The Biologics Manufacturing Rivalries: A Strategic Trilogy

Episode I: A New Geopolitical Order - The Rise of the Biomanufacturing Empire

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July 2025

Executive Summary

As global demand for monoclonal antibodies accelerates, the race to secure and scale manufacturing capacity has become a defining strategic imperative.

However, this ambition is increasingly challenged by escalating geopolitical turbulence. Supply chain dominance is shifting, and the ability to manufacture at scale is no longer just a technical or operational challenge – it is a geopolitical one.

The $2 trillion antibody derived biologics market

by 2040[(a)] will be won not by those who react fastest to headlines, but by those who design manufacturing networks resilient to 15-year horizons.

This thought leadership article serves as a strategic lighthouse for C-suite leaders navigating this uncertainty.

Our conclusion is unequivocal: Leadership teams that connect network decisions to long-term therapeutic pipelines, evolving manufacturing technologies, and patient population shifts rather than temporary cost or trade incentives will dominate the coming decade.

This demands insulating strategic capacity planning from volatility through scenario-based governance models, ensuring today's investments remain viable amid tomorrow's breakthroughs or supply shocks.

The message to the C-suite is clear:

> **Owning the biologics market now and in 2040 requires a leading network strategy.**

In a time of uncertainty, C-suite leaders must aim for the stars to chart a bold and forward-looking course through the storm.

Note(s): (a) Based on current market value and assuming a consistent annual growth rate of 17%, the compound annual growth rate over the past five years, 2020 to 2024.

Note to the reader

This series aims to provide leadership with a **lighthouse perspective** – guidance that cuts through the noise and illuminates long-term strategic decision-making. Network strategy in pharmaceuticals involves **consequential long-horizon commitments that should transcend short-term disruptions**, however turbulent they may appear.

At the time of writing, we navigate a **volatile period** with an uncertain outcome. Recent developments include the U.S. administration threatening trade tariffs, new executive orders promoting domestic production of critical medicines, and initiatives to deliver "most-favored-nation" pricing to American patients.

This paper reflects **challenges at a specific moment**, acknowledging that emerging events continually present new concerns for biopharmaceutical executives.

This series was developed through a combination of in-depth expert interviews with leaders in the network strategy domain, alongside extensive secondary research.

Introduction:
The New Frontier of Biopharmaceutical Sovereignty

I. Strategic network design for biologics manufacturing: navigating complexity in a volatile world

This article opens a **three-part thought leadership series** examining manufacturing and supply chain network strategy for biologics manufacturers.

Biologics networks comprise multiple nodes with distinct functions to manufacture drug substance or active pharmaceutical ingredient (API), drug product and packaged final product, encompassing both internal operations and external third-party facilities.

We focus on **antibody-derived biologics**[(b)] due to their market maturity and high growth trajectory, inherently greater complexity and vulnerability to disruption, strategic importance for national security, and the extended lead times required for network modifications. We prioritize drug substance where investment, risk, and strategic differentiation in the biologics supply chain are greatest.

While mammalian-based therapeutic drugs encompass diverse product categories, therapeutic antibody-derived biologics **represent the largest and highest-value market segment**, warranting our primary focus.

However, the strategic frameworks and insights in this article remain relevant for microbial-based therapeutics and other critical biologics classes, including peptides, recombinant proteins, blood products, and vaccines.

While our primary emphasis is on biologics, we maintain **distinct perspectives on network strategies** for small molecules and cell and gene therapies, recognizing that network design must be tailored to each modality's needs.

II. Series overview and context

The complete series will comprise three interconnected articles:

Episode I:
A New Geopolitical Order – The Rise of the Biomanufacturing Empire

Episode II:
The CDMO Strikes Back – Alliances in Global Capacity

Episode III:
The Dual Fronts – Biosimilar Conquests and Biomanufacturing Revolutions

At its core, the pharmaceutical industry exists to ensure **medicines reach patients** – a mission that fundamentally depends on manufacturing and distribution networks that deliver products at the right location and time.

Network strategy revolves around **calculated trade-offs**: balancing control, capital expenditure and opportunity capture, while mitigating risks across the value chain.

The complexity of these strategic decisions is magnified by **biomanufacturing's distinctive challenges**.

Facilities require up to **8 years** from decision to first GMP batch with investment costs approaching **$2 billion**

During this extended timeline, technological advancements may outpace business decisions, forcing companies to adapt, pivot, or abandon original plans.

Note(s): (b) Antibody-derived biologics include monoclonal antibodies (mAbs), antibody-drug conjugates (ADCs), bispecific antibodies as well as other next-generation antibodies such as nanobodies.

Further complicating matters is the **inherent uncertainty** surrounding new molecular entities (NMEs):

- **Future commercial portfolio composition** remains speculative, making long-term planning challenging
- **High clinical trial failure rates** mean infrastructure investments carry substantial risk
- **Required manufacturing technologies** such as continuous manufacturing, device assembly and bioconjugation evolve rapidly
- **Demand trajectories**, including potential upside and downside scenarios, resist precise forecasting
- **The industry trend toward licensing and acquiring NMEs from smaller biotechs** often results in inherited contract development and manufacturing organization (CDMO) relationships, leading to network sprawl

Beyond these structural challenges, network strategists must navigate **numerous unpredictable external factors**.

Looking at the past decades, decision-makers were equally navigating geopolitical economic shocks(1), regulatory unpredictability(2), and climate-driven supply chain failures(3).

Current external factors include:

- **Geopolitical shifts** such as escalating United States (U.S.)-China tensions, the U.S. BioSecure Act, and growing U.S. protectionism in the world's largest biopharmaceutical market, which complicates global supply from U.S. manufacturing bases
- **Economic volatility** across global markets
- **Shifting taxation and tariff landscapes**, for example, Base Erosion and Profit Shifting (BEPS) initiatives have diminished the appeal of low-tax jurisdictions, while tariff considerations increasingly influence manufacturing location decisions for specific markets
- **Unprecedented capacity expansion** across the industry which creates risk of “global overcapacity” and obsolescence of non-amortized assets (see episode II of our series)
- **Cost pressure on health systems** globally fueling biosimilars growth (see episode III of our series).

The critical question now is **whether these developments will disrupt the established order in biologics manufacturing**, necessitating a fundamental reassessment and potential restructuring of global production and supply chain strategies.

