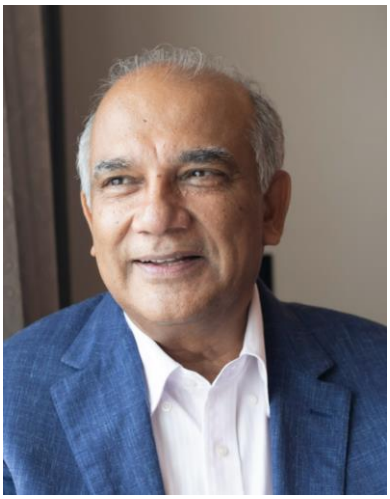
The Great Pharmaceutical Supply Chain Realignment: Why Global Pharma is Actively Seeking New CDMO Partners Outside China



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Introduction: A Structural Shift That Will Redefine Global Pharmaceutical Leadership

For over two decades, global pharmaceutical supply chains were architected around a single organising principle: cost and scale efficiency. China became the central backbone of this system, emerging as the dominant supplier of pharmaceutical intermediates, key starting materials (KSMs), and active pharmaceutical ingredients (APIs), with multiple industry analyses placing its share of global API volume at roughly one-fifth and confirming its position as the world's largest chemical API producer and exporter by value and volume.[134] In 2023, Chinese API exports reached approximately 12.489 million tonnes with an export value of about USD 40.93 billion, while 2024 estimates indicate exports of around USD 43 billion and 14.9 million tonnes, reflecting a deliberate "volume-for-price" strategy and continued consolidation of global market share.[145]

China's overall pharmaceutical and healthcare market has simultaneously expanded into a multi-hundred-billion-dollar opportunity, creating a powerful dual role as both supplier to the world and high-growth domestic market.[67] This dominance rests on deep integration between basic chemicals, intermediates, APIs, and formulations, supported by extensive industrial parks, port infrastructure, and a

large base of export-oriented manufacturers.[134] Yet, the very concentration that once maximised efficiency has now become a strategic vulnerability.

Today, pharmaceutical leadership is being redefined. Global companies no longer optimise solely for lowest cost; they optimise for resilience, diversification, regulatory stability, and long-term security of supply.[89] Multiple governments have explicitly identified pharmaceutical supply chains as a strategic and national security priority, forcing boards and regulators to re-evaluate geographic concentration risks in APIs, intermediates, and finished formulations.[89] This shift is catalysing a once-in-a-generation realignment of global contract development and manufacturing organisation (CDMO) partnerships, creating unprecedented opportunity for capable, compliant, and innovation-oriented partners outside China—most notably in India.[1011]

"Supply chains built on efficiency create profits. Supply chains built on resilience create leadership."

China's Dominance in Pharmaceutical Manufacturing: Leadership in Both Volume and Value

China's competitive strength in pharmaceuticals originates upstream, in its control of chemical building blocks, intermediates, and key starting materials that feed the global API and formulation ecosystem.[134] Over the past decade, China has built a dense, export-oriented API and intermediate industry, with more than 1,500 API manufacturers and production capacity exceeding 2 million tonnes per year across more than 2,000 distinct drug substances.[1] In value terms, Chinese API exports rose from about USD 23.6 billion in 2013 to roughly USD 51.8 billion in 2022, with volumes reaching around 11.94 million tonnes, highlighting a structural rise in both scale and sophistication.[15]

Several structural features underpin this dominance:

- An integrated petrochemical and fine-chemicals base that provides competitive access to solvents, reagents, and intermediates at scale.[34]

- Large, specialised industrial clusters with shared utilities, effluent treatment, and logistics, creating significant economies of scale.[3]

- A broad spectrum of manufacturers, from commodity API producers to advanced intermediates and regulated-market suppliers, enabling end-to-end sourcing strategies for global buyers.[13]

- Increasing investment in higher-value and innovative APIs, supported by policy incentives and strong export orientation.[45]

China has also rapidly expanded its innovation footprint. In recent years it has consistently ranked among the top countries globally by number of clinical trials initiated, particularly in oncology, biologics, and cell and gene therapies, signalling a transition from pure volume supplier to innovation-linked manufacturing hub.[412] The combination of upstream chemical dominance, export scale, and growing R&D intensity has made China deeply embedded in the global pharmaceutical value chain.

Yet, this centrality has a corollary: systemic concentration risk. When a single geography becomes the irreplaceable source for a large share of KSMs, intermediates, and APIs, any disruption—whether pandemic-related, geopolitical, environmental, or regulatory—can cascade rapidly into global shortages and price volatility.[89]

"When one country becomes the pharmacy of the world, the world inherits that country's risks along with its strengths."

