MKA Insights
Management Consulting for Life Sciences

Market Report

Compliance Is Not Discretionary

BIOSECURE Act Impact: Reshoring Projects and Equipment Demand

A policy deadline is driving manufacturing investment that market demand would not have produced.

The BIOSECURE Act names WuXi AppTec, WuXi Biologics, BGI and MGI as companies of concern and bars federally funded entities from using them after compliance deadlines. Industry estimates place 15 to 20 percent of U.S. biologic manufacturing with the named contractors, across 100 to 150 active drug programs. The resulting reshoring is estimated at $20–24B over its full course, with $8–12B concentrated in the peak procurement years and 90 percent of it landing in North America.

Policy | Reshoring | Equipment Demand

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Content

Executive Summary 4

01 | The Legislation 5

02 | Three Company Responses 7

03 | Sizing the Opportunity 8

04 | Geographic Distribution 10

05 | Technology Requirements 12

06 | Engagement and Pricing 14

07 | Risks to the Estimate 15

08 | Conclusion 17

Methodology and Data Sources

This analysis tracks publicly announced reshoring projects, policy developments and industry commentary related to the BIOSECURE Act. Investment figures extrapolate from announced projects and historical manufacturing capital intensity.

The legislative landscape remains fluid. Compliance requirements and timelines may differ from current provisions. All figures are analytical estimates and the qualification applies throughout.

A note on legislative currency

The legislative status recorded in this analysis reflects the position at the time the underlying research was conducted. Policy on this subject moves faster than a quarterly research cycle. Confirm current legislative status before acting on any timing assumption in this document.

A note on the sizing figures

Two figures appear and they measure different things. The full-course reshoring opportunity across all affected programs is estimated at $20–24B spread over several years. The concentrated peak, representing 40 to 50 percent of that total falling in the two heaviest procurement years, is estimated at $8–12B. Where a single figure is needed for planning, the peak figure is the relevant one.

Executive Summary

The Largest Policy-Driven Demand Event in Biopharma Manufacturing

The BIOSECURE Act targets dependency on China-based biomanufacturing and creates an estimated $8–12B in incremental North American equipment demand concentrated in the peak procurement years.

The legislation names WuXi AppTec, WuXi Biologics, BGI and MGI as companies of concern, and prohibits federally funded entities from using them after the compliance deadlines. Industry estimates place 15 to 20 percent of current U.S. biologic manufacturing with the named contractors, representing $3–5B in annual CDMO revenue and 100 to 150 active drug programs.

What distinguishes this from ordinary demand

- **It is non-discretionary.** Compliance is a condition of federal funding, not a business case. Companies that do not act lose contracts and grants.
- **It is geographically concentrated.** Roughly 90 percent of reshoring lands in North America, and 40 percent of that in the Northeast corridor.
- **It is time-boxed.** Compliance deadlines create a procurement peak rather than a sustained increase.
- **Roughly half of it goes to CDMOs, not equipment.** Only companies choosing to in-source generate direct equipment demand. Those shifting to alternative CDMOs generate none for the innovator.

The last point is the one most often missed in supplier planning, and it halves the addressable figure.

01 | The Legislation

Four Named Companies and Two Compliance Phases

Companies of concern

WuXi AppTec, a small molecule and biologic CDMO with an extensive U.S. client base. WuXi Biologics, a pure-play biologics CDMO with 13 global facilities including a U.S. site in Philadelphia. BGI Group and its subsidiaries MGI and Complete Genomics, covering genomics and sequencing services. The legislation permits additional companies to be named by the executive branch.

Prohibited activities

After the compliance deadline, federal contracts cannot be awarded to entities using the named companies. NIH-funded research cannot use them. Medicare and Medicaid purchases cannot involve products manufactured by them.

Compliance phases

The first phase bars new contracts and grants involving the named companies. The second phase requires existing contracts to transition away from them. Limited grace periods exist for critical medicines, assessed case by case.

Who is affected

Any company receiving federal funding, which covers NIH grants, DARPA contracts and Medicare or Medicaid reimbursement. That includes large pharmaceutical companies holding government contracts and the vast majority of biotech companies, which receive NIH or SBIR grants at some point.

