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7 Forces Reshaping Global Biologics Manufacturing

White Paper

Policy, trade, and security are prompting proactive moves to the U.S. — before capacity tightens.

EXECUTIVE INSIGHT

Biologics manufacturing is being reshaped by a new mix of policy, trade, and security pressures. What once felt like a stable global supply network is now influenced by legislation including the BIOSECURE Act, talk of tariffs on drugs manufactured outside the U.S., evolving security scrutiny, and the lingering supply chain fragility revealed during COVID-19. Investors, boards, and regulators are now asking harder questions about supply chain, data security, and speed to market.

From our perspective as a United States contract development and manufacturing organization (CDMO), we have been seeing a clear shift: drug developers aren't waiting for disruption to hit. They are conducting early risk assessments, onshoring programs, and locking in U.S. capacity strategically rather than reactively.

In this whitepaper, we explore seven forces reshaping global biologics manufacturing: policy risk, geopolitical tension, trade and tariff volatility, regulatory access, IP and data security, operational complexities, and supply chain fragility. Drawing on lessons from recent technology transfers, we see how forward-looking companies are future-proofing their pipelines before U.S. capacity tightens and market conditions force rushed moves.

BIOSECURE is now law, fundamentally reshaping biotech supply chains.

1 Policy and legislative pressure: the BIOSECURE Act

Over the past 18 months, one of the most consequential pieces of U.S. biotechnology legislation has been the BIOSECURE Act[1]. Introduced in 2023 and passed by the House of Representatives in September 2024 with strong bipartisan support, the Act was subsequently enacted into law in 2025. It restricts federally funded entities, and companies working with them, from contracting with designated "biotechnology companies of concern."

Among the companies named in earlier drafts and hearings were some of China's largest CDMOs, including BGI Group, MGI, Complete Genomics, WuXi AppTec, WuXi Biologics, and their affiliates [2]. While the specific scope and implementation timelines vary, the signal to the market is clear: supply chain relationships that were once viewed primarily through a cost and capacity lens are now being evaluated through a national security and compliance lens.

The impact is no longer theoretical. Sponsors are reassessing their supply chains proactively rather than waiting for enforcement milestones. If a program is tied to a restricted entity, technology transfer requirements, contractual constraints, or loss of eligibility for federal funding could create costly and time-sensitive disruptions. The challenge is compounded by the reality that if multiple sponsors seek to shift capacity simultaneously, alternative manufacturing slots may become constrained.

Industry observers have noted a structural shift in manufacturing strategy following the Act's passage. PwC outlines potential implications including increased compliance costs, supply chain realignment, contractual adjustments, heightened due diligence, and greater scrutiny[3] across development and manufacturing partnerships.

The takeaway is preparation. With the Act now enacted, supply chain strategy is no longer a hypothetical exercise, it is an active compliance and risk management priority. Sponsors are evaluating exposure, strengthening domestic partnerships, and planning deliberately to avoid a forced, time-compressed transfer or capacity scramble.

Drug supply chains are increasingly exposed to political disruption.

2 Geopolitical tensions

Biotechnology and biopharmaceutical manufacturing have moved squarely into the conversation about national security alongside semiconductors and clean energy.[4] Export control, sanctions, and data security regulations are now used as policy tools on both sides. Washington has tightened oversight of Chinese biotech firms, citing concerns about genomic data security and intellectual property exposure. Beijing, for its part, has strengthened its own technology protection laws and at times limited the flow of critical raw materials.[5]

For drug developers, the impact is immediate. A supply chain that was once predictable can now be affected by rapid, politically driven changes, whether it's a new export restriction, a sanction on a corporate parent, or a heightened scrutiny of data transfer. What was once a commercial decision is now entangled with political dynamics.

Public commentary reflects this shift. The New York Times has reported that U.S. lawmakers are increasingly treating Chinese biotech firms as strategic assets of a potential adversary [6]. Health-ISAC has warned that biotechnology data and manufacturing networks are now seen as national security assets and may be subject to sudden policy restrictions.[7]

No one can predict the exact arc of U.S.-China relations, but most leaders now assume volatility, not stability. That assumption has been driving a more cautious and forward-looking approach to manufacturing strategy. The move to onshoreis steady and accelerating.