COVID-19, Geopolitics, and the Exposure of Structural Vulnerabilities

The COVID-19 pandemic was the most visible stress test of modern pharmaceutical supply chains. Global surveys of healthcare and life-science companies found that an overwhelming majority experienced significant supply chain disruptions during 2020–2022, including delays, stockouts, and sudden spikes in procurement costs.[13] In multiple segments, these disruptions affected not only finished drugs but also APIs, excipients, packaging materials, and critical raw materials required for sterile injectables and vaccines.[138]

In Europe, policymakers documented the extent of external dependence: around 60% of APIs used in the EU are imported, with China and India as the principal suppliers, and certain antibiotic and analgesic classes showing extremely high concentration in a handful of offshore facilities.[8] Parallel reviews in the United States classified pharmaceutical supply chain dependence—especially in antibiotics, oncology medicines, and sterile injectables—as a strategic vulnerability, leading to new initiatives on reshoring, near-shoring, and diversification of essential medicine production.[9]

Lockdowns, port closures, container shortages, and export restrictions during the pandemic demonstrated how quickly local disruptions could turn into global supply crises.[13] Geopolitical tensions, sanctions risk, and trade disputes have further

amplified the perceived fragility of long, tightly optimised supply chains that stretch across multiple continents and regulatory regimes.[912]

"The pandemic did not create supply chain risk. It revealed its true magnitude."

For global pharmaceutical companies, this experience has fundamentally altered the risk calculus. Supplier selection is no longer purely a procurement decision; it is a strategic, board-level decision tied directly to business continuity, patient safety, and national security.[89]

From Cost Optimisation to Strategic Diversification: The Rise of 'China Plus One'

In response to these structural vulnerabilities, a clear strategic paradigm has emerged: "China Plus One." This approach does not attempt to disengage from China; rather, it seeks to reduce over-concentration by building credible, scalable, and regulatory-compliant capacity in at least one additional geography.[412]

Several trends illustrate the momentum behind this shift:

- Multinational originator companies are segmenting their portfolios, retaining certain products and technologies in China while intentionally relocating others—especially critical, politically sensitive, or high-risk categories—to alternative sites.[412]

- Generics and biosimilars companies are increasingly adopting dual-sourcing and multi-regional sourcing models for APIs and intermediates, spreading production across China, India, and select sites in Europe, the United States, and Southeast Asia.[141518]

- Governments in the EU, US, Japan, and other markets are incentivising local and allied-country production of essential medicines, antibiotics, and critical raw materials through grants, tax credits, and preferential procurement policies.[89]

This is not a short-term reaction but a structural re-engineering of supply chains. While China will remain an indispensable partner, no responsible global pharmaceutical company or regulator is prepared to accept single-point-of-failure exposure in APIs and intermediates.[89] In parallel, there is sustained demand for robust CDMO ecosystems in alternative hubs—India being the most prominent among them.[101117]

"De-risking is not about abandoning incumbents. It is about ensuring that patients are never hostage to a single postcode."

India's Pharmaceutical Industry: Volume Leadership and Accelerating Value Creation

India has long been recognised as the "pharmacy of the developing world," but its role has now expanded to that of a globally indispensable supplier of generics, vaccines, and increasingly complex therapies.[1011] Recent government and industry data underscore this structural importance. India accounts for a substantial share of the global supply of generic medicines by volume and is a leading supplier to highly regulated markets including the United States and Europe.[101117] India's pharmaceutical exports reached approximately USD 30.47 billion in FY 2024–25, recording about 9.4% year-on-year growth and continuing a decade-long upward trajectory.[17272830]

India's broader pharmaceutical market is currently estimated at around USD 60 billion in domestic value and is projected to grow to approximately USD 130 billion by 2030, driven by rising healthcare access, increased chronic disease burden, and expansion in biologics and complex generics.[2730] This growth is supported by more than 3,000 companies and over 10,500 manufacturing units, making India the world's third-largest pharmaceutical producer by volume and fourteenth by value.[27]

The country is home to the largest number of US FDA-approved manufacturing sites outside the United States, alongside extensive approvals from EMA, MHRA, and other stringent regulatory authorities, providing global companies with a vast network of facilities already aligned to international quality standards.[101114] India exports pharmaceutical products to over 200 countries, with more than 60% of exports directed to highly regulated markets.[2723]

India's contribution to global public health is particularly visible in vaccines and life-saving therapies:

- A large share of UNICEF's vaccine procurement is supplied by Indian manufacturers, underpinning childhood immunisation programmes in low- and middle-income countries.[1023]

- India supplies a majority of WHO-prequalified antiretroviral therapies for HIV/AIDS, significantly reducing treatment costs and enabling wide access in resource-constrained settings.[23]

"Volume creates relevance. Reliability creates trust. Trust creates leadership."

