Enabling the Reshoring of Pharma Manufacturing with Integrated Continuous Manufacturing

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A Fragile Supply Chain Built on Foreign Dependence

Concerns over the pharmaceutical industry's dependence on foreign suppliers for key starting materials (KSMs), active pharmaceutical ingredients (APIs), and even finished drug forms (FDFs) began surfacing nearly two decades ago. As governments in emerging markets — especially China and India — invested heavily in scaling up pharmaceutical manufacturing, Western companies increasingly outsourced production to take advantage of lower labor costs and looser environmental regulations.

As a result, domestic manufacturing capacity and institutional expertise in the United States and Europe steadily declined. The global pharmaceutical supply chain became increasingly fragmented and complex, leading to a host of practical benefits, as well as vulnerability to disruption. Today, approximately and used in the United States are sourced from overseas — with China and India being major suppliers. From a strategic, quality, and geopolitical perspective, this concentration of sourcing poses greater risk than reliance on countries with stronger regulatory alignment and shared oversight norms, such as Switzerland. This dependency has contributed to recurring drug shortages, often triggered by quality or compliance issues at offshore facilities.

While some industry stakeholders recognized the strategic risk this posed to both national security and public health, the issue gained sporadic attention and little traction until the COVID-19 pandemic. Suddenly, the dangers of an overextended, foreign-reliant supply chain were thrust into sharp relief. As global logistics faltered and critical medications became scarce, the conversation around reshoring pharmaceutical manufacturing gained unprecedented urgency.

CONTINUUS Pharmaceuticals was founded in 2012 to address precisely this challenge. The company set out to develop a fully integrated, end-to-end continuous manufacturing platform for small molecule drugs — one capable of streamlining production, reducing costs, and accelerating time to market. Over the ensuing decade, CONTINUUS made steady progress, laying the groundwork for a solution that could reshape how drugs are made and delivered.

The pandemic served as a tipping point, not only underscoring the fragility of the status quo but also sparking renewed government interest in domestic manufacturing resilience. Federal investments were made to support advanced manufacturing initiatives and bolster supply chain security. However, political turnover and shifting priorities have slowed momentum, and many of the structural issues remain unresolved. While pharmaceutical companies are now being urged — or in some cases pressured — to bring manufacturing back onshore, achieving that goal will require more than relocation. It will demand a fundamental rethinking of how drugs are made.

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Real Reshoring is Dependent on Innovation

The call to reshore pharmaceutical manufacturing is well-founded — but simply returning legacy processes to domestic facilities will not solve the problem. There is a reason drug production migrated overseas in the first place: dramatically lower labor costs, less stringent environmental regulations, and efficiencies that made outsourcing the default economic choice. Replicating those same batch-based processes in the United States or Europe would only reintroduce their inefficiencies — at a higher cost.

True reshoring requires reimagining how drugs are manufactured. Without innovation, bringing production back risks becoming unsustainable, economically nonviable, and environmentally burdensome. New technologies and manufacturing paradigms must be adopted to ensure that domestic drug production can be cost-competitive, scalable, resilient, and environmentally sustainable.

This shift will not happen overnight. The pharmaceutical supply chain's reliance on overseas production was the result of decades of investment in manufacturing infrastructure and government intervention and sponsorship in countries like China and India. Reversing that trend will require sustained effort — and political will — on longer timescales that extend beyond shorter-term initiatives. Achieving a reshored, secure pharmaceutical supply chain at meaningful scale demands long-term commitment, cross-sector collaboration, and regulatory alignment.

CONTINUUS Pharmaceuticals has been pursuing this vision for over 10 years. From the outset, the company recognized that meaningful change would require more than automation or digital overlays to existing systems. That's why we developed the Integrated Continuous Manufacturing (ICM) platform — a ground-up redesign of small molecule drug production built for efficiency, quality, and scalability. Building such a system involves more than just engineering innovation. Every element must be designed, fabricated, tested, and validated in full compliance with current Good Manufacturing Practices (cGMP). It is a rigorous, multi-year process, but one that yields a manufacturing platform ready to support a new era of domestic pharmaceutical production.

A New Blueprint for Continuous Manufacturing

CONTINUUS Pharmaceuticals' ICM platform represents a fundamental departure from conventional approaches to small molecule drug production. Unlike most systems that attempt to establish continuity by simply linking existing batch-based unit operations into connected systems, the ICM platform was built from the ground up. Each unit operation was redesigned to operate seamlessly as part of a fully integrated, end-to-end continuous process.

This distinction is critical. True continuous manufacturing is not just about running isolated steps in a nonstop fashion; it's about integration. Without that, you may still be operating in a fundamentally batch-oriented paradigm, with all the inefficiencies and delays that come with

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it. The power of the ICM platform lies in its holistic design, which eliminates the gaps between upstream and downstream processes, enabling a fluid, uninterrupted flow from starting materials to finished drug product.

