

The Great CDMO Constriction

Why time, not capacity, is now breaking the CDMO system

Execution friction, oversubscribed capacity, and the collapse of the merchant CDMO model reshaping pharma manufacturing in 2026-2028



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THE SYSTEM AFTER THE RECKONING

The CDMO Reckoning examined the structural shift underway in pharmaceutical manufacturing: the end of capacity-led competition and the emergence of sovereignty, complexity, and execution as the primary determinants of value. This report addresses the operating reality that followed.

As the industry entered 2026, the central constraint ceased to be the existence of manufacturing capacity in aggregate. Instead, the limiting factor became the ability to deploy that capacity predictably - within compressed timelines, across multiple modalities, and under heightened regulatory, geopolitical, and organisational constraints.

Across biologics, Antibody-Drug Conjugates, Cell and Gene Therapy, and radiopharmaceutical manufacturing, a consistent pattern has emerged. Significant capital has been deployed, new facilities have been commissioned, commercial agreements have been executed, and headcount has expanded. Despite this, execution performance has deteriorated.

Programme timelines are extending, decision pathways are becoming more complex, and operational flexibility is eroding. Commitments made at the commercial layer are increasingly translating into sequential, rather than parallel, execution at the site level. The resulting friction is not driven by weak demand or insufficient investment, but by internal compression within the CDMO operating system itself.

This condition - referred to in this report as **The Great Constriction** - describes a market in which physical capacity exists, yet usable, schedulable, and governable capacity is structurally constrained. It is not cyclical in nature. It is the outcome of overlapping forces, including geopolitical realignment, persistent oversubscription, rising modality complexity, and organisational models that have not adapted at the same pace as infrastructure expansion.

The purpose of this report is to examine how and where this constriction forms in practice, and to assess why a growing number of CDMO platforms are unlikely to withstand it without material changes to their operating model.

Disclaimer

This document is provided for informational, strategic planning, and market-intelligence purposes only. It does not constitute financial advice, investment advice, legal counsel, or a substitute for formal operational or regulatory due diligence.

The observations and conclusions presented are derived from a combination of publicly available information, anonymized market signals, and aggregated insights from active executive search and advisory engagements across the CDMO, pharmaceutical, and biotechnology sectors.

Any references to timelines, capacity constraints, operational failure modes, or organisational behaviours represent directional intelligence intended to support strategic discussion, not guaranteed outcomes or exhaustive analysis. The examples referenced are illustrative of broader market dynamics and are not intended to attribute causality or operational performance to any individual organisation.

This report reflects ProGen Search's view of the CDMO operating environment as it is unfolding in the 2026–2028 planning horizon. Readers are encouraged to conduct independent diligence and seek appropriate professional advice before making capital allocation, outsourcing, or organisational decisions.



Executive Preamble: The End of the Rental Market

The global biopharmaceutical industry is currently navigating a period of profound cognitive dissonance. In boardrooms across Boston, Basel, and San Francisco, the prevailing narrative suggests that the sector is merely working through a "post-pandemic correction" - a cyclical downturn defined by interest rates and a temporary capital crunch that will resolve into a new period of growth. This view is dangerously obsolete. We are not in a cycle; we are in a structural regime change.

For the better part of two decades, the biotechnology operating model was predicated on a single, unexamined assumption: that manufacturing capacity was a commodity - a fungible utility available to the highest bidder on a "rental" basis. We assumed that if the science worked, the supply chain would follow. We assumed that labor arbitrage in Asia provided a permanent deflationary pressure on development costs. We assumed that "capacity" was simply a function of steel tanks and square footage.

As we stand in the first quarter of 2026, those assumptions have collapsed.

Following a forensic analysis of the current market - ranging from the municipal utility infrastructure in North Carolina to the AI-driven regulatory enforcement in Washington - this report posits that the industry has hit a "**Capacity Wall**." This is not a wall of steel; strictly speaking, nominal global bioreactor volume is increasing. Rather, it is a wall of *addressable, compliant, and operational utility*.

The convergence of the "Great Decoupling" from China (driven by the BioSecure Act), the unprecedented volumetric shock of GLP-1 agonists, and a severe scarcity of technical talent has created a kinetic friction so intense that it is rendering the traditional "fee-for-service" outsourcing model obsolete. We have entered the era of **The Great Constriction**. In this new reality, capital is no longer the scarcest resource; **Time** is. The companies that survive the next 36 months will not necessarily be those with the best molecules, but those that recognize supply chain access as the primary existential threat.