Purely private companies with no federal funding are not technically covered, though reputational and supply chain considerations apply regardless.

Table 1 | Scale of exposure

One hundred to one hundred and fifty programs must move, and each move is a manufacturing decision

Measure	Estimate
U.S. biologic manufacturing outsourced to named contractors	15–20%
Annual CDMO revenue from U.S. clients at risk	$3–5B
Active drug programs manufactured at named facilities	100–150

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02 | Three Company Responses

Only One of Them Buys Equipment

Reshore to in-house manufacturing — estimated 40 to 50 percent of programs

Advantages: full supply chain control, elimination of geopolitical risk, and margin improvement from removing the CDMO markup. Costs: $300–800M in capital per facility depending on scale, a 24 to 36 month timeline from site selection to operation, and internal expertise for process transfer and validation.

This is the only response that generates direct equipment demand, and it is chosen by companies with existing manufacturing infrastructure and available capital.

Shift to an alternative CDMO — estimated 40 to 50 percent

Advantages: faster than in-sourcing at 12 to 18 months for transition, no capital requirement, and leverage of existing CDMO expertise. Costs: constrained CDMO capacity as the industry reshores simultaneously, a 20 to 30 percent cost increase against the named contractors, and continued supply chain dependency.

Equipment demand from this path accrues to the receiving CDMO rather than the innovator. Beneficiaries include Lonza across U.S. and Swiss facilities, Samsung Biologics, Catalent's U.S. network, Fujifilm Diosynth across the U.S. and Europe, and Patheon within Thermo Fisher.

Exit the program — estimated 5 to 10 percent

Applies to non-core assets where reshoring capital cannot be justified against the revenue, early-stage programs carrying high clinical failure risk, and orphan drugs with limited commercial potential. No equipment demand results.

03 | Sizing the Opportunity

Twenty Billion Over the Course, Ten in the Peak

The total opportunity is $20–24B. The two heaviest procurement years carry $8–12B of that. Capacity planning should be built against the second figure, not the first, because the total spreads across a period long enough to absorb.

That number rests on two inputs, and both should be stress-tested before anyone commits capacity against it.

How many programs generate demand

Of 100 to 150 active programs at the named facilities, 40 to 50 percent choose in-sourcing — 40 to 75 programs generating direct equipment demand. A further 40 to 50 percent shift to alternative CDMOs, which moves the work without creating new capacity. Five to 10 percent exit.

Only the first group buys equipment. The reshoring headline covers all three.

What each in-sourced program costs

Cost per program varies by a factor of five across modalities, so the blended average is doing more work in this estimate than any other single input. A portfolio weighted toward gene therapy produces a materially larger number than one weighted toward small molecule, on the same program count.

Table 2 | Equipment investment per in-sourced program by modality

The blended average of $300–500M is what drives the total – modality mix moves the answer substantially

Modality	Equipment investment per facility
Small molecule (API synthesis, formulation)	$50–150M
Biologic (mAb)	$300–500M
ADC (biologics plus conjugation)	$400–700M
Gene therapy (AAV production, specialized analytics)	$500–800M
Blended average	$300–500M

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The resulting figures

At the conservative end, 40 programs at $300M gives $12B. At the optimistic end, 75 programs at $500M gives $37.5B. A realistic midpoint of 50 to 60 programs at $400M gives $20–24B, spread across several years.

Of that total, 40 to 50 percent falls in the two heaviest procurement years, giving the $8–12B peak figure used throughout this analysis. Supplier capacity planning should be built against the peak, not the total, because the total spreads across a period long enough to absorb.

When it lands

Site selection is underway now. Equipment procurement follows through the RFP and purchase order sequence. Installation and commissioning run ahead of the compliance deadlines rather than at them, since facilities have to be operational before the date, not on it.

04 | Geographic Distribution

Ninety Percent Lands in the United States

BIOSECURE is U.S. legislation, which requires US manufacturing compliance. That is reinforced by federal and state tax incentives and by the concentration of the existing biopharma workforce in U.S. hubs.