In the first episode of this series, we begin by examining the global biologics market in this evolving geopolitical landscape

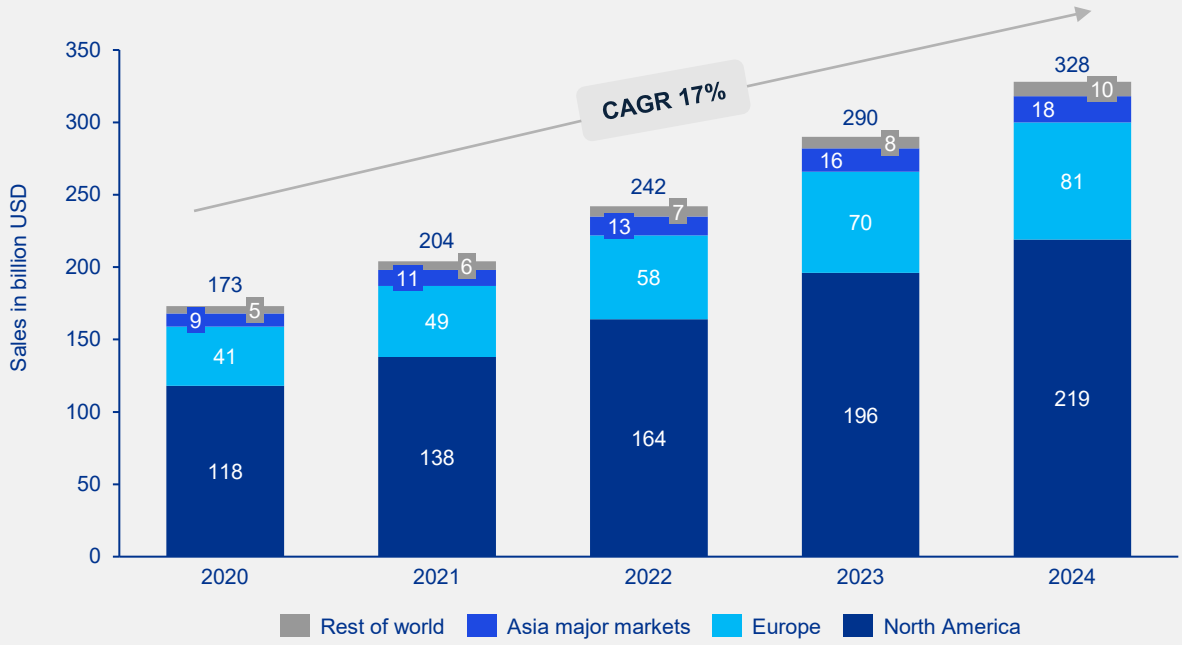
01

The Global Biologics Market: Regional Sales and Profit Dynamics

The biologics market is experiencing robust growth, with the antibody-derived segment alone projected to surpass **$380 billion by 2025**, assuming growth at the current five-year compound annual growth rate of approximately 17%. **North America** is the largest market by sales **(67% of global sales)**, driven by high demand for innovative therapies **(Figure 1)**.

Europe follows with 25% of global sales, leveraging its established pharmaceutical infrastructure and regulatory harmonization, while major Asian markets represents 6% of global sales and is growing at a faster pace (19% CAGR overall, 34% CAGR for China).

Figure 1: Global sales of antibody-derived biologics 2020 – 2024 (in billion USD)



Based on internal analysis by KPMG using data from the following source: IQVIA Analytics Link for the period 2020-24, for North America, Europe, Asia Major Markets, South East Asia and Australasia, Middle East and Africa and Latin America regions for 141 pharmaceutical molecules. Accessed: June, 2025. Reflecting estimates of real-world activity. Copyright IQVIA. All rights reserved.

The antibody-derived biologics market is poised for growth, with projections indicating an **expansion to $700-920 billion by the early 2030s**, representing a robust CAGR of 11-15%[4,5,6].

If the current five-year annual compound growth rate continues, the market is projected to reach **$2 trillion by 2040**. This trajectory is being fueled by **revolutionary innovations in antibody engineering**, particularly next-generation formats including bispecific antibodies, which are expected to grow to $50 billion by 2030[7], tri-specific antibodies that offer enhanced multi-targeting capabilities against complex diseases, and antibody-drug conjugates (ADCs) projected to reach $30 billion by 2034[8].

Simultaneously, the biosimilar segment is experiencing robust growth with a projected CAGR of 23.2%, potentially reaching $105 billion by 2034 as these more affordable alternatives expand access across previously underserved markets[9].

As the monoclonal antibodies category continues to mature, its dominance is steadily increasing within the pharmaceutical landscape. Biologics are forecasted to outpace small molecules by $120 billion by 2027 and ultimately account for 55% of all innovative drug sales, solidifying biologics as a cornerstone of modern medicine[10].

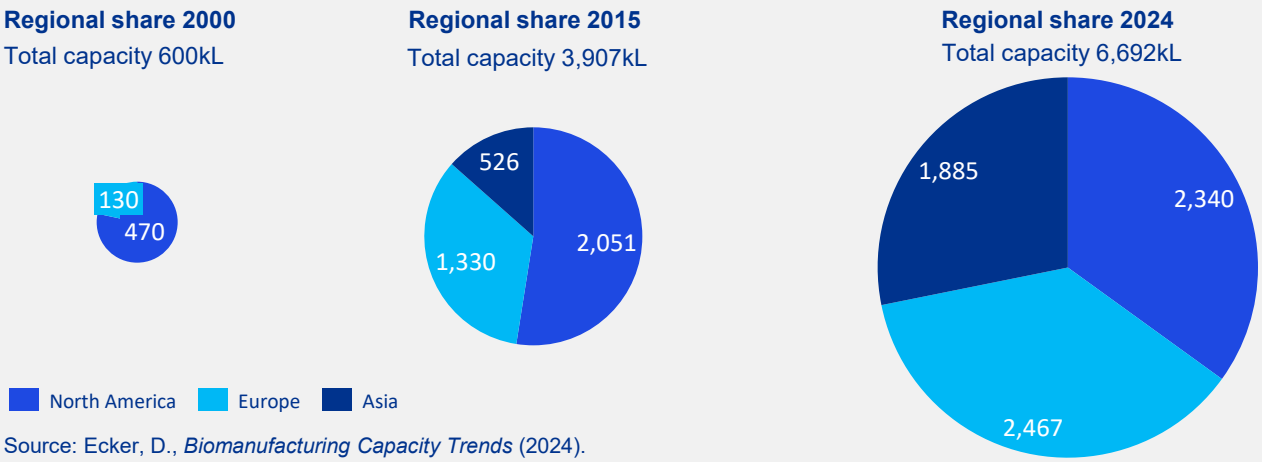
02

Where is biomanufacturing capacity located?

With the **biologics boom in the 2000s**, **North America** was the **most dominant region for biomanufacturing** capacity **(Figure 2).**

The U.S. was home to the earliest and most significant biotech companies such as Genentech, Amgen, Regeneron and Biogen. Many first-generation biologics were discovered and developed in the U.S., leading companies to build manufacturing infrastructure locally to support clinical and commercial production.

Figure 2: Evolution of share of biomanufacturing capacity by region from 2000 to 2024.



Source: Ecker, D., *Biomanufacturing Capacity Trends* (2024).

Biomanufacturing capacity in Europe grew significantly from the 2000s into the 2010s driven by a convergence of scientific growth, policy shifts, economic drivers and CDMO evolution.

Countries like **Switzerland**, Germany, the UK, Ireland and the Nordics saw a surge in biotech startups and mid-sized biopharma companies. European governments introduced **tax incentives**, **grants** and **research and development (R&D) credit** to attract manufacturing investments, with Ireland in particular becoming a magnet due to low corporate taxes and European Union (EU) access.