Trade instability is accelerating proactive shifts to domestic manufacturing.

3 Tariffs and trade instability

The past few years have brought a wave of new tariffs[8], threatened trade wars, and shifting customs rules that directly affect drug development and manufacturing.

Beginning with material inputs, specialty resins, filters, and single-use components, strategic supplies are now facing unexpected tariffs [9]. Some sponsors have been absorbing the costs; others say schedules have slipped while they renegotiated with suppliers. More recently though, the conversation has escalated to finished biologics. President Donald trump has publicly floated the idea of imposing a 100% tariff on drugs manufactured outside the United States [10] – a proposal aimed at incentivizing domestic production but one that could, if enacted, double the landed cost of offshore supply overnight.

Even without such sweeping measures, smaller tariff changes have proven disruptive to sponsors who have had to re-price programs mid-development, pause to re-do cost forecasts, and navigate delays as shipments have been flagged for new customs procedures. Each delay ripples through clinical and commercial timelines.

Trade analysts have warned that biopharma is particularly vulnerable because complex supply chains often cross multiple borders for raw materials, intermediates, and drug substance [11]. Grassi Advisors noted that recent tariffs pose significant uncertainty for biotech and pharma supply chains, increasing costs, and potentially delaying production [12]. Abzena has cautioned that sudden duties on critical inputs, can introduce supply interruptions and cost volatility with downstream effects on development speed.[13]

We've seen that sponsors no longer treat tariffs as hypothetical. Many have initiated domestic transfer planning, and some are locking in U.S. manufacturing slots before broader trade action makes a reactive transfer urgent and difficult.

Regulatory access constraints are reshaping manufacturing strategy.

4 Regulatory and Audit barriers

Global biologics manufacturing depends on regulators being able to inspect, review, and approvefacilities. When that access breaks down, programs stall. Over the past few years, FDA oversight of facilities in China has been inconsistent, and at timesseverely delayed.

During the COVID-19 pandemic, FDA foreign inspections were largely suspended. Some resumed in 2022, but only gradually [14]. Diplomatic complexities, travel restrictions, and logistics continue to slow scheduling. Even now, sponsors sometimes wait months longer than expected for an FDA visit or follow-up action. Every month can delay IND acceptance, BLA review, or commercial launch.

Industry analysts and counsel have documented these gaps. The GAO noted in a 2022 report that the FDA conducted significantly fewer foreign drug inspections during the pandemic, creating a backlog and delaying oversight. [15] Regulatory attorneys have warned that for complex biologics, any additional documentation requests or remediation steps triggered by an overseas facility can add significant time and cost to product approval. [16]

Sponsors have drawn a simple conclusion – regulatory timelines are unpredictable when oversight is constrained by geography and politics.

Process IP exposure is reshaping global manufacturing decisions.

5 Intellectual Property and Data Security exposure

In today's global environment, process, cell lines, analytical data, and proprietary manufacturing methods are often among a company's most valuable assets. When those assets live outside the U.S., they are subject to foreign legal systems, local practices, and local government access laws.[17]

In China, for example, data localization requirements and national security statutes can compel disclosure and limit how information leaves the country.[18] It has been reported that enforcement of IP rights can be unpredictable and recourse for misuse, slow and uncertain. And regulators and investors now ask not only whether a CDMO can make your drug, but whether it can safeguard the blueprint of your product.

We've seen this concern become a board level conversation. Legal and security teams review data governance, system access, and information sharing practices. If your valuable data sits under a jurisdiction of weak IP enforcement, and government access rights, you may face valuation pressure. Onshoring of critical programs can reassure investors.

Operational friction quietly erodes speed across global programs.

6 Operational friction: time zones, language, and culture

While geopolitics and trade policy dominate headlines, some of the more costly delays in drug development come from day-to-day execution challenges when working across continents. Sponsors report that even when science and quality standards align, the operational gap between a U.S. team and an overseas CDMO can quietly erode speed and predictability.

Time zone lag is the most visible friction. Many Chinese facilities operate 12-13 hours ahead of U.S. headquarters. A deviation flagged on Tuesday afternoon in Boston may not reach the right subject matter expert overseas until Wednesday morning, and any follow up questions return the next day. What could be solved in a couple hours locally can easily stretch into a multi-day exchange overseas.