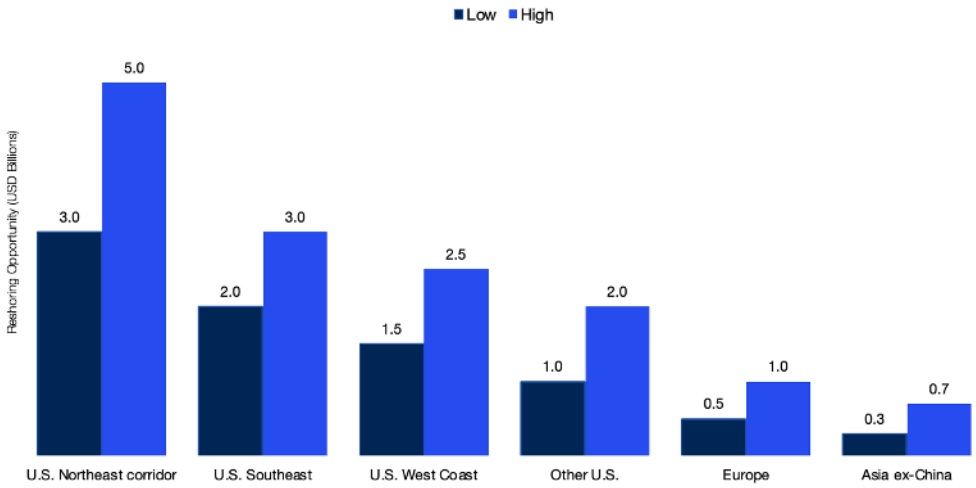

Figure 1 | Reshoring activity by region

The Northeast corridor alone carries more reshoring equipment demand than Europe and Asia combined, several times over

Table 3 | Reshoring activity by region

Region	Share of activity	Estimated projects	Equipment opportunity
U.S. Northeast corridor	40% of U.S.	20–30 facilities	$3–5B
U.S. Southeast	25% of U.S.	12–18 facilities	$2–3B
U.S. West Coast	20% of U.S.	10–15 facilities	$1.5–2.5B
Other U.S.	15% of U.S.	8–12 facilities	$1–2B
Europe	5% of total	3–5 facilities	$500M–1B
Asia ex-China	5% of total	2–4 facilities	$300–700M

Regional equipment figures sum slightly above the $8–12B peak range, reflecting that individual regional estimates were built independently and carry overlapping uncertainty. **MKA Insights**

Northeast corridor — Boston, Philadelphia, New Jersey

Existing biopharma density, talent availability from MIT, Harvard, Penn and Rutgers, and state incentives through the Massachusetts Life Sciences Center and Pennsylvania biotech programs. This is the priority coverage requirement.

Southeast — Research Triangle, Atlanta, Nashville

Lower operating cost than the Northeast, strong academic institutions in Duke, UNC and Emory, and growing biopharma presence through Biogen and Fujifilm Diosynth at Research Triangle Park.

West Coast — Bay Area, San Diego, Seattle

Biotech headquarters density, gene and cell therapy expertise concentrated in San Francisco and San Diego, and existing manufacturing infrastructure at Genentech and Amgen.

Europe and Asia — the residual

European companies may prefer reshoring within Europe, with the UK competing for post-Brexit biopharma investment and Ireland and Switzerland offering tax-advantaged jurisdictions. In Asia, Singapore, South Korea and India capture limited activity, principally from companies diversifying supply rather than complying with U.S. law.