This report is structured to dismantle the illusions of the current market, expose the structural problems staring us in the face, and provide a strategic roadmap to prevent **Operational Bankruptcy** - a new and lethal financial state where companies possess capital but lack the runway to navigate the friction of the supply chain.



PART I: THE PROBLEMS STARING US IN THE FACE

Why the "Recovery" Feels Like a Crisis

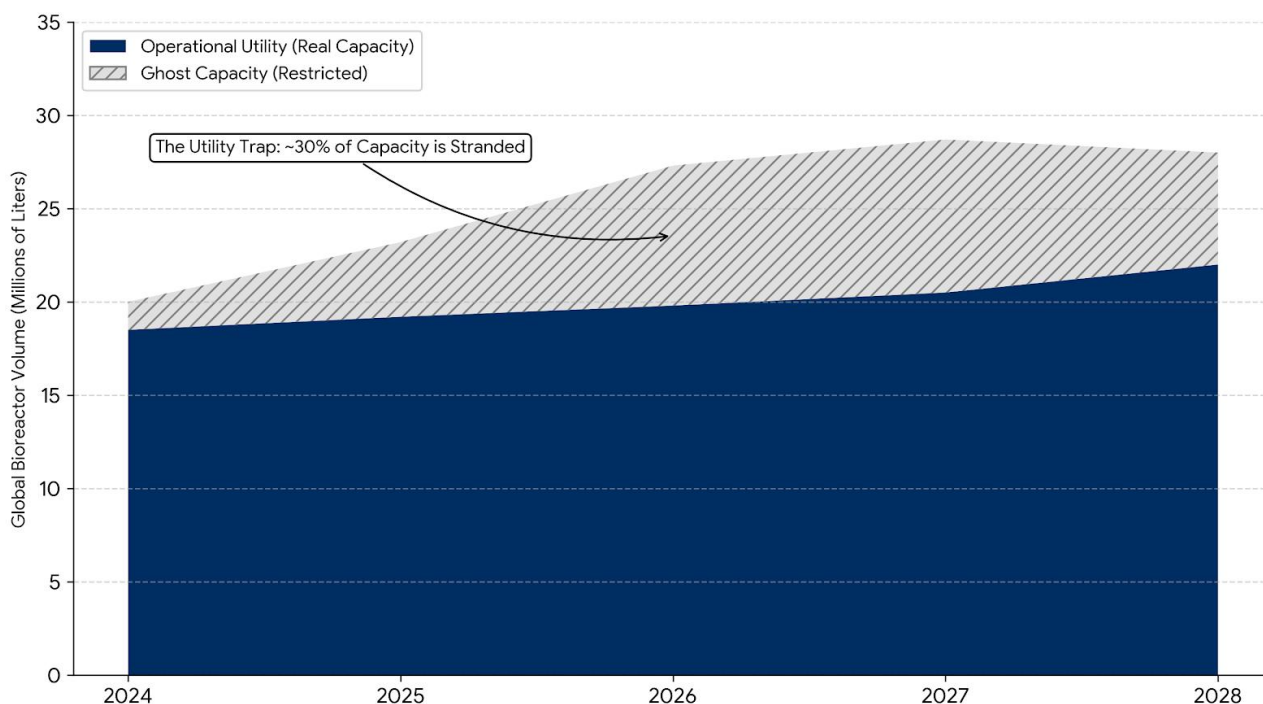
The industry is currently suffering from a "Phantom Surplus." Aggregated global data often shows total bioreactor volumetric capacity growing at 10–12%. Yet, procurement officers cannot book a sterile fill-finish slot for 18 months, and tech transfers are failing at rates of 20–30%. This disconnect arises from three "Non-Obvious" structural fractures that most cyclical models fail to account for.

1. The "Ghost Capacity" Phenomenon: Why Steel Tanks Are Not Output

The most immediate anomaly in the market is the presence of "Ghost Capacity." Between 2021 and 2024, the industry committed over \$480 billion to domestic manufacturing investments. By early 2026, many of these "Super-Plants" - from Fujifilm Diosynth Biotechnologies (FDB) in North Carolina to Samsung Biologics in Korea - were announced as "Operational."

