of Pharmaceuticals regarding the Pharmaceutical Technology Upgradation Assistance Scheme to support greater accessibility for eligible MSMEs. We have also highlighted the need for phased implementation timelines, recognizing that smaller units may require additional time to undertake engineering modifications while managing operational and financial considerations.

Q2. India has historically worn the badge of "low-cost generic provider" with pride. However, shifting to a global leader in innovation requires a fundamentally different risk appetite. What specific, structural changes is IDMA pushing for transition our domestic industry culture from safe, reverse-engineered volumes to high-risk, high-reward novel drug discovery?

Bharat Shah: For decades, India has worn the badge of a low-cost generic provider with justifiable pride, scaling immense manufacturing heights through volumes. However, graduating to a global leader in genuine innovation requires a fundamental shift in our collective risk appetite and a departure from the short-term payback cycles that have traditionally dominated the domestic industry culture. High-risk, high-reward novel drug discovery demands structural patience and robust fiscal cushioning. IDMA is actively driving this cultural pivot by working hand-in-hand with policymakers to ensure the efficient, targeted rollout of certain schemes. We are focusing our efforts on ensuring this substantial state capital flows directly into industry-led consortia that are actively tackling complex generics, biosimilars, and new chemical entities.

Beyond direct funding schemes, achieving a true innovation mindset requires an ecosystem. We continue to engage with stakeholders on the importance of strengthening fiscal support for in-house R&D investment. At the same time, through initiatives such as Vriddhi, IDMA is facilitating greater interaction between mid-market pharmaceutical companies and global life sciences investors to encourage collaborative approaches toward innovation and drug development.

Q3. Chinese suppliers are aggressively slashing prices on Key Starting Materials (KSMs) and APIs specifically to undermine India's domestic PLI achievements. How can Indian companies realistically capture "value" and build supply chain resilience when our core input costs remain highly vulnerable to targeted price manipulation from Beijing?

Bharat Shah: The aggressive price cutting of key starting materials and active pharmaceutical ingredients by overseas competitors is a deliberate, targeted move designed to undermine the early achievements of India's schemes. Relying primarily on price-based competition against heavily supported external ecosystems may present long-term challenges for domestic manufacturers. Instead, Indian companies may benefit from placing greater emphasis on non-price value, quality differentiation, and broader supply chain resilience. In this context, IDMA is working to compile detailed pricing inputs from member units for submission to the authority, with the objective of supporting informed policy discussions around appropriate trade measures and a balanced competitive environment for domestic PLI beneficiaries.

True value, however, must also be strengthened from within. Under the framework of the Revised Schedule M guidelines, Indian-manufactured inputs are increasingly becoming more system-driven, traceable, and aligned with higher standards of data integrity. We are encouraging domestic formulation units to recognize the broader value associated with strengthening local API supply chains, particularly in the context of long-term operational reliability and supply continuity. Concurrently, wider adoption of green chemistry, continuous flow manufacturing, and advanced enzymatic synthesis among mid-market API players may be encouraged. By improving engineering efficiency, optimizing solvent usage, and enhancing chemical yields, Indian manufacturers can progressively narrow cost differentials through technological advancement alongside supportive policy measures.

Q4. As Indian manufacturers weigh high margin opportunities in MENA (Middle East and North Africa)—especially Saudi Arabia and the UAE, which are shifting from importing finished formulations to building local manufacturing hubs—does this pivot threaten India's premium export volumes, or is IDMA pushing for frameworks that enable Indian firms to co invest directly in Gulf based plants?

Bharat Shah: The strategic evolution of MENA nations—particularly Saudi Arabia under its Vision 2030 and the UAE—from simple import-dependent models to self-sustaining domestic manufacturing hubs should not be viewed as a threat to India's export volumes. Rather, it represents one of the most lucrative geographical expansions available to our industry today. If Indian pharmaceutical firms treat this transition merely as a defensive export challenge, we will eventually be replaced by local players; but if we view it as a collaborative investment landscape, we can secure dominant regional market shares for the next generation. IDMA actively supports its member companies and navigate this pivot by facilitating joint ventures and technology-transfer frameworks where Indian firms provide the core chemical expertise, operational experience, and bulk intermediates, while Gulf partners provide the necessary local capital, infrastructure, and priority regulatory access.