European pharma companies such as Roche, Sanofi, and Novartis sought to de-risk global supply chains by building or expanding regional capacity.

Since the 2010s, countries like China, South Korea, Singapore, and India made biomanufacturing a national priority with investments in state funding, infrastructure development, and targeted incentives.

For example, South Korea launched its “Bioeconomy Strategy”[11] aiming to become a top biotech hub, China’s Five-Year Plans included biotech as a strategic sector[12] and Singapore invested heavily through Biopolis[13] and tax incentives to attract multinationals.

Asia offered significantly lower costs for labor, utilities, and facility construction versus North America or Europe.

03

Decision triggers to build a new biomanufacturing facility

Biopharmaceutical originators focus on capital-efficient profitable growth

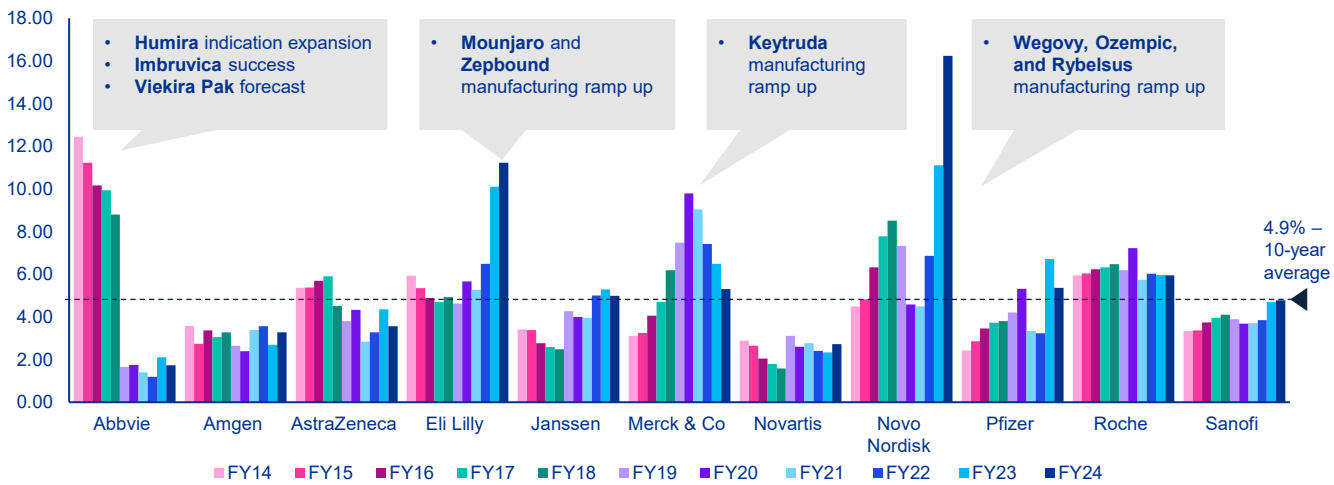
Capital-efficient profitable growth has emerged as a defining strategic philosophy in biopharma, evidenced by sector-wide capex-to-revenue ratios that hover between 4-6% for established players **(Figure 3).** This demonstrates a disciplined approach that prioritizes R&D yield over infrastructure sprawl.

This lean operational model reflects an industry-wide recognition that **therapeutic innovation, not manufacturing scale, drives valuation**. The pattern shifts dramatically when blockbusters emerge: successful drug launches trigger temporary capex-to-revenue spikes to 10-16% as companies scale production for therapies like Humira, Keytruda, and GLP-1 receptor agonists[(c)] (see Figure 3), before rationalizing to baseline levels.

This pendulum swing – spending cautiously during development, then investing strategically in infrastructure for successful therapies – reflects the sector's evolution into a **capital-savvy innovation engine**.

Since commercial success in biologics depends not only on scientific breakthroughs, but also on precisely aligning capacity investments with therapeutic adoption curves, network strategy must support early planning to avoid the opportunity cost of capacity shortfalls and ensure patient access.

Figure 3: Capex-to-revenue ratios for pharmaceutical manufacturers over past 10 years.



Note: Capital expenditure figures are used as a proxy for network investments; however, they also include other investments such as research and development facilities. Balloons indicate potential reasons for observed peaks (non-exhaustive).
Source: Company annual reports

Note(s): (c) GLP-1 receptor agonist peptides are synthesized by microbial fermentation or chemical synthesis. They are thus excluded from antibody-derived biologics that are the main focus of this article but are presented here due to their massive impact on supply chains in the past five years.

CDMO investment strategy: Managing Risk in a Capital-Efficient Originator Environment

While pharmaceutical originators increasingly adopt capital-efficient growth models that prioritize **asset-light strategies** and **outsourcing**, CDMOs face a different set of triggers and risk management imperatives for their capacity investments.

As **originators rely more on CDMO networks** to avoid major capital expenditure, CDMOs must paradoxically make substantial **infrastructure investments** to serve this growing demand. This creates a complex risk-reward dynamic that requires sophisticated portfolio management approaches.

Leading CDMOs have invested heavily in building ultra-large capacities (see Episode II of the series) across multiple platform technologies. Companies like Lonza, Samsung Biologics, Boehringer Ingelheim, and Fujifilm Diosynth have announced expansion plans totaling $12.6 billion in investments with over 1.7 million liters of added capacity since 2021[14]. These investments are driven by the recognition that multi-product facilities spread risk across their portfolios.

This “design one, build many” paradigm allows CDMOs to **offer manufacturing slots to multiple potential clients** simultaneously, fundamentally distributing investment risk in ways that single-product originators cannot[15].

The **risk-sharing imbalance** between originators and CDMOs creates additional investment decision complexities. As industry experts note, “if you have a drug that is coming through that could potentially go big in the market, the CDMO isn't going to see the big returns from that drug”, yet CDMOs bear substantial **development and manufacturing risks**.

Successful CDMOs increasingly negotiate risk-sharing agreements that recognize their infrastructure investments, moving beyond traditional fee-for-service models toward partnerships where **"either everybody wins or everybody loses"**.

04

Policies and incentives accelerating U.S. reshoring

As discussed in Section 2, North America, particularly the U.S., has seen its share of global biomanufacturing capacity decline over the past 25 years. While pharmaceutical originators and CDMOs continued to invest in the U.S., they also strategically diversified their global footprints. However, since 2019, the COVID-19 pandemic has acted as one of the catalysts reshaping the landscape. Policies, incentives, and heightened awareness of supply chain vulnerabilities have significantly increased the appeal of the U.S. as a destination for new biomanufacturing capacity.

Below, we outline a non-exhaustive list of key drivers behind this renewed focus on U.S.-based investments.

Pandemic-exposed vulnerabilities (2019 – 2020)

COVID-19 exposed the fragility of global supply chains, especially for complex biologics, prompting calls for greater domestic self-sufficiency.

Tariffs and trade policy (2025)

Escalating tariffs and trade disputes have increased the cost and complexity of importing biologics and raw materials, incentivizing local production.