Supported by a strong base of chemists, process engineers, and formulation scientists, India now offers not just low-cost manufacturing but high-quality, innovation-linked, and regulatory-credible capacity at scale.[101114]

The Global CDMO and CRDMO Boom: Outsourcing as Structural Strategy

Pharmaceutical outsourcing to CDMOs and CRDMOs (Contract Research, Development and Manufacturing Organisations) has evolved from a tactical cost-saving measure into a structural feature of the global industry. A recent market analysis estimated the global CDMO market at about USD 128 billion in 2023, with projections to reach approximately USD 191.6 billion by 2029, implying a compound annual growth rate of around 7% over 2024–2029.[15][29][31] Other forecasts, using broader service definitions, place the 2024 market at roughly USD 140–145 billion with a trajectory to more than USD 380 billion by 2033.[18]

Several forces drive this sustained expansion:

- Escalating R&D complexity, particularly in oncology, rare diseases, and advanced biologics, which pushes innovators to externalise development and manufacturing to specialist partners.[18][31]

- Capital intensity and technical risk of building, validating, and maintaining multipurpose GMP facilities for modalities such as high-potency APIs, sterile injectables, and biologics.[18][31]

- The need for speed: CDMOs with existing capacity and know-how can accelerate time-to-market compared with greenfield in-house builds.[15][18][31]

Outsourcing now spans the entire value chain—from pre-clinical route scouting and process development to late-stage clinical manufacturing, commercial APIs, finished dosage forms, and lifecycle management.[15][18] CDMOs already manufacture a large share of global API volume and an increasing proportion of complex formulations, biosimilars, and specialised dosage forms.[18][31]

India's CRDMO sector is at the forefront of this trend. Anchored by strong capabilities in process chemistry, scale-up, and cost-efficient GMP manufacturing, Indian providers are moving up the value chain into end-to-end offerings that integrate discovery chemistry, development, and commercial supply.[10][11][14][17] With exports already exceeding USD 30 billion and a pipeline of capacity additions in high-potency APIs, injectables, biologics, and specialty generics, India's CDMO and CRDMO industry is well positioned to capture a disproportionately large share of the incremental global outsourcing demand.[14][17][23]

"In a world of finite capital and infinite scientific ideas, outsourcing is not a choice. It is the operating system of modern pharma."

Biotechnology Innovation and the Manufacturing Bottleneck

The pharmaceutical innovation engine has rarely been more productive. Industry R&D intelligence platforms report thousands of active molecules in clinical and late-preclinical development, spanning small molecules, monoclonal antibodies, antibody–drug conjugates, RNA-based therapies, cell and gene therapies, and novel modalities.[14][15][18] The cumulative, risk-adjusted commercial potential of this global pipeline over the next decade is estimated at well over USD 1 trillion in peak sales value.[15][18]

Yet, most biotechnology companies—especially early-stage ventures—do not possess commercial-scale manufacturing infrastructure. Building such capability demands high capital expenditure, multi-year lead times, sophisticated regulatory and quality systems, and a specialised workforce.[15][18][31] Even large pharmaceutical companies selectively externalise manufacturing for certain modalities or regions to CDMOs to preserve flexibility and reduce balance-sheet intensity.[18][31]

This creates a structural manufacturing bottleneck: while the number of molecules in development continues to rise, the number of companies capable of reliably scaling, validating, and commercialising these molecules under global GMP standards remains comparatively limited.[14][15] For venture-backed biotechs, the availability, capacity, and reliability of CDMO partners can determine whether promising molecules progress or stall.[15][18]

"Innovation without manufacturing capability remains unrealised potential."

In this context, the global shortage is not of scientific ideas, but of high-quality, dependable scale-up and commercial manufacturing partners with the right blend of scientific, engineering, and regulatory competence.[14][15][18]

Scale-Up, Process Excellence, and Regulatory Depth: The New Strategic Currency

Scale-up and process industrialisation are often underestimated in strategic discussions, yet they determine the majority of long-term manufacturing economics. Multiple consulting and industry analyses indicate that a substantial share of lifetime manufacturing cost is effectively locked in during process development and early scale-up, where choices on route, yield, impurity profile, solvent recovery, and plant configuration are made.[15][18][31] Small differences in process design can translate into large differences in cost of goods, environmental footprint, and robustness at commercial scale.[15][18]

Key differentiators of the next-generation CDMO include:

- Process design and optimisation: Ability to design robust, scalable routes with high atom economy, optimised solvent usage, and minimal hazardous operations.[14][18]

- Scale-up and technology transfer: Proven methodologies for de-risking tech transfer from laboratory to kilo lab, pilot, and commercial scale, including digital tools, models, and rigorous process safety frameworks.[1831]

- Regulatory and quality depth: Strong track record with US FDA, EMA, and other major regulators; comprehensive data integrity systems; and capability to support complex regulatory filings across multiple jurisdictions.[101114]

- Operational resilience and EHS performance: Redundant utilities, robust supply of critical consumables, strong environmental controls, and demonstrable compliance with evolving ESG expectations.[8918]

"A molecule's destiny is not decided in the laboratory. It is decided in the discipline with which we scale it."