This dual-track strategy ensures that even as final formulation or packaging transitions locally into the Gulf, the high-value core chemistry and intellectual property remain firmly anchored within the Indian pharmaceutical ecosystem. Furthermore, as local Gulf facilities focus their initial capacities on high-volume, basic oral solids, exporters to elevate their product portfolios toward complex injectables, biologics, and novel drug delivery systems that regional hubs cannot yet manufacture locally. By systematically upgrading what we ship to these corridors, we protect our premium financial volumes while positioning Indian pharma as an indispensable, long-term technical partner in the MENA region's healthcare self-reliance journey.

CONTINUED ON p19▶

Risk sharing finance and policy reform...

CONTINUED FROM p18▶

Q5. As Gulf regulators tighten alignment with European Medicines Agency (EMA) standards, the cost of export registration for Indian firms has surged. Is the Indian Drug Manufacturers' Association (IDMA) actively pursuing a mutual recognition framework with MENA authorities so that Revised Schedule M certification is automatically accepted—shielding MSMEs from the financial strain of duplicative audits?

Bharat Shah: As Gulf regulatory bodies tighten their alignment with stringent European Medicines Agency and USFDA standards, the regulatory barriers for entry have naturally heightened. For mid-market Indian enterprises, the financial and operational strain of undergoing multiple, highly duplicative international audits and compiling varied localized registration dossiers has become a severe bottleneck. To help reduce the burden of these additional expenses on smaller manufacturers, IDMA is engaging with relevant authorities at the government-to-government level. We are also supporting discussions around the international alignment of the Revised Schedule M framework, which incorporates several elements of global WHO-GMP guidelines, with the aim of reinforcing confidence in the quality standards of Indian pharmaceutical manufacturing.

We are actively utilizing institutional channels, such as the India-UAE Comprehensive Economic Partnership Agreement, to urge the Ministry of Commerce and the Central Drugs Standard Control Organisation to negotiate formal mutual recognition agreements with the GCC (Gulf Cooperation Council) Health Council. Our ultimate objective is to establish a streamlined, fast-track compliance corridor where an Indian facility audited and approved under our updated national standards can enjoy a paperless desk-review approval in Gulf markets. This framework would effectively eliminate the need for duplicative site inspections, allowing mid-market manufacturers to deploy their limited capital toward product development and market expansion rather than redundant administrative compliance.

Q6. Transitioning to complex biologics and novel drug delivery systems requires deep, long-term capital that typical mid-market balance sheets cannot absorb. When smaller manufacturers target competitive corridors, what specific trade-finance models or risk-sharing funds is IDMA advocating for to help them survive the steep costs of global bioequivalence studies and clinical trials?

Bharat Shah: Transitioning into the complex world of biologics, biosimilars, and advanced drug delivery systems requires a depth of long-term capital that typical mid-market balance sheets simply cannot absorb on their own. The reality is that a single global bioequivalence study or a multi-center clinical trial can easily consume the entire annual net profit of a mid-sized manufacturer, presenting an unacceptable risk of operational insolvency if a molecule fails to achieve its endpoints. To bridge this critical financing gap, IDMA is actively advocating for the creation of specialized, non-traditional trade-finance models and sovereign-backed risk-sharing instruments that cushion the financial blow of advanced clinical development.

The financing structures are being discussed with extended periods that are better aligned with the timelines typically associated with clinical development and regulatory approvals in target markets. At the same time, IDMA is encouraging smaller manufacturers to consider product-specific R&D consortia, enabling multiple non-competing regional firms to share the significant development and trial costs associated with complex molecules. We are also advocating discussions around a potential partial credit guarantee mechanism for clinical research, where a portion of the financial risk could be supported institutionally in cases where complex generics do not achieve the desired regulatory outcomes, thereby helping mid-market firms participate more confidently in global opportunities while managing financial exposure more effectively.