U.S. BioSecure Act (introduced 2023, waiting for Senate action)

This proposed legislation aims to restrict federal procurement from companies with ties to adversarial nations, accelerating the shift of manufacturing away from China and other geopolitical rivals.

Regulatory streamlining

The U.S. Food and Drug Administration (FDA) has simplified approval pathways, particularly for biosimilars, and offers expedited review for products manufactured in the U.S., further incentivizing domestic investment.[16]

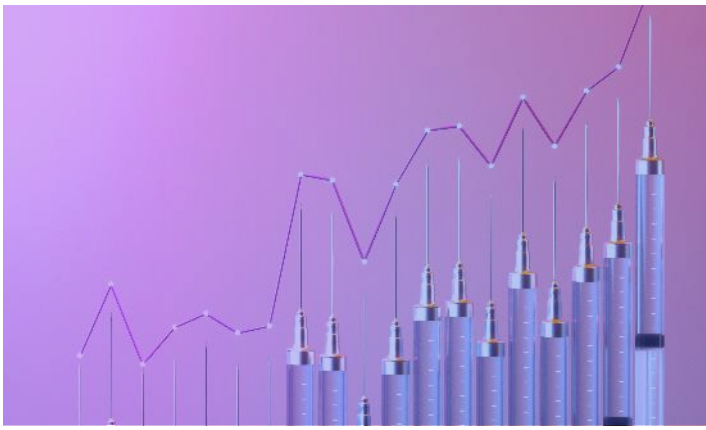
National security imperatives and politics agenda (announced 2022, report published April 2025)

The U.S. National Security Commission on Emerging Biotechnology (NSCEB) has underscored the strategic importance of domestic biomanufacturing, citing risks of supply chain dependency and intellectual property (IP) leakage.

The U.S. government increasingly views biologics as critical assets, akin to semiconductors or rare earth elements.

05

The U.S. Biomanufacturing Renaissance



Precisely tracking the origin of biologic drugs is notoriously difficult due to the global nature of supply chains and limited transparency across manufacturing steps. One study analyzing publicly available data found that 36% of biological drugs sold in the U.S. in 2020 were manufactured on U.S. territory, down from 49% in 2012. European countries accounted for most of the remainder (Germany 21%, Sweden 10%, and Ireland 7%)[18]. While presenting some limitations, such as the lack of disclosure of API manufacturing country likely to underrepresent China for example, this study gives directional information, and it is the only one to our knowledge that focused on the origin of biologics products.

A report by the Pharmaceutical Research and Manufacturers of America claims that 64% of finished biopharmaceuticals sold in the U.S. in 2023 were produced in the U.S.[19] However, this number likely reflects only the final packaging of products while previous process steps (Drug Substance and Drug Product) may be executed abroad.

Avalere Health found that 53% of API consumed in the U.S. in 2021 came from the U.S.[20], a number stable through 2019 to 2021. This study considers total API, and the value is likely to be higher when considering biologics only as generics and branded small molecule products' API are more likely to be sourced out of the U.S.[21,22]

Pre-2025 investments in U.S. biopharmaceutical manufacturing

The biopharmaceutical industry consistently ranks among the top three sectors investing in U.S. manufacturing[17]. Between 2016 and 2022, capital investment in biopharmaceutical plants and equipment surged by more than 72%. Notably, from 2018 to 2022, the industry's total capital investment exceeded $126 billion, underscoring its significant commitment to expanding and modernizing its manufacturing capabilities.

Notable recent investments in biopharmaceutical in the U.S. include:

- Johnson & Johnson, Wilson, North Carolina,
- Lonza, Vacaville, California,
- Fuji, Holly Springs, North Carolina,
- Amgen, Holly Springs, North Carolina,
- AstraZeneca, Rockville, Maryland,
- WuXi Biologics, Worcester, Massachusetts,
- Catalent, Bloomington, Indiana & Madison, Wisconsin.

Despite these investments and a large biomanufacturing footprint, data shows a stagnation in terms of biomanufacturing volume[23] and the number of biopharmaceutical manufacturing facilities[17] post-2021. Interestingly this trend follows a sharp increase in biomanufacturing volume both in Europe and in Asia.

2025 – The Trump effect: Unprecedented surge in announcement of U.S. biomanufacturing investment

Since the Trump administration took office for its second term, we have witnessed a remarkable acceleration of investment announcements in U.S. biomanufacturing capacity, signaling a potential significant reshoring trend in pharmaceutical production. In the first five months of 2025 alone, major pharmaceutical and biotechnology companies have committed over $270 billion to expanding their American manufacturing footprint[d].

Note(s): (d) Announcements are not only in biomanufacturing, R&D and non-biologics manufacturing investments are also included.

This **unprecedented level of domestic investment** is largely attributable to the administration's policies aiming at boosting the U.S. manufacturing sector such as import tariffs and incentives through the FDA activities. The **"America First" approach** to manufacturing has incentivized companies to **strengthen domestic supply chains** and create thousands of high-skilled American jobs.

When considering the top ten reshoring investments announced in 2025 and projecting the impact on the capex-to-revenue ratio of the top ten companies, we found that the average ratio would jump from ~4-5% to 6-7% for the 2025-2030 period **(Figure 4)**. Note that this projection only considers investments announced in the U.S., so the total percentage would likely be higher. This projection indicates that top biopharma companies are not only announcing a reshoring effort, but equally an acceleration of investment commitment compared to the past five years.

Post-2025: Beyond the press releases, how to execute

The recent wave of pharmaceutical manufacturing commitments in early 2025 signals a significant strategic pivot in the biopharma landscape. While these investments demonstrate industry confidence, pharmaceutical executives must prepare for substantial execution headwinds.

The sector already faces a worsening **35% talent deficit** that threatens to undermine expansion plans, with 80% of pharmaceutical manufacturers reporting critical skills mismatches particularly in advanced manufacturing technologies and digital capabilities[24,25,26].

Raw material and **equipment security** represents another material constraint creating vulnerability in an increasingly fragmented geopolitical environment. Companies must also contend with an **industrial land shortage** that has left available space near record lows in key biotech hubs, potentially delaying facility construction timelines.