However, a forensic audit of these facilities reveals a divergence between "Mechanical Completion" and "Commercial Readiness." We estimate that **30–40%** of the capacity announced for 2025 start-up is currently trapped in this "Ghost" phase: physically built but operationally dormant.

Global Bioreactor Volume: Nominal vs. Addressable Capacity (2024-2028)



The Utility Trap (The Holly Springs Case Study) The situation in Holly Springs, North Carolina, serves as the definitive case study for this phenomenon. The region hosts massive new facilities from FDB (\$3.2 billion investment), Amgen, and CSL Seqirus. FDB celebrated its "Grand Opening" in late 2025. However, the facility is effectively throttled by a mundane but fatal constraint: **Water**.

Biologics manufacturing is aggressively water-intensive, requiring vast quantities of municipal water to feed Water-For-Injection (WFI) stills and clean-steam generators. The Town of Holly Springs has admitted in utility reports that its current infrastructure cannot support the peak industrial load of this cluster. A critical 14-mile water conveyance line from the City of Sanford is not due for completion until **2028**. Furthermore, wastewater discharge permits are capped until the Utley Creek reclamation facility expands in 2029.

- **The Implication:** FDB is technically "open," but operationally capped. It likely cannot run all its 160,000L of bioreactor capacity at high-density perfusion rates simultaneously without collapsing the local water table or violating discharge permits. This is capacity that exists on a balance sheet but cannot produce saleable commercial product at scale. Sponsors banking on this capacity for 2026/2027 launches are facing unexplained scheduling delays, which are, in reality, utility throttling.

The Regulatory "Hold" (The Samsung Case Study) Simultaneously, the assumption that Asian "friendly" capacity would save us is flawed. Samsung Biologics' Plant 5 (180,000L) was declared "operational" and cGMP ready in April 2025. Yet, Q3 2025 earnings calls were silent on its revenue contribution. The reason lies in a May 2025 FDA inspection that resulted in a **Form 483** citing cross-contamination control deficiencies - specifically regarding the movement of personnel and materials in their multi-product "ballroom" suites.

- **The Implication:** Until these citations are cleared - a remediation process taking 9–12 months - risk-averse Western clients cannot file Biologics License Applications (BLAs) using this facility. It is "Ghost Capacity" - staffed and running, but legally toxic for new commercial launches.

2. The "Elsa" Effect: The Weaponization of Regulatory Data

Why are these new facilities failing inspections? Because the regulatory environment has fundamentally changed. In FY2025, the FDA fully deployed "Elsa," an internal AI-driven targeting system. Unlike previous risk models that relied on lagged indicators, Elsa correlates data from Field Alert Reports, biological deviations, and historical 483s to predict failure.

- **The Precision Strike:** Inspectors are no longer arriving for random spot checks; they are arriving with a "hit list" of high-risk systems. This has driven a **73% surge in Warning Letters** in the first half of FY2025.
- **The Quality Recession:** This heightened scrutiny is colliding with a "Quality Recession" driven by rapid expansion. Facilities are staffed by inexperienced personnel. Citations for "Inadequate Training" and "Data Integrity" are skyrocketing because the industry diluted its talent density to staff the new mega-plants. We are seeing Tier 1 facilities with **20% batch failure rates** (e.g., Sanofi Framingham) because the staff lack the deep GMP intuition required for complex biologics.
- **The MRA Breakdown:** This has fractured the Mutual Recognition Agreement (MRA) between the US and EU. Because the FDA is aggressively classifying sites as Official Action Indicated (OAI), European regulators (EMA) can no longer automatically accept FDA inspections, forcing them to trigger their own audits. This creates a "Double Jeopardy" environment where a site must clear two independent, rigorous hurdles to be globally active.

3. The "Time Tax" of Decoupling: The Physics of Friction

The second structural problem is the industry's gross underestimation of the friction involved in exiting China. The BioSecure Act has forced a "Great Displacement" of approximately 450–500 active therapeutic programs. Boards of Directors viewed this as a logistical "lift and shift" - a simple change of shipping address. It is, in fact, a scientific reconstruction project.