Q7. India's pharmaceutical R&D spend as a percentage of revenue remains significantly lower than Western counterparts, and academic research rarely translates into commercial products. Beyond high-level policy discussions, what concrete and collaborative frameworks is IDMA championing to force academia and commercial pharma to co-develop marketable IP?

Bharat Shah: The observation that India's extensive academic research has not always translated into commercially viable pharmaceutical products reflects a longstanding gap between academic and industrial priorities. Traditionally, academic institutions have focused on research publications and scientific recognition, while the pharmaceutical industry places greater emphasis on regulatory feasibility, stability requirements, and commercial scalability. To help bridge this gap in a more structured manner, IDMA is supporting practical collaboration frameworks aimed at encouraging closer alignment between academia and industry.

IDMA is exploring frameworks to facilitate greater participation of industrial analytical and regulatory experts within leading academic institutions such as the NIPER. This approach is intended to help align academic research more closely with practical scale-up considerations and commercial requirements. We are also encouraging discussions around milestone-linked grant models such as pilot-scale optimization and stability evaluation.

Q8. You have been a strong proponent of digital health and technology integration. Realistically, given the fragmented nature of our domestic logistics, where will the Indian pharma industry stand in the next five years regarding the mandatory adoption of AI-driven supply chain transparency and track-and-trace compliance?

Bharat Shah: Given the deeply fragmented nature of our domestic logistics network, which relies on thousands of independent distributors and varied regional transport systems, the mandatory adoption of advanced technology cannot happen overnight. However, global regulatory mandates and the absolute necessity of anti-counterfeiting measures mean that tech-driven supply chain transparency is rapidly becoming mandatory. Over the next five years, the Indian pharmaceutical industry will undergo a calculated, inevitable transformation, moving systematically from basic digital serialization to fully integrated, intelligent logistics networks.

The immediate horizon is expected to focus on progressing toward item-like QR coding, with the aim of extending these systems from large exporters to mid-market domestic formulation units. Following this foundational phase, the industry may move toward greater integration of software interfaces linking manufacturers with their primary distributors. To help ease the transition for smaller stakeholders, scalable and cost-efficient digital frameworks are being explored through simpler, mobile-based applications, rather than requiring full-scale ERP system upgrades. Over the coming years, AI-enabled supply chain platforms are likely to become more widely adopted across the mid-market, using aggregated logistics data to better anticipate regional demand trends, support cold-chain monitoring in challenging geographies, and improve inventory planning with the objective of reducing product expiry-related losses and improving overall efficiency.

India's pharmaceutical industry stands at a defining inflection point. The transition from volume-led growth to value-driven leadership will require a collective commitment. At IDMA, our focus remains on ensuring that this transformation is inclusive. By strengthening the systems, we are confident that Indian pharma will continue to be not only the pharmacy of the world, but also an increasingly influential force in shaping the future of global healthcare.

Reimagining pharma manufacturing...

CONTINUED FROM p17▶

A Defining Decade for Pharmaceutical Sustainability

The pharmaceutical industry is entering an era where industrial growth and environmental responsibility can no longer operate separately.

India and China have already transformed global healthcare access through scale, affordability, and manufacturing strength. Their next challenge is even more significant: creating a pharmaceutical ecosystem capable of meeting global healthcare demand without compromising environmental sustainability.

Green chemistry offers a pathway toward that future.

The next phase of pharmaceutical leadership will not be determined solely by production capacity or cost advantages. It will belong to countries and companies capable of combining scientific innovation, sustainable manufacturing, technological advancement, and resilient global partnerships.

The evolution of the India-China pharmaceutical relationship reflects this broader industry transformation.

The conversation is no longer just about APIs

It is about cleaner processes, smarter factories, responsible innovation, low-carbon manufacturing, and a shared commitment to building a sustainable healthcare future for generations to come.

(The author is a Leading Pharmaceutical Consultant and ditor- in Chief of IJMToday.)