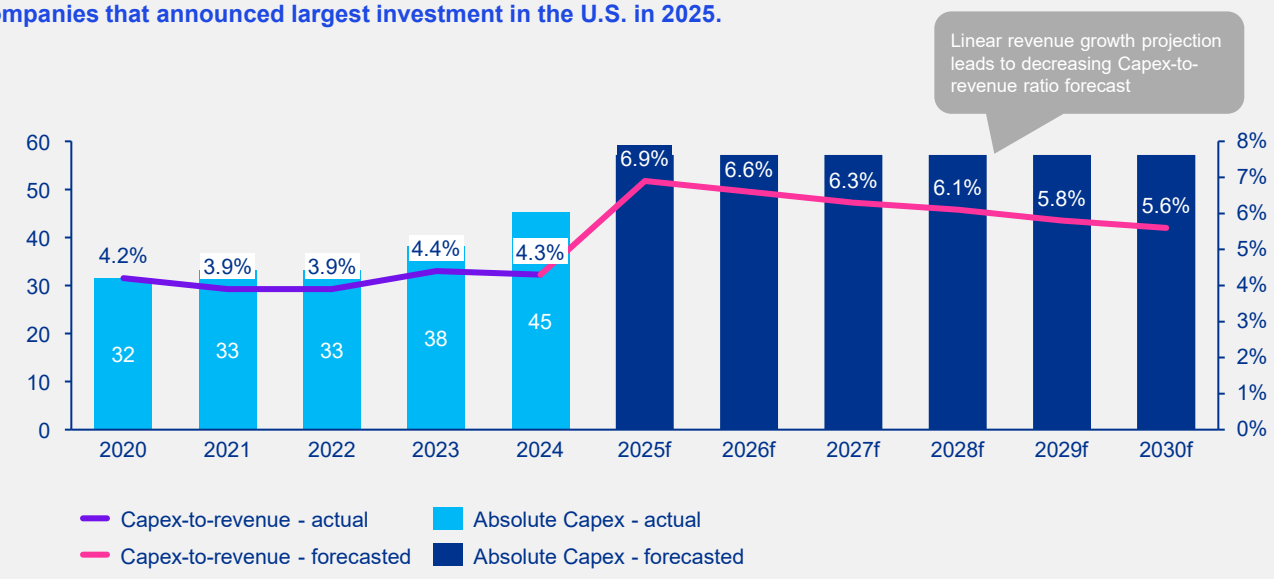
What's more, the locations of these investments largely overlap with regions already hosting the largest hubs of biomanufacturing with New Jersey, California and North Carolina being the most represented states.[17,27]

Talent shortages are likely to worsen in these states and the attractiveness of the biopharmaceutical sector could affect other sectors and local communities. In New Jersey, the average worker compensation in the biopharmaceutical sector is 2.5 times higher than the average compensation across all jobs in the state (~1.5 times higher in California and North Carolina)[28].

Further complicating matters, if major trading partners implement **reciprocal tariffs in response** to U.S. trade policies, the economic calculus underlying these investments could shift dramatically, potentially eroding expected returns.

Successfully delivering on these ambitious manufacturing commitments will require pharmaceutical leaders to develop comprehensive strategies addressing these **interconnected constraints** while maintaining flexibility in an uncertain trade environment.

Figure 4: Absolute capex in billions USD and capex-to-revenue % (actuals and forecast) for ten biopharma companies that announced largest investment in the U.S. in 2025.



Note: Companies included AbbVie, AstraZeneca, BMS, Eli Lilly, Gilead, J&J, Merck, Novartis, Roche and Sanofi). Revenue projected using 2020-2024 CAGR, investment announced in the U.S. divided by six and split equally over the 2025-2030 period.

06

Europe's Bid for Biopharma Independence

Europe accounts for about 25% of global biologics sales and hosts more than one-third of global biomanufacturing capacity[21]. Ireland, Germany and Switzerland are among the largest contributors to biopharma exports to the U.S.[27,28]

Renowned for quality, Europe has benefited from **"friendshoring"** – seen as an IP-protective destination providing high quality standards as well as lower taxation and labor costs than the U.S. However, recent dynamics like the rise of Asian CDMOs (see Episode II for more information) and the push for U.S. biopharmaceutical reshoring put Europe at a crossroad: Can Europe remain a major biopharmaceutical manufacturing destination?

Geopolitical factors further exacerbate these challenges. The potential imposition of U.S. tariffs on pharmaceuticals could **disrupt transatlantic trade and supply chains**. In response, European leaders are urging pharmaceutical companies to maintain and expand their manufacturing presence within the EU.

The Critical Medicines Act and Strategic Projects

The Critical Medicines Act (CMA) is an EU legislative proposal designed to safeguard supply of essential medicines, reduce EU dependency on third-country suppliers, in particular APIs from Asia, and strengthen EU manufacturing and resilience (Table 1).

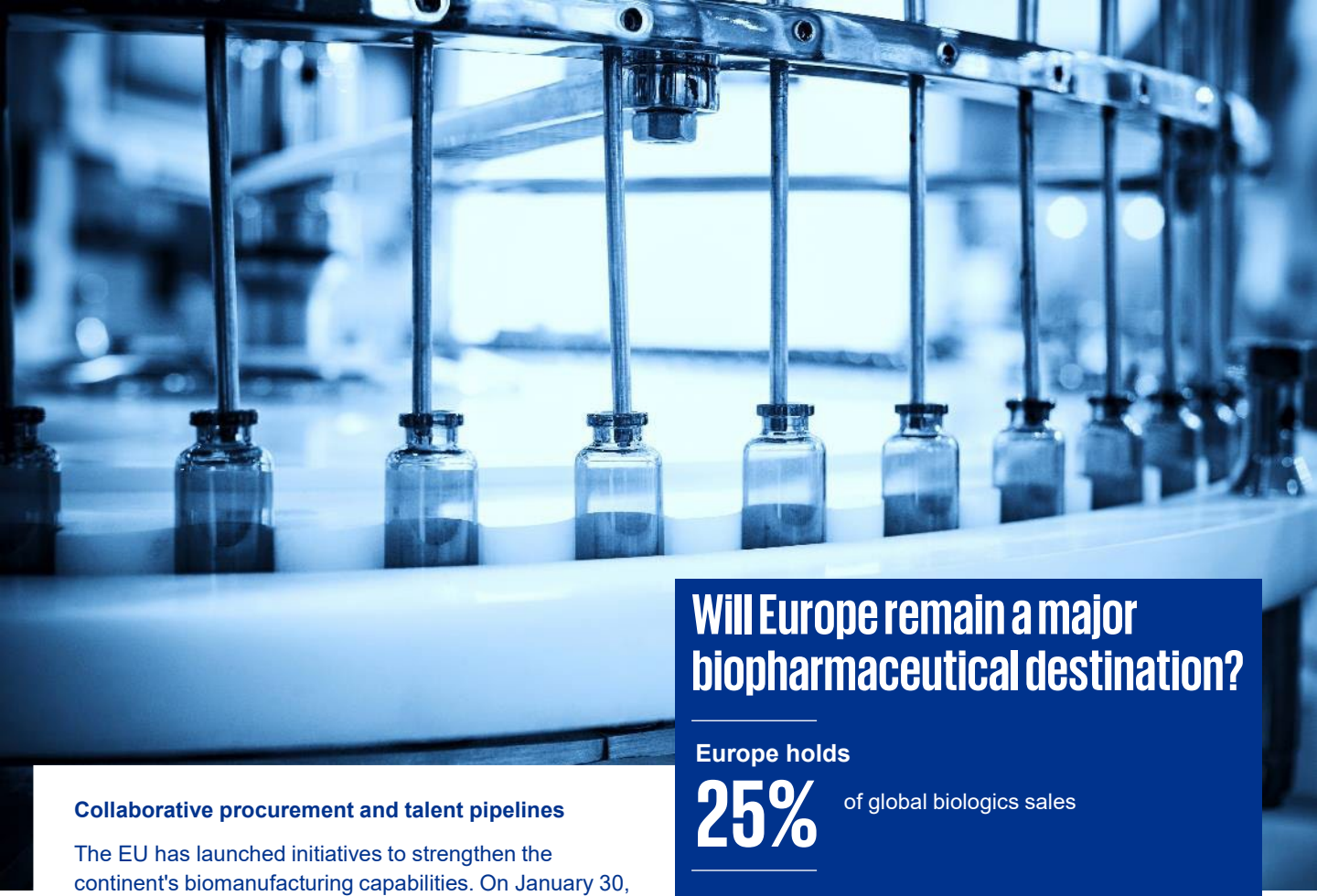
Recent events such as COVID-19 supply shocks, medicine shortages across EU states and rising geopolitical and trade tensions have exposed deep vulnerabilities. The CMA can be considered the pharmaceutical counterpart to the EU Chips Act and Green Deal Industrial Plan.

