Reshoring Pharmaceutical Manufacturing

Unlocking domestic capacity through CDMO infrastructure

- 100K sq. ft.
- Commercial Manufacturing
- 27 GMP Suites

The Race to Reshoring

The United States is in the midst of an unprecedented push to bring pharmaceutical manufacturing back to domestic soil. The catalyst is a convergence of national security concerns, pandemic-era supply chain failures, and increasingly aggressive trade policy from the Trump administration, including Section 232 investigations, executive orders to streamline FDA approvals for U.S.-based facilities, the creation of a Strategic API Reserve (SAPIR), and the recent imposition of 100% tariffs on imported patented and branded pharmaceuticals for companies that do not meet pricing or onshoring requirements.

The vulnerability in the U.S. drug supply sits at the level of the finished drug product. A substantial share of the pharmaceutical preparations sold in the United States are manufactured overseas, and imported finished medicines represent one of the largest categories of U.S. imports by value. The country depends heavily on foreign production capacity for completed dosage forms, not just raw ingredients.

While generics are widely offshored, the same structural vulnerability persists for branded products. Many originator companies rely on international sites for finished dose manufacturing and packaging, creating concentrated points of failure across global facilities. As a result, tariffs, trade restrictions, or other economic shocks affecting overseas sites can quickly cascade into supply constraints and reduced patient access, highlighting a fragility that is operational, immediate, and directly impacts the availability of finished medicines.

In response, pharmaceutical companies have announced hundreds of billions of dollars in cumulative U.S. manufacturing investments since February 2025, spanning 22 new manufacturing sites and approximately 44,000 projected new jobs. The table below captures the scale of these commitments.

Company	Investment	Focus Areas
Pfizer	$70 billion	R&D and capital projects
J&J	$57 billion	Manufacturing, R&D, biologics
AstraZeneca	$50 billion	Medicines manufacturing, R&D, Virginia facility
Roche/Genentech	$50 billion	Manufacturing and R&D
BMS	$40 billion	Manufacturing, R&D, technology
Gilead Sciences	$32 billion	Manufacturing hub at Foster City HQ, biologics plant
GSK	$30 billion	New Upper Merion, PA facility; respiratory and oncology
Eli Lilly	$27 billion+	4 new facilities for APIs, sterile injectables, biologics
Novartis	$23 billion	Radioligand therapy, chemical/biological manufacture
Sanofi	$20 billion	U.S. manufacturing expansion and CDMO partnerships
AbbVie	$10 billion	U.S. manufacturing expansion, including API facility
Merck	$9.9 billion	U.S. manufacturing, including Durham vaccine site
Novo Nordisk	~$9 billion	Acquired 3 Catalent sites for GLP-1 drugs

Table 1 select pharmaceutical manufacturing investments since February 2025

These numbers are promising, but announcements are not the same as operational capacity. The real question is whether the industry can deliver on these commitments given the structural challenges involved.

The Challenges: Why Announcements ≠ Capacity

Timelines: 5–10 Years from Announcement to First Batch

Building a pharmaceutical manufacturing facility from scratch is one of the most time-intensive construction undertakings in any industry. A greenfield biopharma plant typically requires 5 to 10 years from initial planning to regulatory approval and full-scale production. Construction alone can take 12–36 months for the physical structure, but that's only the beginning. The facility then needs to be outfitted with specialized equipment (bioreactors, cleanrooms, HVAC systems), undergo commissioning and qualification, and pass FDA inspection before a single commercial batch can ship.

Most of the announced facilities will not break ground until 2026–2027 at the earliest, with production realistically beginning in the 2028–2030 window. Eli Lilly's $5 billion Virginia API plant, for example, was announced in September 2025 with a projected 5-year completion timeline. J&J's Wilson, North Carolina biologics facility won't be operational until approximately 2030. No major new plant from this wave of announcements is finishing before 2026.