05 | Technology Requirements

What a Reshored Facility Contains

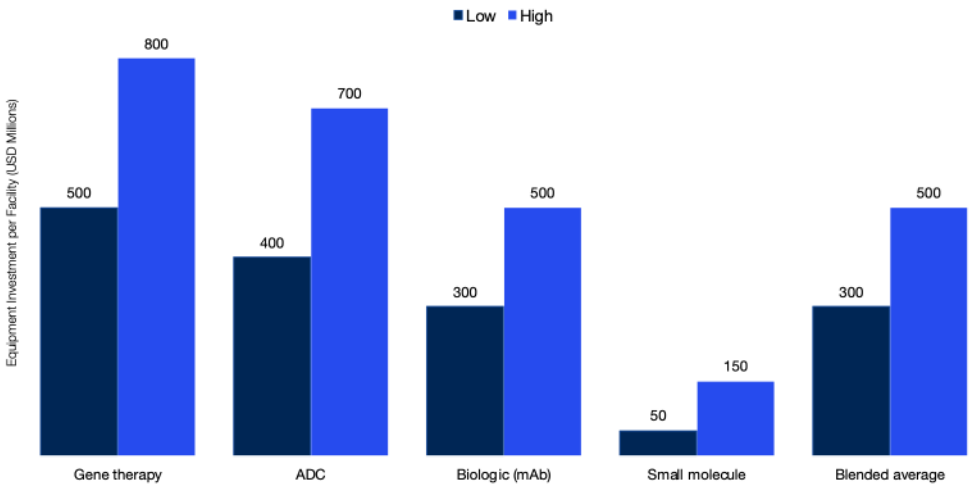

Figure 2 | Equipment investment per reshored facility and by modality

Gene therapy carries the highest per-facility cost and the smallest share of projects.

Biologics reshoring — roughly 60 percent of projects

A greenfield biologics facility requires upstream capacity of 10,000 to 20,000 liter bioreactors with cell culture media preparation; downstream multi-column chromatography, tangential flow filtration and viral inactivation; fill-finish covering vial filling, prefilled syringes and visual inspection; and QC laboratories with HPLC, mass spectrometry, bioassays and stability chambers. Equipment cost runs $300–500M per facility.

Small molecule reshoring — roughly 20 percent

An API and formulation facility requires synthesis reactors, crystallization and purification, formulation equipment including tablet press, encapsulation and coating, and QC laboratories with HPLC and dissolution testing. Equipment cost runs $50–150M per facility — materially lower capital intensity than biologics, and a smaller share of the opportunity than the project count suggests.

ADC reshoring — roughly 10 percent

Standard biologics production plus a conjugation suite with high-containment OEB 4 to 5 isolators, conjugation reactors and specialized analytics. Equipment cost runs $400–700M per facility.

Gene therapy reshoring — roughly 10 percent

AAV production across adherent and suspension bioreactors, tangential flow filtration and affinity chromatography, with analytics covering qPCR, ELISA, empty and full capsid analysis and potency assays. Equipment cost runs $500–800M per facility, the highest in the analysis.

06 | Engagement and Pricing

Urgency Creates Leverage and a Trap

Immediate actions

Identify which existing customers use the named contractors for manufacturing and engage proactively on reshoring support. The positioning is specific: an understanding of the compliance implications and the ability to help meet the deadline.

Develop compliance-specific messaging around delivery timelines that support the operational deadline, FDA compliance support for new U.S. facilities, and component sourcing with no exposure to the named jurisdictions.

Establish geographic presence in priority order: the Northeast corridor first at 40 percent of activity, the Southeast second at 25 percent, and West Coast coverage maintained at 20 percent.

Where suppliers hold advantage

Domestic manufacturing capability removes tariff and supply chain risk from the buyer's own compliance calculation. In-stock inventory or rapid customization wins projects where urgency is the binding constraint. FDA validation support packages differentiate where buyers are building unfamiliar facility types.

Where suppliers are exposed

Capacity constraints affect the whole industry simultaneously, because everyone reshores at once. And buyers face unexpected capital they had not planned for — the named contractors were inexpensive — which produces aggressive negotiation regardless of urgency.

Pricing

Reshoring is urgent and non-discretionary, which creates genuine pricing leverage because buyers have fewer alternatives. The trap is that buyers remember what happened during a compliance crisis, and a relationship damaged here does not recover when the deadline passes.

The recommended approach is a modest premium of 5 to 10 percent against standard pricing, reflecting urgency and capacity constraint, justified explicitly by speed, regulatory support and supply chain security rather than by scarcity alone. Flexible terms including payment milestones and performance guarantees share risk and are valued more than discount in this situation.