Strategic Projects are key pharma and biomanufacturing initiatives in Europe that directly support CMA goals. Intended benefits are to fast-track regulatory approvals, provide EU-level funding and infrastructure support and enable favorable state aid rules e.g. eligibility for Important Projects of Common European Interest (IPCEI). Example projects include new EU-based API plants, advanced biologics facilities and dual-sourcing or continuous manufacturing infrastructure.

This reflects an industry opportunity for access to funding, public contracts, political alignment and incentive to localize biomanufacturing, packaging, and raw material sourcing. However, it may also bring new compliance obligations such as supply chain transparency and risk reporting.

Table 1: Key pillars of the Critical Medicines Act

Pillar	Summary
Critical medicines list	EU to publish and update a list of high-risk, essential medicines
Supply chain mapping	Companies must provide end-to-end visibility of ingredients and sources
Diversification and onshoring	Incentives for EU-based or near-EU manufacturing
Monitoring and early warning	Stronger EU coordination to prevent and respond to shortages
Strategic stockpiles	Joint procurement and EU-funded emergency reserves
Regulatory fast-track	Simplified permits for critical and "strategic" facilities



Will Europe remain a major biopharmaceutical destination?

Europe holds

25% of global biologics sales

37% of global biomanufacturing capacity[23]

Collaborative procurement and talent pipelines

The EU has launched initiatives to strengthen the continent's biomanufacturing capabilities. On January 30, 2025, the European Commission established a Biotech and Biomanufacturing Hub to help startups and small firms bring innovative biotechnology-based products to market.

The hub directs entrepreneurs to critical information on EU funding, research infrastructure, networks, pilot and testing facilities, market insights, intellectual property, and the regulatory framework. This initiative forms part of the Commission's broader strategy outlined in its March 2024 Communication on biotechnology and biomanufacturing.

Additionally, the Commission's Competitiveness Compass, published in January 2025, earmarks the life sciences sector as a pillar for innovation. The EU plans to develop a comprehensive strategy for this sector in the second quarter of 2025, with biotechnology and the manufacturing of critical medicines identified as areas requiring close coordination between the EU and member states.

Novartis and Sanofi CEOs letter urge EU to reward innovation at the right price

In a recent joint letter, Novartis CEO Vas Narasimhan and Sanofi CEO Paul Hudson called on the EU to reform its pharmaceutical pricing policies to better reward innovation[31]. They argue that Europe's current pricing structures, which often result in lower drug prices compared to the U.S., discourage investment in research and development.

This has led to a situation where 30% of medicines approved in the U.S. remain unavailable in Europe two years post-approval. The CEOs suggest that aligning EU drug spending closer to U.S. net prices could incentivize innovation and strengthen Europe's position in the global pharmaceutical industry.

This appeal comes amid growing concerns about Europe's competitiveness in the biopharmaceutical sector. While the U.S. has attracted over $150 billion in biopharma investments due to favorable policies and broader patient access to new medicines, Europe's share in global R&D investment has been declining.

The CEOs warn that without significant policy changes, Europe risks falling behind, not only in innovation, but also in manufacturing capabilities, potentially compromising its health sovereignty and economic resilience.

However, without competitive pricing and supportive policies, companies may find it more attractive to invest elsewhere, thereby weakening Europe's pharmaceutical manufacturing base.

Notable European investments

The pharmaceutical and CDMO industries have been making investments in Europe over the past years:

Pharma

- In 2023, Eli Lilly announced a $2.5 billion investment to build a global injectable and device manufacturing facility to support the production of diabetes and obesity treatments in Alzey, Germany. In 2024, the company committed an additional $1.8 billion to expand manufacturing sites in Kinsale and Limerick, Ireland to support production of obesity and diabetes treatments and active biologic ingredients for Alzheimer's treatments.[32,33]
- In 2023, Novo Nordisk announced a $2.3 billion investment to meet growing demand for anti-obesity medications in Chartres, France.[34]
- Sanofi has invested over $3.5 billion in France since the COVID-19 pandemic, including a new facility in Vitry-sur-Seine to double production capacity for monoclonal antibodies.[35]
- Following a $354 million expansion in 2019, J&J Innovative Medicine announced a further $176m expansion of their Ringaskiddy biomanufacturing facility in Cork, Ireland.[36]

CDMO

- Fujifilm Diosynth announced a $1.6 billion investment in 2022 to expand its cell culture manufacturing services in its facility in Hillard, Denmark.[37]
- In 2022, Lonza invested CHF 500 million in a large-scale commercial drug product fill-and-finish facility in Stein, Switzerland. In 2024, the company announced an expansion of its bioconjugation capabilities in Visp, Switzerland, including two additional manufacturing suites. Lonza also revealed plans to relocate and expand its biologics facility in the UK.[38,39,40]
- WuXi Biologics invested $325 million 2018 to build a singe-use bioreactor facility in Dundalk, Ireland. In 2020, it acquired drug substance and drug product sites in Leverkusen and Wuppertal, Germany, followed by further investment in 2023 to expand manufacturing capacity at both locations.[41,42,43]

As of 2025, no major biomanufacturing investments have been announced in Europe, in contrast to the sizable investment announcements in the U.S.

potentially signaling that leading biopharma are postponing investment decisions until there is more clarity on the global geopolitical situation.

07

Asia's Strategic Recalibration

Growth of biologics sales in the region and forecast

Asia currently accounts for 6% of global antibody-derived biologics by value. Japan and China dominate with 54% and 33% of Asia's market share respectively. India represents 1% of Asia's market share emerging as the fastest-growing market at 29% CAGR, driven by biosimilar development and cost-competitive manufacturing.