We have identified a **"Time Tax" of 12 to 18 months** attached to these transfers, driven by deep technical divergences:

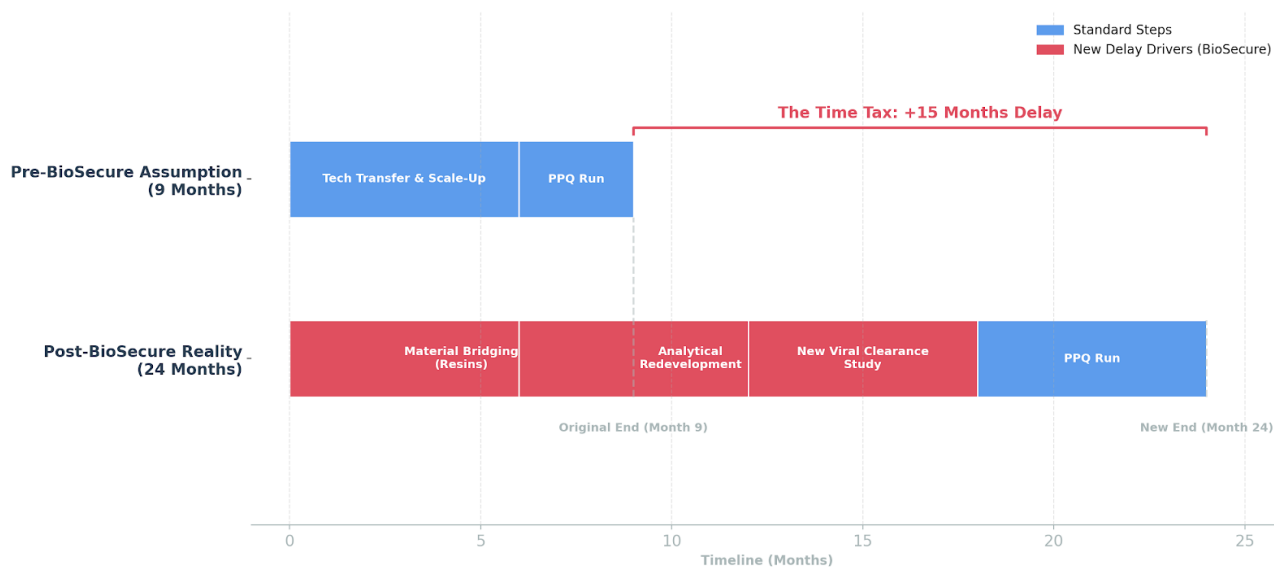
The Material Wall (Resins & Films) Chinese CDMOs spent a decade integrating domestic supply chains (e.g., NanoMicro resins, LePure single-use bags) to lower costs. Western facilities do not stock these materials.

- **The Physics:** Switching a protein purification step from a Chinese resin (NanoMicro) to a Western resin (Cytiva) is not a simple procurement swap; it alters the binding selectivity and pore size distribution. This invalidates the **Viral Clearance Study** - the critical safety data package proving the process removes viruses.
- **The Cost:** This necessitates a new viral clearance study at a third-party lab (e.g., Texcell). Due to the stampede of companies leaving China, lead times for these labs are 6–9 months. You cannot expedite biology. This single step adds nearly a year to the timeline before a GMP batch can be run.

The Analytical Gap (The "Ghost Impurity") The most frequent failure mode in 2026 transfers is analytical divergence. Transferring a product from a generic Chinese HCP (Host Cell Protein) ELISA to a specific Western assay (e.g., Cygnus 3G) often reveals impurities previously undetected.

- **The Consequence:** The product is suddenly "Out of Specification" (OOS). The process is not worse, but the ruler is sharper. This triggers a "Process Adaptation" scenario where the purification steps must be re-developed to remove the newly discovered impurity, adding another 9–12 months to the timeline.

Anatomy of a Transfer: The 'Lift & Shift' Illusion vs. Structural Reality



4. Strategic Enclosure: The Death of the Spot Market

The final "problem staring us in the face" is the death of the "Rental Market." Historically, CDMOs acted as public utilities. Today, they are being privatized by Big Pharma through a strategy of **Strategic Enclosure**.