This means the current reshoring surge offers no near-term relief for supply chain vulnerabilities. For the next 3–5 years at minimum, the U.S. remains just as dependent on foreign API and finished drug product sources as it is today.

Technology Transfer: The Hidden 18–30 Month Bottleneck

Even when a facility is built, it cannot simply begin producing medicines. Every product requires a formal technology transfer the systematic migration of manufacturing knowledge, process parameters, analytical methods, and quality controls from a sending site to the receiving facility. The average pharmaceutical tech transfer takes approximately 20 months, involves around 30 cross-functional experts, and costs upwards of $5 million per product. External transfers (between different organizations) add an additional 5.8 months on average compared to internal site-to-site moves.

The complexity is formidable. Up to 50% of tech transfer projects experience significant delays or quality issues during scale-up. Even seemingly routine oral solid dosage transfers can stumble on equipment differences, site-specific environmental variability, or communication gaps between sending and receiving teams.

For reshoring, this challenge compounds: companies must transfer processes that have been optimized for overseas facilities, often over many years, into entirely new U.S. sites with different equipment, different workforce experience levels, and different institutional knowledge bases. Each product in a company's portfolio requires its own dedicated transfer, meaning a facility producing dozens of products could face years of sequential tech transfer campaigns before reaching full operational capacity.

The Volume Gap: Hundreds of Billions is Still Not Enough

Perhaps the most sobering challenge is the sheer scale mismatch between what the U.S. currently imports and what these investments can realistically produce. The United States imported $212.7 billion in

pharmaceutical products in 2023 alone, more than double the $94.4 billion it exported. Only about two in five finished drug products are currently made domestically.

The announced investments are heavily concentrated in advanced therapies, biologics, cell and gene therapies, radioligand therapies, GLP-1 agonists, and antibody-drug conjugates. These are high-value, strategically important categories, but they represent a small fraction of total prescription volume.

Even if every announced facility is built on schedule, which history and market signals suggest is unlikely, the resulting capacity will be oriented toward the highest-margin specialty drugs, not the high-volume oral backbone of the American pharmacy.

The Solution: Leveraging Existing CDMO Infrastructure

The Forgotten Asset: America's Legacy Pharmaceutical Manufacturing Base

There is a faster, cheaper, and lower-risk path to meaningful reshoring that is hiding in plain sight, and it runs through the nation's existing network of contract development and manufacturing organizations (CDMOs).

The United States once had a robust domestic generic pharmaceutical manufacturing base. For decades following the 1984 Hatch-Waxman Act, American facilities produced the bulk of the nation's generic medicines. Companies like Par (later Endo), Mylan (later Viatris), Merck, and dozens of mid-size manufacturers operated FDA-inspected plants across the country, in Irvine, California; Morgantown, West Virginia; Danville, Pennsylvania; and elsewhere. This infrastructure represented billions of dollars in sunk capital, decades of institutional knowledge, and deep relationships with the FDA's inspection and compliance apparatus.

The offshoring wave that accelerated after 2000 didn't physically demolish these facilities. Many were shuttered, downsized, or, critically, sold to CDMOs that repurposed them for contract manufacturing.

These are not derelict buildings. They are fully operational, FDA-inspected, cGMP-compliant manufacturing plants that are already producing medicines. A landmark 2022 survey by Washington University's Center for Analytics and Business Insights found that 57% of active American manufacturing sites could be repurposed to full production within one year, and 86% within two years, a dramatic contrast to the 5-10 year timeline for greenfield construction. Nearly 30 billion additional doses of essential and critical medicines could be produced domestically without building a single new plant.

CDMOs as the Bridge to Onshoring

CDMOs are uniquely positioned to serve as the critical bridge between the current state of foreign dependency and the future state of domestic self-sufficiency. The U.S. pharmaceutical CDMO market was valued at $36.5 billion in 2024 and is projected to reach $68.3 billion by 2029. In 2025, 74% of all global CDMO capital investment flowed to the United States signaling that the market is already betting on U.S.-based contract manufacturing as the solution.