In a world prioritising resilience, originator and generic companies will increasingly favour CDMOs that combine scientific depth with industrial discipline—partners that can deliver on time, every time, under varying external conditions.[1518]

India as the Strategic 'Plus One': Beyond Low Cost to Strategic Co-Creation

India's rise as the preferred "Plus One" in the China Plus One strategy is driven by a confluence of capabilities rather than a single advantage. It offers:

- Proven export scale: More than USD 30 billion in annual pharmaceutical exports across over 200 countries, with a significant share destined for highly regulated markets.[17272830]

- Regulatory credibility: Hundreds of US FDA-approved and EU-inspected sites, including for complex injectable, oncology, and biologic products.[101114]

- Deep talent pool: Large numbers of chemists, pharmacists, and engineers, many with experience in global multinationals and exposure to international quality standards.[10111423]

- Cost-effective yet sophisticated operations: Competitive cost base without a compromise on quality, increasingly supported by digitalisation, QbD (Quality by Design), and advanced analytical capabilities.[101114]

In addition, the Indian policy environment is increasingly supportive of pharmaceutical and CDMO investment. Initiatives such as production-linked incentives for APIs, KSMs, and drug intermediates, as well as dedicated bulk-drug parks, seek to strengthen upstream self-reliance and reduce import dependence

from any single geography.[101117] This directly aligns with the diversification objectives of global customers.[8918]

"The future of pharma will not be decided by who is cheapest, but by who is trusted to be there when it matters most."

Strategically, India is moving from a role as a transactional supplier to that of a co-creation partner—engaging earlier in the development lifecycle, jointly investing in capacity, and sharing risk and reward in long-term programmes.[10111723]

What Global Pharma Now Expects from New-Age CDMOs

As global companies rebalance their manufacturing footprints, expectations from CDMO partners are evolving in three distinct dimensions: risk, capability, and partnership model.[151831]

1. Risk and resilience

- Geographic diversification to reduce exposure to single-country shocks.[8912]

- Demonstrated business continuity planning, including multi-site strategies, backup utilities, and robust supply networks for critical raw materials.[1518]

- ESG-aligned operations, including responsible waste management and carbon-conscious process design.[8918]

2. Technical and regulatory capability

- End-to-end offering from route scouting and process development to commercial manufacturing for APIs and formulations.[141518]

- Modality breadth, including small molecules, high-potency APIs, complex generics, peptides, biologics, and, increasingly, advanced therapies.[141518]

- Strong regulatory dossier support for global submissions (US, EU, Japan, and key emerging markets).[101114]

3. Partnership and governance

- Strategic, multi-year partnerships rather than transactional, tender-driven engagements.[151831]

- Transparent governance, clear KPIs, and data-driven performance management.[1831]

- Willingness to co-invest in capacity, technology, or risk-sharing models for critical assets.[1518]

Indian CDMOs that can match these expectations are well placed to become the preferred partners for a diversified global pharmaceutical ecosystem.[1011141723]

"In the new order, CDMOs will not merely execute projects. They will co-author the industrial history of each molecule."

Conclusion: A New Global Pharmaceutical Order Is Emerging

China will continue to be a dominant force in global pharmaceutical manufacturing, underpinned by its extensive chemical ecosystem, export scale, and growing innovation engine.[13410] Its role as a critical supplier of APIs and intermediates will remain central, particularly for volume-driven products and certain advanced chemistries.[115] However, the era of unconstrained dependency on a single geography is over. Patients, regulators, and boards are aligned on the need for diversified, resilient, and transparent supply chains.[8912]

Global pharmaceutical companies are reshaping their manufacturing strategies accordingly. Dual-sourcing, multi-region sourcing, and "China Plus One" models are now embedded in long-term planning.[412] In this emerging order, India stands out as the most strategically positioned alternative and complementary hub, combining scale, scientific depth, regulatory credibility, and a rapidly maturing CDMO and CRDMO ecosystem.[1011141723]

For India's leading CDMOs, this moment is more than a commercial opportunity; it is a generational inflection point. Those who invest early in scale-up excellence, digital quality systems, ESG performance, and true partnership models will not simply participate in the reconfigured landscape—they will help define it.[141518] The realignment of global pharmaceutical supply chains will, in retrospect, be seen not as a marginal optimisation, but as a turning point in how the world secures access to essential medicines.[891215]

"Every structural shift creates new leaders. Those who prepare early do not follow the future. They help shape it."

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sources and may evolve as new data emerge. The article does not represent investment, legal, regulatory, or medical advice and should not be used as a substitute for professional consultation.[8][9][15][18]