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RISK FRAMEWORKS FOR CHINA+1 STRATEGIES

PLAYBOOK

SUMMARY

Global pharma and biotech companies are accelerating China+1 strategies to reduce over dependence on Chinese supply chains while preserving cost and capacity advantages. India has emerged as the leading "plus one" destination for small molecules and selected biologics, supported by the largest base of US FDA-compliant plants outside the US, a deep pool of CROs/CDMOs, and competitive labor costs.

This document proposes an end-to-end risk framework for designing and executing China+1 strategies in pharmaceuticals and biotechnology covering macro geostrategic risks, supply-chain and quality risks, regulatory and data-integrity risks, and partnership/ESG risks.

1. STRATEGIC CONTEXT TO CHINA +1 STRATEGIES

1.1 Drivers of China+1 in Pharma and Biotech

China has a hyper-concentration of the key APIs, intermediates and biologics manufacturing market. Many strategic factors such as US–China tariff escalations, the valsartan/NDMA contamination crisis revealing single-source API vulnerabilities and Covid-19 supply disruptions deemed this hyper-concentration in china as an operational risk.

The key strategic drivers include:

- **Geopolitical risk and sanctions exposure:** US BioSecure Act discussions and export controls increase perceived risk of relying solely on Chinese CDMOs for sensitive categories (e.g., biologics, GLP-1, oncology APIs).
- **Cost evolution:** Chinese manufacturing wages and compliance costs have risen sharply, eroding the historical cost gap versus India and other Asian markets.
- **Regulatory/integrity scrutiny:** Heightened FDA/EMA scrutiny of data integrity, supply quality, and chain-of-custody encourages diversification into jurisdictions that can demonstrate robust GMP and traceability systems.
- **Supply assurance:** Boards expect resilient supply of critical medicines even under pandemics, regional lockdowns, or geopolitical shocks, which requires dual-sourcing with geographically separated sites.

1.2 Why India Is the Primary "Plus One"

India combines three structural advantages that are directly relevant for pharma and biotech China+1 strategies:

- **Regulatory footprint:** India hosts the largest number of US FDA-approved drug manufacturing plants outside the US, with widely cited gures of more than 600 sites for APIs and formulations.
- **CRO/CDMO ecosystem depth:** Over half of Asia-Pacific CROs are based in India, and a signicant share of API and FDF CDMO capacity is concentrated in the country, especially for small molecules.
- **Cost and talent:** Labor and operating costs remain structurally below while India offers a large English-speaking scientific workforce, especially in chemistry, formulations, and bioanalytics.

At the same time, India’s R&D intensity as a percentage of GDP remains far below China’s, limiting domestic originator innovation but providing a strong base in generics, complex generics, and biosimilars. China currently leads in novel biologics, oncology innovation, and advanced modalities, but India offers a commercially and regulatory attractive diversification node for manufacturing and selected development work.

2. China vs India in Pharma and Biotech Outsourcing

2.1 Manufacturing and Regulatory Footprint

- **FDA-approved plants:** India hosts the largest concentration of US FDA-approved manufacturing plants outside the US, often cited at 600+ facilities; China has far fewer.
- **CRO distribution:** Over 50% of Asia-Pacific CROs are located in India, while about 18% are in China, illustrating India's historical depth in clinical and bioequivalence work.
- **Market trajectory:** India's pharmaceutical contract services market is capturing a growing share of global outsourcing ows as China+1 contracts materialize.

2.2 Cost and Capability Benchmarks

- **Labor and manufacturing costs:** Wages and operating costs in India remain structurally below China's, providing a cost advantage for labor-intensive manufacturing and development tasks.
- **Capability mix:** India is strongest in small-molecule APIs, oral solid dose formulations, and certain biologics and biosimilars, while China has built capabilities in novel biologics, cell and gene therapies, and advanced oncology platforms.
- **CDMO market dynamics:** The global CDMO market is projected to grow at about 6.3% CAGR from 2026 to 2031, with Asia-Pacific as the fastest-growing region; API manufacturing accounts for more than half of CDMO revenues, with HPAPIs among the fastest-growing segments.

3. Risk Framework Architecture for China+1 with India as a Nod

3.1 Core Principles

- **Dual-Qualified Supply:** Critical products must have at least two geographically distinct, regulatory-compliant manufacturing sites (e.g., one in China, one in India or elsewhere) qualified under the same regulatory dossier.
- **End-to-End Visibility:** Risk assessment should span KSMs, intermediates, APIs, FDFs, and clinical operations — not just the nal manufacturing step.
- **Regulatory Equivalence:** Alternative sites must meet target agency expectations (FDA/EMA/PMDA), not just domestic regulators, including data-integrity systems and change-control regimes.
- **Dynamic Risk Adjustment:** Risk scores and mitigation actions should be periodically updated as geopolitical, regulatory, and performance signals change.