07 | Risks to the Estimate

Five Ways the Number Shrinks, Four Ways It Grows

The $8–12B peak figure is a projection built on legislation that has not fully taken effect, applied to companies that have not announced their responses. Both halves of that sentence carry risk, and the risks are not symmetrical.

The downside risks are concentrated and near-term. Every one of them turns on the same variable — how much of the affected work moves to another CDMO rather than in-house. That single choice separates a $20B equipment opportunity from a $5B one, and it gets made company by company over the next eighteen months, largely out of public view.

The upside risks are broader and slower. None of them changes what the named companies do. They change how many companies are in scope, which means the number grows by widening rather than deepening.

That asymmetry is what should shape a supplier's posture. The downside arrives fast and can be watched for. The upside arrives late and rewards having built the capability early.

Factors that reduce the opportunity

- **Legislative modification.** Provisions may be amended, passage delayed, or exemptions added.
- **Grace periods.** Critical medicines exemptions reduce urgency for a subset of programs.
- **CDMO absorption.** If 80 percent shift to alternative CDMOs rather than the assumed 40 to 50 percent, direct equipment demand falls substantially.
- **Program exits.** Estimated at 5 to 10 percent but could run higher if reshoring capital cannot be justified.
- **Timeline delays.** Legal challenge or lobbying could push compliance deadlines out, flattening the procurement peak.

Factors that increase it

- **Additional named companies.** The legislation permits future additions by the executive branch.
- **Voluntary reshoring.** Companies without federal funding may reshore for reputational or supply chain reasons.
- **Allied legislation.** The UK, EU or Australia passing comparable measures would create a global reshoring wave.

- **Domestic content requirements.** Future legislation could add percentage-of-U.S.-manufactured-components rules.

What this means for planning

Build capacity against the conservative end of the range and treat the upside as optionality rather than forecast. A supplier that staffs for $20B and sees $12B has a cost problem that lasts years. A supplier that staffs for $12B and sees $20B has a good problem, and lead times long enough that competitors cannot exploit it quickly.

08 | Conclusion

Non-Discretionary Is Not the Same as Certain

The error this analysis is written against is treating a compliance mandate as a sales forecast. Both halves of that sentence matter.

The mandate is real. Companies receiving federal funding must move manufacturing away from the named contractors or lose contracts and grants. That is not a business case to be evaluated, and it produces investment that ordinary market demand would not.

The forecast is not. Roughly half of affected programs will shift to alternative CDMOs rather than in-source, generating no direct equipment demand for the innovator. A further 5 to 10 percent will exit. Legislative provisions may be modified and deadlines may move. The $8–12B peak figure rests on an in-sourcing rate that is an assumption, not an observation.

What is defensible is the shape: demand concentrated in North America at roughly 90 percent, concentrated further in the Northeast corridor at 40 percent of that, arriving as a peak rather than a sustained increase, and rewarding suppliers who can commit to delivery dates over those who compete on price.

The practical posture is to build coverage against the geography, prepare compliance-specific positioning and price with restraint despite the leverage so that the in-sourcing rate becomes an observation rather than an assumption.

Disclaimer

Policy and legislative risk

This document analyses legislation that remains subject to modification, implementation delay and changes in enforcement. Legislative status described here reflects the position at the time the underlying research was conducted and should be independently confirmed before use. Compliance requirements, named entities and deadlines may differ from those described.

Forward-looking statements

This document contains forward-looking statements and market estimates based on announced projects and capital intensity benchmarks as of January 2026. Sizing rests on assumptions regarding in-sourcing rates, investment per program and timeline, each of which is an analytical judgement rather than an observation. Figures are not guarantees of future performance.

Data sources and limitations

This report synthesizes publicly available sources including policy documents, company announcements, regulatory filings and industry publications. Regional equipment figures were built independently and carry overlapping uncertainty.

Not investment, legal or financial advice

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Management Consulting for Life Sciences & Bioprocessing

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