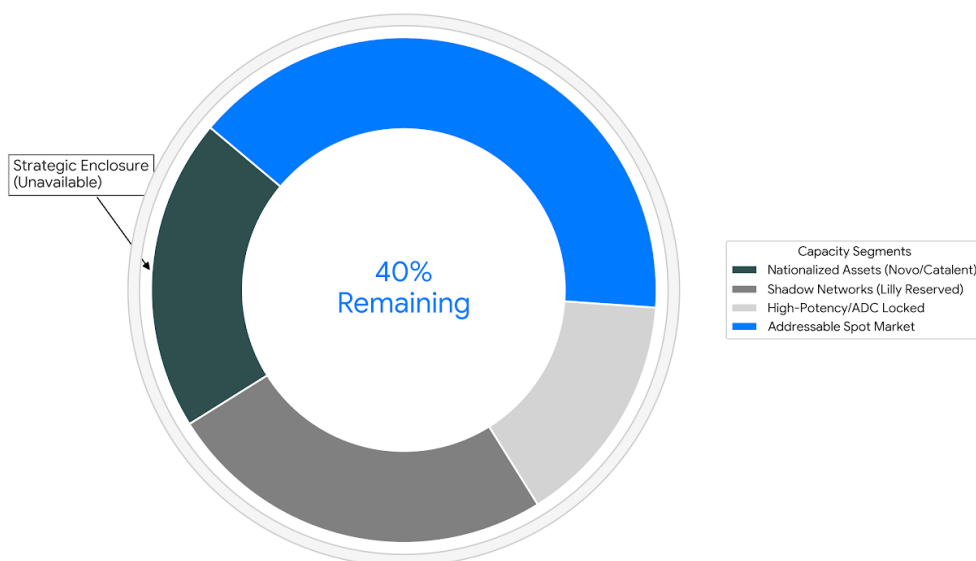
Driven by the "Black Hole" volume demand of GLP-1 agonists (requiring hundreds of millions of sterile syringes) and the fear of the BioSecure Act, the Top 20 Pharma companies have moved to **Block-Booking**:

The Hard Block (Asset Nationalization) Novo Holdings' **\$16.5 billion acquisition of Catalent** was the watershed moment. It permanently removed three key sites - Anagni (Italy), Brussels (Belgium), and Bloomington (IN) - from the merchant market. These sites were the "overflow valves" for the entire industry, serving hundreds of clients. They are now effectively private Novo Nordisk factories, dedicated to Wegovy/Ozempic. This removed **~20%** of the world's premier sterile fill-finish capacity overnight. The "OneBio" integrated model that small biotechs relied on is dead.

The Shadow Network (Ecosystem Booking) Eli Lilly has executed a similar strategy but more subtly. By signing "dedicated-capacity pacts" with providers like **Cambrex** and acquiring the **Nexus Pharmaceuticals** facility in Wisconsin to be "solely dedicated" to Lilly, they have created a "Shadow Network." If you are a Lilly-backed biotech (via Catalyze360), you have capacity. If you are independent, you are locked out.

The "One-Way" Trap of ADCs For Antibody-Drug Conjugates (ADCs), CDMOs are retrofitting flexible suites into high-containment (HPAPI) suites (SafeBridge Cat 3/4). Once a suite is designated for high-potency toxins, it is rarely converted back to standard biologics due to cleaning risks. This permanently subtracts flexible capacity from the market to serve the high-margin ADC boom, creating a "Secondary Shortage" for standard mAbs.

The Death of the Rental Market:
Global CDMO Capacity Availability (2026)



PART II: THE IMPACT (SHORT, MEDIUM, AND LONG TERM)