3.2 Risk Domains and Scoring Model

Sponsors can structure risk assessment across different domains, each scored on likelihood and impact, then weighted for product criticality such as:

- Geopolitical and macro risk
- Regulatory and quality risk
- Operational and capacity risk
- Financial and contractual risk
- ESG, cyber, and reputation risk

Each domain can be broken into criteria with 1–5 scoring scales (low to very high risk), and weighted by product criticality (e.g., life-sustaining medicines vs non-critical products). India versus China-specific risk factors (e.g., FDA inspection history, wage in ation, climate-related disruption) can be embedded as sub-criteria.

3.3 Risk Heat Map and Product Segmentation

Apply the scoring model at a product-family or program level and map into a 2x2 or 3x3 grid (e.g., low/high supply risk vs low/high revenue or clinical impact). Products in the upper-right quadrant (high risk, high impact) should be prioritized for China+1 diversification into India or other nodes.

Examples:

- High-risk, high-impact: Oncology injectables relying on a single Chinese HPAPI supplier.
- Moderate-risk, high-impact: Chronic disease oral solids where multiple Chinese suppliers exist but all in same region.
- Lower-risk: OTC and non-critical therapies with multiple global suppliers and long shelf life.

4. Navigating Rising R&D Costs in a China+1 Context

4.1 Global R&D Cost Pressures and Shifts

Biopharmaceutical R&D funding remained high in 2025 but moderated versus 2024, with deal making increasingly concentrated in high-value science and emerging biopharma. At the same time, scientific complexity, longer development timelines, and regional disparities in trial access are pressuring productivity and forcing companies to search for efficiency levers, including geographic arbitrage and smarter outsourcing.
India is capturing more development and manufacturing work rather than early discovery or first-in-class pipelines.

4.2 Leveraging India to Manage R&D Costs

Sponsors can use India within their China+1 playbook to o set rising R&D costs via:

- **Cost-effective early development:** Shifting preclinical toxicology, bioanalytics, and formulation screening to India-based CROs operating under GLP and aligned with FDA/EMA expectations.
- **India-based clinical operations:** Conducting parts of Phase 2/3 and bioequivalence studies in India to leverage lower per-patient costs while complying with CDSCO and Indian GCP guidelines plus FDA/EMA standards for global submissions.
- **Digitally enabled operations:** Partnering with Indian CROs/CDMOs that deploy AI/ML, automation, and digital QMS/LIMS platforms to reduce cycle times and rework.

4.3 Transaction and Partnership Models

To balance cost and control, companies can adopt hybrid partnership structures:

- **Anchor partnerships:** Multi-asset, multi-year contracts with leading Indian CDMOs that integrate research, development, and manufacturing under uni ed governance and performance metrics.
- **Portfolio-based sourcing:** Bundling similar assets (e.g., multiple oral solids or injectable lines) across China and India partners to achieve volume discounts and learning-curve benefits.
- **Co-development and risk sharing:** Structured deals where Indian partners co-invest in development in return for revenue-sharing in emerging markets, reducing upfront sponsor R&D spend.

5. Regulatory and Compliance-Friendly Frameworks

5.1 Multi-Jurisdictional Regulatory Mapping

A core element of the +1 strategy is an integrated regulatory map across FDA, EMA, PMDA, and CDSCO expectations:

- **Drug approval frameworks:** FDA (21 CFR Parts 210/211, IND/NDA/BLA), EMA centralized procedure and national CTAs, and India's New Drugs and Clinical Trial Rules (NDCTR) under CDSCO, which govern approvals of new drugs, biologics, biosimilars, and fixed dose combinations.
- **Clinical trial governance:** India requires CDSCO and DCGI approval, ethics committee clearance, and SUGAM portal submissions, with updated rules mandating registration of CROs performing BA/BE and clinical trials.
- **Post-approval changes:** EMA, FDA, and CDSCO have different classification schemes for variations and post-approval changes, requiring tailored change-control and regulatory filing strategies when switching or adding sites (e.g., China to India).