The strategic logic is straightforward:

- **Speed**: Brownfield expansions at existing CDMO sites are the fastest path to new capacity. Piramal Pharma's $90 million investment at two U.S. sites (Lexington, KY and Riverview, MI) exemplifies this approach, leveraging existing infrastructure, experienced workforces, and established FDA relationships to add commercial-scale sterile injectables and ADC payload-linker manufacturing with operational timelines of 2025–2027. As Piramal's CEO noted: "Brownfield expansions were chosen because both sites already have many years of in-house expertise, experienced work forces, which allows us to become operational more quickly and efficiently and with lower risk".
- **Lower cost and risk**: Repurposing idle capacity in existing cGMP facilities avoids the multi-billion-dollar price tag and regulatory uncertainty of greenfield construction. The Washington University research estimated that reshoring essential medicines via existing facilities could be achieved at an incremental cost to patients of just $0.66–$1.32 per month per prescription.
- **Tech transfer advantage**: CDMOs are, by definition, expert at receiving and executing tech transfers. It is their core business. While pharma companies building their own new facilities face the challenge of standing up entirely new manufacturing organizations, CDMOs already have the cross-functional teams, documentation systems, quality infrastructure, and scale-up experience to absorb new products rapidly. The surge in "move-to-U.S." contracts at CDMOs like Thermo Fisher, Catalent (now partially Novo Nordisk), Lonza, and others reflects this reality.
- **Facility recycling**: The recent wave of CDMO acquisitions of legacy pharma facilities illustrates this dynamic in action. Lonza acquired Roche-Genentech's Vacaville biologics site for $1.2 billion. Novo Nordisk acquired three Catalent fill-finish facilities for $11 billion to scale GLP-1 production. Syngene International purchased Emergent BioSolutions' Baltimore biopharmaceutical plant for $37 million, gaining 50,000 liters of single-use bioreactor capacity. Bora Pharmaceuticals acquired another Emergent fill-finish facility in Baltimore for $30 million. Ardena completed the acquisition of Catalent's Somerset, NJ drug product facility. In each case, existing infrastructure built during an earlier era of domestic manufacturing found new life under CDMO ownership, ready to serve onshoring demand.

The Path Forward: CDMOs as Strategic National Assets

The policy implication is clear: rather than relying exclusively on massive, long-horizon greenfield megaprojects from Big Pharma, many of which may never materialize in their announced form, U.S. reshoring strategy should prioritize activating and modernizing existing CDMO and generic manufacturing capacity.

The building blocks already exist. The Association for Accessible Medicines has called for a targeted approach centered on essential medicines rather than attempting to onshore all 40,000+ FDA-approved drugs. The API Innovation Center has demonstrated that continuous manufacturing technologies deployed in existing idle facilities could reduce costs by 30–50%, neutralizing much of the cost advantage that drove production offshore in the first place. The FDA's May 2025 executive order to streamline inspections and expand pre-operational technical assistance for domestic manufacturers is a step in the right direction.

The pharmaceutical reshoring wave is real, but it is also years away from delivering meaningful new capacity through greenfield construction. The good news is that America's pharmaceutical manufacturing past left behind a network of facilities, expertise, and infrastructure that didn't disappear, it just went underutilized. CDMOs are the vehicle through which this latent capacity can be mobilized, and they represent the most pragmatic bridge between today's vulnerability and tomorrow's resilience.

About Forma

Forma Life Sciences is a U.S. based contract development and manufacturing organization (CDMO) specializing in oral solid dosage formulation development, clinical manufacturing, and commercial drug product manufacturing. Headquartered in Irvine, California, Forma operates two cGMP facilities totaling more than 100,000 square feet and 27 GMP manufacturing suites, with capacity to produce over two billion tablet and capsule units annually. The company supports pharmaceutical and biotechnology partners from early clinical development through commercial scale production and offers expertise in spray-dried dispersion, amorphous solid dispersion systems, fluid bed granulation, and modified-release formulation technologies