The Trajectory of the Constriction

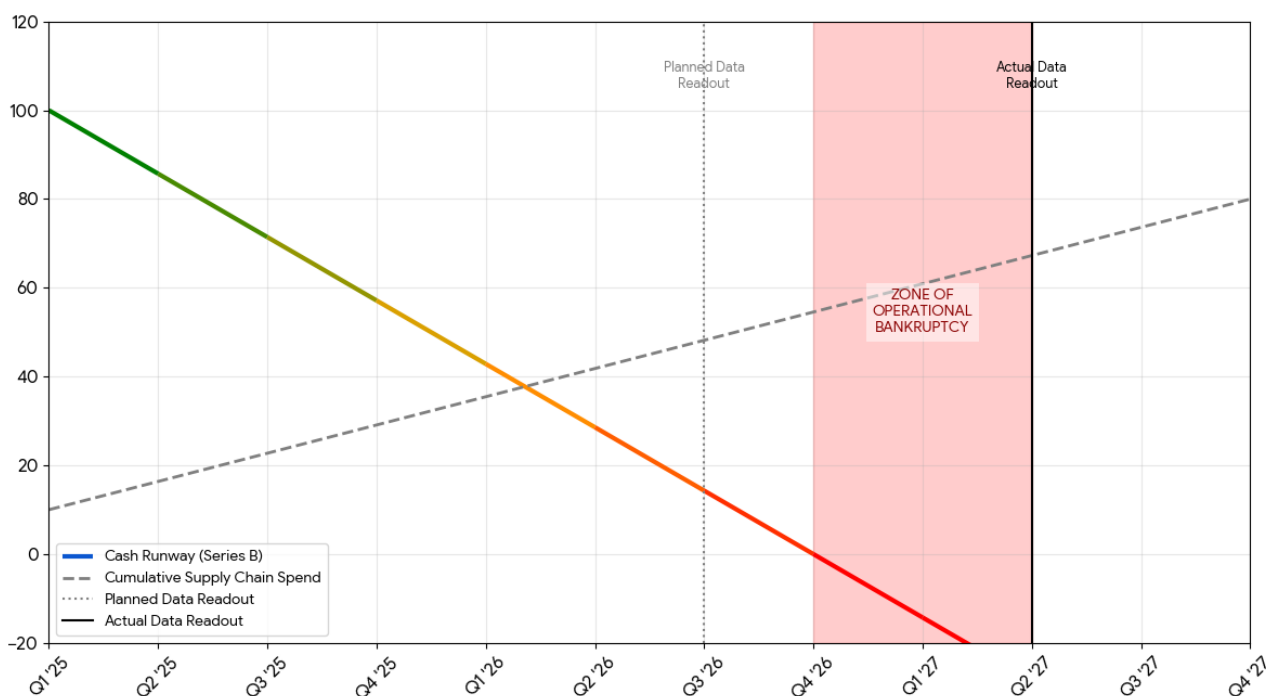
What does this mean for the industry? We are not looking at a soft landing. The data points to a painful three-year recalibration that will liquidate the unprepared.

Short Term (2026–2027): The Crisis of Operational Bankruptcy

The most immediate impact is the rise of **Operational Bankruptcy**. This is a new form of failure where companies are technically solvent (they have cash) but operationally dead (they have no time).

- **The Broken Series B Model:** Consider a Series B company that raises \$60 million for a 24-month runway. In 2022, manufacturing took 6 months. In 2026, due to the "Time Tax" and slot scarcity, it takes **18 months**. The "Delay Burn" - fixed costs incurred while waiting for a bioreactor - consumes the capital intended for the clinical trial.
- **The Evidence:** We are seeing companies like **Rocket Pharmaceuticals** trading people for time (laying off 30% of staff to extend runway while resolving CMC delays) and **Ultragenyx** receiving CRLs driven purely by facility readiness. Companies like **Areteia Therapeutics** and **Mythic Therapeutics** (ADCs) have wound down despite scientific promise, likely because they fell into the "Validation Void" - unable to reach value inflection points before the clock ran out.
- **The Valuation Trap:** Venture capitalists are no longer funding "bridge rounds" for waiting. If a data readout pushes from 2026 to 2028 due to a tech transfer, the Net Present Value (NPV) collapses, and the company is liquidated or sold for parts ("Shell Company Arbitrage").