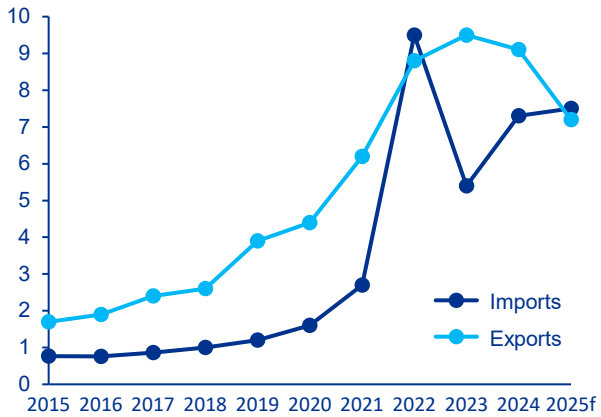
Manufacturing capacity expansion

The region's biomanufacturing capacity is approaching 30% of global capacity. The mismatch between market value and manufacturing capacity may be explained by lower prices in Asia than in developed countries and by the over-representation of CDMOs such as WuXi Biologics and Samsung Biologics that are building large scale bioreactors and exporting API to the U.S. and Europe.

Asia's biopharmaceutical ascendance

Besides the rise of biomanufacturing capacity, Asia is becoming a leader in biopharmaceuticals development, with China at the forefront of this transformation[42]. Chinese biotech licensing deals have reached unprecedented levels, with total deal values surging 66% from $16.6 billion in 2023 to $41.5 billion in 2024.

Figure 5: US pharmaceutical trade with China in $ billions



Source: U.S. Census Bureau.

Note: 2025 figures were forecasted based on actual data trend from January to April.

Note(s): (e) National Security Commission on Emerging Biotechnology

The first quarter of 2025 alone saw 33 licensing deals between Chinese drug makers and overseas pharmaceutical firms, totaling $36.2 billion - a significant increase from the 28 deals recorded in the same period last year[43]. This trend is exemplified by Pfizer's recent record-breaking $1.25 billion upfront payment to license an experimental cancer drug from China's 3SBio, with potential downstream fees of up to $4.8 billion[44]. Large pharmaceutical companies now source 28% of innovator drugs from Chinese biopharma companies, reflecting China's growing prominence in novel drug development. This surge in innovation is further evidenced by China's growing share of the global drug pipeline, which reached approximately 27% in 2024 - six times larger than a decade ago[45].

Geopolitical implications and strategic responses

The rapid ascendance of Asian biotechnology, particularly China's growing dominance, has prompted strategic concerns in Western nations. U.S. pharmaceutical imports from China have grown more than 420% between 2015 and 2024 **(Figure 5),** mainly driven by increased imports of finished-dose formulations.[46] This surge is likely due to pandemic-induced medication shortages in the U.S. and further supported by China's strategic investments in its biopharmaceutical sector[47,48]. Under the country's 14th Five-Year Plan, China expanded its capabilities beyond APIs to include the large-scale production of finished-dose formulations and biologic therapies.

The NSCEB[e] has characterized China's biotechnology rise as "sobering, even frightening", warning that the United States must take "swift action in the next three years" to maintain competitiveness[49,50]. This has resulted in recommendations for a $15 billion federal investment in the U.S. biotechnology sector and the establishment of a National Biotechnology Coordination Office within the Executive Office of the President to coordinate interagency actions on biotechnology competition and regulation[51].

Asia, particularly China, is rapidly emerging as a major hub for new clinical trial activity. The proportion of trial starts in China has risen significantly from 8% in 2013 up to 29% in 2023. This growth is primarily driven by trials conducted exclusively in China[52]. Given this momentum, it is conceivable that China's growing leadership in clinical research could also further translate to a dominant role in biomanufacturing.

China’s regional pivot and strategic adaptations

The geopolitical tensions surrounding biotechnology have catalyzed significant realignments in Asia's pharmaceutical manufacturing landscape. Confronted with potential restrictions under the **BioSecure Act**, which stalled in 2024 but remains poised for reconsideration in 2025, Chinese CDMOs like WuXi Biologics are executing a "China+1" strategy to mitigate regulatory risks[53]. Since 2024, WuXi Biologics has channeled $2.1 billion into Southeast Asia, including a $1.4 billion Clinical Research, Development and Manufacturing Organization (CRDMO) center in Singapore and a $700 million biologics facility in Malaysia’s Tanjong Malim pharmaceutical hub. These investments exploit the Association of Southeast Asian Nations’ (ASEAN) preferential trade agreements and lower geopolitical friction, enabling Chinese firms to maintain access to Western markets while sidestepping U.S. scrutiny. Singapore, with its robust IP protections and status as a neutral trading partner, has emerged as a critical node[54]. Meanwhile, Malaysia’s establishment of biopharmaceutical industrial zones, backed by tax incentives and streamlined approvals, has positioned the country as a cost-competitive alternative for antibody and vaccine production[55].

This regional pivot reflects broader Chinese ambitions to dominate Asia’s biologics market while insulating supply chains from Western decoupling efforts. Despite these opportunities, China faces challenges including the region's immature supply chain infrastructure, fragmented regulatory environment, and uncertainty about whether this pivot will effectively secure reliable supply chains in the face of intensifying U.S. pressure during Trump's second administration[56].

South Korea’s niche dominance in high-tech biomanufacturing

As U.S.-China decoupling accelerates, South Korea’s Samsung Biologics has capitalized on its geopolitical neutrality and technological edge to capture a significant share of the global CDMO market[57]. The company’s $3.3 billion contract portfolio as of 2024, including a record $1.4 billion deal with an Asian pharmaceutical firm, underscores its role as the preferred partner for Western companies[58].

South Korea-headquartered Celltrion BioSolutions and Lotte Biologics have emerged as disruptive forces in the CDMO market, leveraging multi-billion investments to offer end-to-end services from drug discovery to commercialization. Launched in 2022 and 2024 respectively, Lotte Biologics and Celltrion BioSolutions are executing a fast scale-up strategy. Both firms exemplify South Korea’s strategic shift from scale-driven to modality-specialized CDMO services, balancing innovation with geopolitical hedging.

Emerging role of India in biomanufacturing

Most commonly known for small molecule and generics manufacturing, India has emerged as a key beneficiary of geopolitical tensions, with its CDMO sector growing 37% year-over-year in 2024 through $1.9 billion in new contracts[59]. Government initiatives like the Production-Linked Incentive (PLI) scheme, which offers 15-20% subsidies for biologics infrastructure, have enabled Indian firms to undercut Chinese pricing by 30% while meeting FDA compliance standards.

08

Future Trajectories in Biologics Manufacturing

The global biologics manufacturing landscape stands at a crossroads, with geopolitical tensions, regulatory shifts, and technological innovations reshaping how and where critical medicines are produced. As decision-makers contemplate strategic investments spanning decades, understanding potential futures and associated trade-offs becomes crucial for resilient planning.