Language and documentation nuances add another layer. While English is the working language for most global CDMOs, subtle differences in phrasing often cause misunderstandings.

Cultural expectations around escalation and quality can also diverge. U.S. teams may expect immediate notification and root cause analysis when an issue appears. Some overseas teams follow a more hierarchical or delayed reporting style. These differences are rarely intentional, but they slow resolution and can challenge programs on tight timelines.

These don't make dramatic headlines, but they are real, recurring costs in time and coordination such that many sponsors decide the smoother communication and immediate oversights of a domestic partner outweighs theoretical cost savings offshore.

Long, complex global supply chains have shown structural fragility.

7 Supply chain fragility

The global life sciences supply chain was built for efficiency, not resilience. COVID-19 exposed that trade-off in dramatic fashion. When the pandemic hit, factories shut down, ports clogged, and international travel froze. Critical supplies sat in shipping containers. FDA inspectors could not reach overseas facilities. Many development programs slowed or stopped altogether. [19]

Public reporting underscored the vulnerability. The U.S. Government Accountability Office noted in 2022 FDA conducted significantly fewer foreign drug inspections during the pandemic, creating a backlog and delaying oversight. Academic analysis showed how shortages of raw materials and finished biologics during COVID disrupted trials and launch timelines [20], in some cases costing millions per month in burn and lost market opportunity.

Although travel has resumed, the lesson stayed with boards and investors – long, complex supply chains are brittle. Many sponsors are planning to get ahead of the next shock and the shift is real. Resilience is not a buzzword; it's become a core part of how drug developers are planning commercialization today.

Practical steps for sponsors

1. Audit your exposure – Identify where critical programs rely on high-risk CDMOs
2. Monitor policy – track the BIOSECURE Act and tariff proposals that could impact your supply
3. Engage early – Secure U.S. capacity before pivotal trials or filings create time pressure
4. Plan transfers strategically – Run bridging early to avoid downtime
5. Communicate resilience – Boards and investors reward proactive supply risk management

Speak with our technical transfer team to conduct an onshoring assessment and to build a plan that protects your timelines and product value.

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References

[1] H.R.8333 - 118th Congress (2023-2024): BIOSECURE Act | Congress.gov | Library of Congress
[2] Big pharma's growing China ties under threat from US crackdown - SWI swissinfo.ch
[3] US regulatory shifts in biotech and pharma | PwC Switzerland
[4] Trump threatens up to 250% tariffs on pharma imports | BioPharma Dive
[5] US-Chinese relations put the brakes on biotech cooperation | pharmaphorum
[6] U.S. Drugmakers Warn White House of Chaos as Trump Weighs Curbs on China - The New York Times
[7] Impacts of the BIOSECURE Act on the Global BioTech Industry - Health-ISAC - Health Information Sharing and Analysis Center
[8] What to know about Trump's new pharmaceutical tariff plan
[9] U.S. Tariffs Shake Up the Chemical & Materials Industry in 2025
[10] Trump says US will impose new tariffs on heavy trucks, drugs and kitchen cabinets
[11] The Biopharma Supply Chain: Post-Pandemic Challenges and Innovations – CIO CARE
[12] Understanding the Tariff Impact on the Biotech and Pharmaceutical Industries - Grassi
[13] Pharmaceutical Outsourcing: How Tariffs Could Impact Your Drug Development Supply Chain | Abzena
[14] Nearly 2,000 drug plants are overdue for FDA checks after COVID delays, AP finds | The Associated Press
[15] Drug Safety: FDA Should Implement Strategies to Retain Its Inspection Workforce | U.S. GAO
[16] Differential Legal Protections for Biologics vs Small-Molecule Drugs in the US - PubMed
[17] A Bitter Pill: America's Dangerous Dependence on China-Made Pharmaceuticals - Exiger
[18] USTR Report Highlights China's Ongoing IP Challenges
[19] The Pandemic and the Supply Chain: Gaps in Pharmaceutical Production and Distribution - PMC
[20] Drug Shortages: HHS Should Implement a Mechanism to Coordinate Its Activities | U.S. GAO