The Solvency Gap: When Supply Chain Friction Exceeds Capital Runway

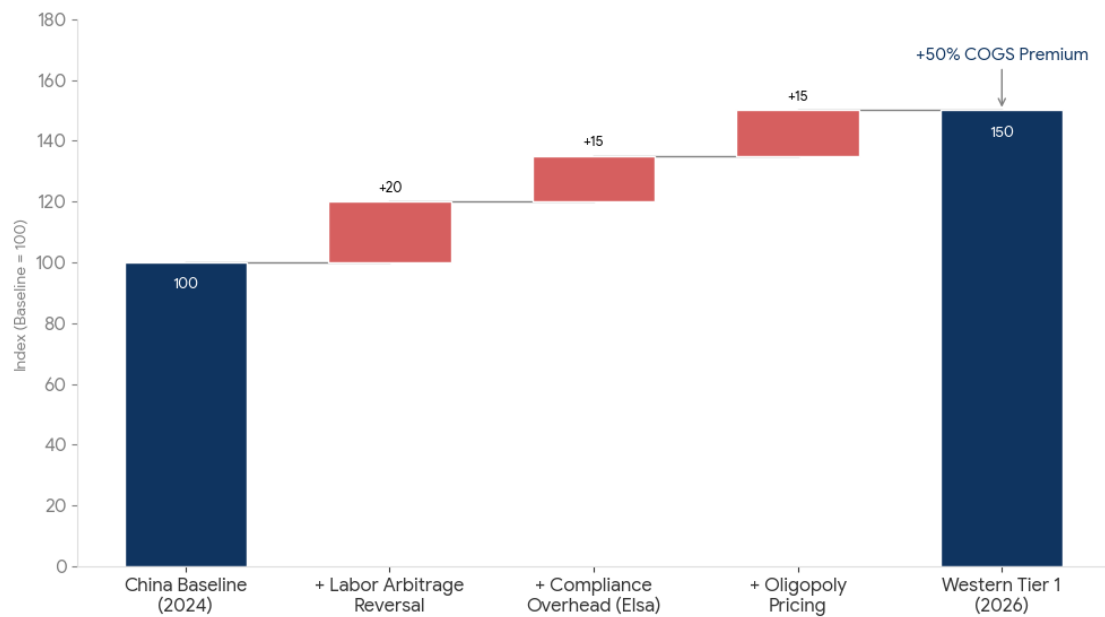


Medium Term (2027–2028): The Quality Recession & Western Premium

As the industry frantically attempts to bring "Ghost Capacity" online to meet this demand, we will hit a **Quality Recession**.

- **Talent Scarcity:** The physical infrastructure has outpaced the human infrastructure. Building a plant takes 3 years; training a Senior Validation Engineer takes 7. In hubs like Research Triangle Park (RTP) and Basel, we are seeing wage inflation and "cannibalization," where companies steal staff from each other.
- **The Result:** The dilution of talent density leads to "Ghost Factories" - plants that run only one shift because they can't staff the night shift - and a spike in error rates. We are already seeing a resurgence of "Inadequate Training" citations in FDA warning letters.
- **The Cost:** This leads to the "**Western Premium**." Moving from a Tier 1 Chinese CDMO to a Tier 1 Western CDMO increases Cost of Goods Sold (COGS) by **40% to 60%**. This is driven by labor arbitrage reversal, compliance costs ("The Elsa Effect"), and the pricing power of the Western oligopoly (Lonza, Samsung, Fuji) who know their competition has been legislated out of the market.

The Western Premium: Structural Drivers of COGS Inflation



Long Term (2028+): The Bifurcated Market

Normalization is not projected until **Q3 2028**. This is when the massive capital projects (Samsung Plant 5, Fuji Holly Springs, Lonza Stein) will finally clear the "Validation Lag" and utility hurdles to reach steady-state commercial output.

However, the market that emerges in 2028 will be permanently **Bifurcated**:

1. **The Secure Western Sphere:** Characterized by high costs, high compliance, and "block-booked" access, serving the US/EU government and commercial markets.
2. **The "China-for-Global" Sphere:** Serving domestic China and non-aligned markets, operating at a distinct cost/quality tier.

The "Globalized" era of interchangeable capacity is over. We are entering an era of "Industrial Regionalism," where a drug's origin is as regulated as its chemistry. The "Virtual Biotech" model - where a CEO and a few scientists outsource everything - will become a relic. The surviving companies will be "Thick Biotechs" that treat CMC as a core competency.

PART III: STRATEGIC RECOMMENDATIONS

What You Should Do About It

Passive navigation of this landscape is a strategy for liquidation. Executives must adopt an active, defensive posture regarding their supply chains.

Short-Term Strategies (Survival Mode: 0–12 Months)

1. Audit for "Shadow" Dependencies (The Paper Bridge) Do not assume you are BioSecure compliant simply because your CDMO is Western.

- **Action:** Conduct a forensic audit of your Bill of Materials (BOM). Are you using Chinese resins (BestChrom)? Chinese single-use films (LePure)? If your Western CDMO relies on these for your process, you are still exposed to the "Time Tax" if you need to switch.
- **Tactic:** Invest in "Paper Bridging" immediately. Pay a Western lab to perform small-scale wet lab comparisons of your current Chinese materials against Western equivalents *before* you are forced to move. Identify the "Ghost Impurities" now, not during a PPQ run.