This episode, **"A New Geopolitical Order - The Rise of the Biomanufacturing Empire",** explores a defining question: What kind of global order will share the future of biomanufacturing? The biologic manufacturing sector's future will be profoundly shaped by the geopolitical environment in which it operates. We consider three potential scenarios along the geopolitical risk scale **(Figure 7)**:

Figure 7: Three potential scenarios along the geopolitical risk scale

	1	2	3
Foresight scenario	The republic prosperity	The separatist movement	The imperial isolation
Geopolitical tension grade	Low		High
Description	Stable rule of law, strong institutions, minimal geopolitical friction, open markets	Politically stable but exposed to external economic or strategic pressures	Rising tensions, tariff risks, regulatory unpredictability	Open trade conflicts, regulatory fragmentation

1:
The republic prosperity

Under conditions of stability and open markets, the biologics sector would gravitate toward highly integrated global supply chains that prioritize economic optimization above all other considerations. Decision-making would prioritize technical capabilities and economic considerations, with production concentrated in specialized hubs. This scenario enables broad access to biologics through significant economies of scale but may reintroduce vulnerabilities observed during recent supply disruptions.

The concentration of critical manufacturing capabilities in geographically clustered facilities creates single points of failure that can disrupt global supply chains. Recent disruptions during the COVID-19 pandemic demonstrated how centralized systems, while economically optimal, can leave entire regions without access to essential medicines when transportation networks fail, or production facilities face operational challenges. Additionally, the heavy reliance on a limited number of suppliers increases risks of intellectual property theft and reduces negotiating power for purchasing organizations.

2:
The separatist movement

As tensions rise to moderate levels, a more nuanced regionalization strategy emerges that attempts to balance efficiency gains with risk mitigation. Critical biologics would increasingly be produced within their consumption regions, particularly for novel therapies and emergency countermeasures. This creates three primary blocs with reduced exchange between them: the Americas, Europe and Asia each developing semi-autonomous production capabilities for critical biologics. Established products and biosimilars might continue flowing through global supply networks, but with redundant sourcing becoming standard practice. This balanced approach preserves many efficiency benefits while introducing strategic buffers against disruption.

The trade-offs of this scenario are significant. Regional manufacturing requires substantial capital investments to establish redundant capabilities across multiple blocs, thus increasing overall production costs and supply chain complexity compared to fully integrated global systems. Smaller regional markets may struggle to achieve optimal economies of scale for specialized or low-volume therapies. The need for redundant sourcing and regional inventory management also increases working capital requirements and operational complexity.

3:
The imperial isolation

In scenarios of severe geopolitical fragmentation, biologics manufacturing would prioritize security above efficiency. Nations would mandate domestic production of critical medicines, establish strategic stockpiles, and dramatically reduce cross-border dependencies. Advanced economies would develop end-to-end manufacturing capabilities across the biologic's spectrum, while smaller markets might form regional consortia to achieve viable scale. This approach maximizes resilience but introduces significant inefficiencies and potentially limits access to advanced therapies in regions lacking robust manufacturing infrastructure.

Domestic manufacturing mandates would fragment global production, eliminating economies of scale. Smaller markets would face particularly acute challenges, requiring formation of regional consortia to achieve viable manufacturing scale or accepting limited access to advanced therapies. The duplication of manufacturing infrastructure across multiple countries would represent massive capital inefficiencies, while the need for comprehensive domestic capabilities would strain skilled workforce resources. This scenario could create a two-tiered global system where advanced economies maintain access to cutting-edge biologics while developing regions face significant barriers to treatment access. The requirement for comprehensive domestic manufacturing capabilities would likely slow innovation, as resources shift from research and development toward building redundant production infrastructure. Quality standardization across fragmented national systems could also prove challenging, potentially compromising patient safety and therapeutic efficacy.

Key takeaway

For global biologics leaders, these divergent scenarios demand flexible, forward-looking strategies that balance efficiency with resilience. The coming decade will require thoughtful positioning across multiple regions, strategic partnerships spanning geopolitical boundaries, and modular manufacturing approaches adaptable to rapidly changing conditions.

Conclusion: Strategic Imperatives for Biopharma Leaders

In navigating today's volatile biopharma landscape, executives must anchor strategic decisions in long-term value creation and capital-efficient growth while deploying agile operational levers to absorb near-term shocks. While reactive measures address immediate pressures like talent shortages or tariff uncertainties, leaders should differentiate transient disruptions from structural market shifts. A dual-track planning framework is essential - preserving core R&D and manufacturing investments while establishing rapid-response protocols. This enables leaders to manage for supply chain volatility and seize market opportunities when they arise.

An established network strategy capability, nurtured by a dedicated network team, is essential – supported by a governance system that develops clear roadmaps with trigger points to prevent any “surprises” for leadership teams. In an uncertain world, business continuity plans equally become of utmost importance and go far beyond the “hold inventory or dual source” question. A plethora of options such as strategic shell spaces, modular factory blueprints, strategic partnering or maintaining a list of potential acquisitions offer alternative options to ensure supply reliability.

Bolstering predictive capabilities through AI-enhanced demand forecasting forms the cornerstone of resilient network strategies, enabling data-driven capacity allocation across geographies and product lifecycles. Advanced modeling tools now allow real-time simulation of numerous variables, from raw material price fluctuations to regulatory pathway changes, creating dynamic scenario libraries that inform predefined decision triggers at critical risk thresholds. This approach transforms episodic crisis management into systematic opportunity capture.

Strategic partnerships, with third party service providers or with peers, are evolving from transactional relationships to integrated innovation ecosystems, with top performers leveraging agreements to secure faster tech transfer timelines, supply insurance and product allocation flexibility. Concurrently, deal-making can be leveraged as a capacity building lever to access specific manufacturing technology or a regional footprint. The acquisition of Catalent by Novo Holdings in 2024 may create a precedent and prompt companies to maintain a dynamic list of targets holding relevant manufacturing technologies or footprint.

By aligning capital allocation with decade-scale therapeutic pipelines, forward-looking organizations build structural advantages that compound across market cycles, turning today's constraints into tomorrow's competitive advantage.

Wherever you are on your journey, KPMG can help:

Developing your network strategy

Gain a clear understanding of your long-term capacity and technology requirements by stress-testing future scenarios against a broad catalogue of customized strategic options. Our approach highlights critical trade-offs and identifies emerging risks early, enabling proactive planning. To support fact-based investment decisions, we typically deploy a tailored decision-support tool.

Building a sustainable technology infrastructure

Leverage KPMG professionals' experience to design tailored, sustainable technology infrastructure that supports network strategy decisions. A customized, automated decision-support tool can integrate financial, operational and resilience metrics into a network strategy dashboard, enabling informed and data-driven decisions.

Setting-up your network playbook and governance

We help you develop a playbook for your network strategy process, with clearly defined triggers, functional roles, and decision trees. Our approach ensures a structured, repeatable process that supports strategic alignment across functions. Additionally, we support the establishment of a governance framework to guide and approve capital investment decisions, ensuring disciplined execution and value creation.

Finding and acquiring your next assets

Our deal professionals can support you across the full asset lifecycle – whether you are looking to acquire facilities on the market or divest sites that no longer align with your network requirements. We provide end-to-end support for both buy-side and sell-side transactions. In addition, we offer strategic guidance on site selection to help you optimize your footprint and ensure alignment with long-term business goals.

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CREATE: CRT162185A | June

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