5.2 Data Integrity and Quality Systems Alignment

To make China+1 strategies inspection-resilient, sponsors should define minimum quality expectations for all CDMOs, including:

- **ALCOA+ data integrity** principles applied to all GMP, GLP, and GCP data, with harmonized electronic systems, audit trails, and archival practices.
- **Harmonized QMS:** Integrated change-control, deviation management, CAPA, and management-review systems across Chinese and Indian facilities, aligned with FDA/EMA data-integrity and GMP guidance.
- **Cross-site comparability:** For biologics and complex generics, risk-based comparability protocols when transferring processes from China to India, including analytical characterization, impurity profiles, and stability bridging.

5.3 GCP/GLP/GMP Oversight for Indian CROs and CDMOs

For India-based partners, compliance-friendly oversight should include:

- **Pre-contract qualification:** GCP/GLP/GMP audits, verification of regulatory history (CDSCO, US FDA, EMA, PMDA inspections), and review of SOPs, training, and data systems.
- **Ongoing oversight:** Periodic audits, remote review of e-systems, KPI/KRI dashboards on deviations, CAPA effectiveness, and inspection outcomes.
- **Integrated governance:** Joint quality councils and technical committees spanning sponsor, China-based, and India-based partners to align on change-management, deviations, and regulatory interactions

6. Technology and Capability Roadmaps for India within China+1

6.1 Small Molecules and HPAPIs

India is particularly strong in small-molecule APIs, oral solids, and is increasing HPAPI capabilities. A technology roadmap for these segments can include:

- Upgrading containment and OEL banding capabilities for HPAPIs.
- Continuous manufacturing and process analytical technology (PAT) adoption.
- Advanced impurity profiling and nitrosamine risk management.

6.2 Biologics, Biosimilars, and Vaccines

India has built meaningful capacity in biosimilars and vaccines, with select CDMOs offering large-molecule cGMP manufacturing and development services. A roadmap should emphasize:

- Scaling single-use bioreactor capacity and downstream processing capabilities.
- Implementing advanced analytics and digital batch-release systems.
- Developing capabilities for complex biologics such as monoclonal antibodies, fusion proteins, and eventually ADCs, in partnership with innovators.

6.3 Digital, AI, and Data Platforms

Digital and AI capabilities can materially reduce R&D and manufacturing costs and improve risk control:

- AI-supported trial design and site selection to optimize India-based and global trials.
- Predictive maintenance and process control in Indian manufacturing plants to reduce downtime and deviations.
- Integrated data platforms unifying China and India operational data for real-time risk monitoring and regulatory reporting.

7. Stakeholder Engagement in China+1 Programs

7.1 Internal Stakeholders

Internal stakeholders include corporate strategy, R&D, technical operations, QA/QC, regulatory a airs, procurement, finance, and ESG/sustainability teams.

- **Clear governance:** Establish a China+1 steering committee with representation from all critical functions to approve portfolio segmentation, partner selection, and major technology transfers.
- **Incentive alignment:** Align KPIs so that cost savings do not undermine quality or resilience goals (e.g., dual metrics on cost per unit and supply-risk reduction).

7.2 External Stakeholders

External stakeholders include regulators (FDA, EMA, CDSCO, PMDA, NMPA), CDMOs/CROs in China and India, investors, and, in some cases, patient groups and NGOs.

- **Transparent regulatory dialogue:** Early scientific advice and CMC consultation when adding India as an additional manufacturing site to ensure change-control strategies align with agency expectations.
- **Investor communication:** Explaining China+1 diversification as a resilience and compliance initiative rather than a pure cost arbitrage to reduce perceived risk.
- **Local ecosystem partnerships:** Collaborations with Indian industry associations, academic centers, and regulators to anticipate regulatory changes and access talent.

8. **Strategic Upside of India-Focused China+1**

When implemented with a structured risk framework, India-centric China+1 strategies o er multiple upside levers: Resilience and regulatory optionality: Dual sourcing across China and India improves supply continuity and provides options if one geography faces regulatory, geopolitical, or pandemic shocks.

- **Cost competitiveness:** India's lower labor and operating costs help counter rising global R&D and manufacturing expenses without necessarily sacrificing quality, especially for small molecules and biosimilars.
- **Market access and growth:** India's expanding domestic market and role as an Asia-Pacific pharma hub create additional revenue opportunities and a platform for emerging-market expansion.
- **Ecosystem diversification:** Partnerships with Indian CDMOs, CROs, and academic centers broaden the innovation and execution network, reducing overdependence on a single country's policies and industrial cycles.

The most successful China+1 programs treat India not as a low-cost alternative but as a strategic node in a multi-country biopharma network, underpinned by rigorous risk frameworks, technology roadmaps, and compliance-by-design governance.

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