2. Adopt the "Minimum Viable Process" (MVP) The goal is data, not perfection.

- **Action:** Resist the urge to "gold-plate" manufacturing processes in early clinical stages. If you are a Series B company, accept a lower yield or a more manual process if it fits into an available slot *now*. Do not optimize for commercial COGS; optimize for *Speed to Clinic*. The cost of the "Delay Burn" is higher than the cost of an inefficient batch.

3. Radical Transparency with Investors The "standard" timeline is a lie.

- **Action:** Do not present a 12-month manufacturing timeline in your board deck. It will fail, and you will lose credibility. Present the "Risk-Adjusted" timeline (18–24 months) and explicitly model the "Tech Transfer Tax." Investors in 2026 are performing "Manufacturing Diligence" alongside scientific diligence; they respect realism over optimism.

Medium-Term Strategies (Tactical Positioning: 12–36 Months)

1. Engage in "Capacity Reservation" (Pay-to-Play) The spot market is dead.

- **Action:** Move from transactional models to reservation models. You must pay "Option Fees" to reserve slots 24 months out. This requires more upfront capital, but it is the only way to avoid the "Secondary Shortage."
- **Tactic:** If you are too small to block-book, form "**Purchasing Consortia**" with portfolio peers (via your VC firm). A VC firm representing 10 biotechs has the leverage to sign a Master Service Agreement with a Samsung or Lonza; a single biotech does not.

2. Diversify to "Tier 1.5" Geographies Tier 1 hubs (Boston, RTP, Basel) are tapped out on talent and utilities.

- **Action:** Look for CDMO capacity in "Tier 1.5" locations that offer Western regulatory alignment but lower saturation. **Ireland (regional), Singapore, and South Korea** (Samsung/Lotte) are the "Geopolitically Neutral" overflow valves. They offer the safety of Western IP laws without the utility collapse of North Carolina.

3. Solve the "Talent Wall" Internally You cannot hire your way out of the quality recession.

- **Action:** If you are building internal capabilities, do not rely on poaching. Invest in "Grow Your Own" training programs. Partner with local technical colleges to create a pipeline of GMP technicians. Automate "Release by Exception" in QA to reduce the burden on scarce senior Quality leaders.

Long-Term Strategies (Structural Resilience: 2028+)

1. Design for "Modality Portability" Never be trapped by a facility.

- **Action:** In R&D, prioritize platforms that use standard, off-the-shelf consumables and equipment. Avoid "exotic" bioreactors or proprietary CDMO platforms (like WuXi's proprietary vectors) that create "Vendor Lock-in." The ability to lift and shift your process to a different site is your ultimate insurance policy.

2. The "Virtual Integration" Model

- **Action:** If you cannot be vertically integrated (owning the factory), be *virtually* integrated. Embed your own Quality and Engineering staff (Person-in-Plant) permanently at your strategic CDMO partner. Do not rely on their project managers. You need your own eyes on the floor to prevent the "Ghost Capacity" effect where your project is deprioritized for a Big Pharma anchor tenant.

CONCLUSION

The era of cheap, infinite, and flexible biomanufacturing capacity has ended. We have entered the **Great Constriction**.

The "Capacity Wall" is not a temporary inconvenience; it is a structural reality forged by the collision of medical breakthrough (GLP-1s, Alzheimer's) and geopolitical fracture (BioSecure). The winners of the 2026–2028 cycle will not necessarily be the companies with the best science. They will be the companies that recognize **Operational Risk** as the primary existential threat and engineer their supply chains with the same rigor they apply to their molecules.

Capital is no longer the scarcest resource in biotechnology. **Time** - specifically, the time required to navigate a fractured, congested, and regulated supply chain - is the new currency of survival. Spend it wisely.



TALENT INTELLIGENCE FOR THE CDMO INDUSTRY

ProGen Search operates at the intersection of manufacturing strategy, organisational design, and human capital.

We work with CDMO boards, private equity sponsors, and executive teams facing execution risk created by:

- modality expansion
- geopolitical realignment
- oversubscribed capacity
- leadership and knowledge bottlenecks

Our work focuses on the roles that actually determine outcomes:

- Site Heads.
- Quality leaders.
- Tech transfer and MSAT leadership.
- The operators who translate complexity into throughput.

If you are testing assumptions about capacity, timelines, or leadership resilience in the 2026–2028 environment, we welcome the conversation.

Building inside a constrained system requires different thinking.

Let's pressure-test yours.

Book a call with us today - [click here](#).