Integration unlocks the full promise of continuous manufacturing: faster production, greater efficiency, lower costs, and improved quality control. The CONTINUUS ICM platform can operate on a 24-hour basis, dramatically reducing manufacturing footprint, minimizing downtime, and enhancing process control. By combining novel technologies with a fully integrated design, CONTINUUS delivers a manufacturing paradigm that is not only faster and leaner but also more agile, scalable, sustainable, and future-ready.

Breaking Through Resistance to Innovation

The pharmaceutical industry exists in a paradox. It is propelled by scientific innovation and discovery, yet often cautious — even resistant — when it comes to adopting new manufacturing technologies. This conservatism is rooted in a deeply ingrained commitment to patient safety and regulatory compliance. As a result, even well-proven advancements like continuous manufacturing, widely embraced in other sectors, have faced slow adoption in drug production.

Much of this hesitation stems from perception rather than reality. Novel systems like CONTINUUS Pharmaceuticals' ICM platform inevitably raise questions: about qualification, validation, cleanability, and above all, regulatory acceptance. For many companies, the perceived risk of being first to adopt an unfamiliar technology outweighs the potential benefits. Yet without early adopters, systemic change remains elusive.

Fortunately, regulatory agencies have evolved in tandem with technology. Over the past decade, the U.S. Food and Drug Administration (FDA) has become a vocal advocate for continuous processing. The FDA's Emerging Technology Team (ETT) was established specifically to support companies adopting novel manufacturing platforms, providing early guidance to ease regulatory navigation. More recently, the Advanced Manufacturing Technologies (AMT) Designation Program was introduced to formalize and accelerate approvals for drugs produced using innovative, pre-vetted platforms.

The FDA has published data showing that continuous manufacturing applications receive faster reviews on average than traditional batch processes, thanks to established frameworks like ETT. These efficiencies are underpinned by the inherent quality advantages of continuous manufacturing, including real-time monitoring, better process control, and fully contained systems that minimize contamination risk.

The challenge now is no longer technological; it's cultural. With regulatory support in place and the advantages clearly demonstrated, the next step is overcoming industry inertia and making bold moves toward a more modern, resilient manufacturing model.

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The Payoff of Integrated Continuous Manufacturing: Speed, Quality, Cost, and Sustainability

Shifting from traditional batch manufacturing to a fully integrated, end-to-end continuous process delivers transformative advantages across four critical dimensions: speed, quality, cost, and sustainability.

Continuous processes dramatically accelerate production timelines. What once took months — or even years — can now be completed in a matter of days. This acceleration is not just theoretical; it has been demonstrated across multiple stages of the drug life cycle, from development through commercial manufacturing.

Cost reductions follow naturally. The equipment and facility footprint for an ICM-based production suite is significantly smaller than that of a traditional batch operation. Fewer unit operations, higher process efficiency, and improved yields mean less starting material is required, purification steps are streamlined, and waste generation is minimized. These efficiencies translate to lower operating costs while maintaining, if not exceeding, product quality.

Quality, in fact, is where continuous manufacturing offers some of its most compelling benefits. With real-time monitoring and control at every step, continuous systems operate in a state-of-control and can immediately detect and correct deviations. This level of process control ensures greater consistency and purity, while reducing the need for post-production testing and rework.

Sustainability is an increasingly vital metric, and continuous manufacturing delivers here as well. ICM systems consume less energy and water, use solvents more efficiently (both in processing and cleaning), and produce fewer emissions. The carbon footprint of a continuous plant can be three to four times lower than a comparable batch facility, making it a powerful tool in advancing both environmental and ESG goals.

The primary barrier remains capital expenditure (CapEx). Building and installing a new ICM system requires upfront investment, which can pose a challenge, especially for generic manufacturers with narrow margins and contract development and manufacturing organizations (CDMOs). However, the longer-term payoff is compelling. For new facilities, the required CapEx for an ICM-based suite is approximately half that of a comparable batch operation. This lower cost structure, combined with faster timelines and superior performance, makes the platform especially well-suited to greenfield projects and the launch of new-to-market drugs, as well as future-proofing for the manufacture of existing products.

Even so, public investment plays an important enabling role. Government financing to offset the initial buildout can serve as a critical accelerant, helping companies reshore not just facilities, but the future of pharmaceutical manufacturing itself.

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Innovation Favors the Bold—and the Well-Funded

Across the pharmaceutical industry, there is growing consensus on the benefits of continuous manufacturing. But recognizing the advantages and taking the leap are two very different things. Transitioning from an entrenched batch process to a cutting-edge continuous platform requires a significant shift: in capital investment, mindset, and operational design.

So, who is best positioned to make that move?

Generic manufacturers are often laser-focused on keeping costs low while maintaining acceptable quality. Their tight margins and follow-the-leader business model make them unlikely to be first adopters of high-CapEx innovations like ICM. This is especially true for low-margin, yet essential generic drugs that are critical to public health but lack the return on investment needed to attract sustained private-sector interest. For these indispensable but economically unattractive products, government intervention may be required to ensure continued domestic production. Without it, the market alone may not support reshoring, regardless of technological innovation.

CDMOs, while increasingly vital to the industry's global supply chain, tend to follow the priorities of their clients. Since they rarely own the regulatory filings for the products they make, CDMOs are generally not in a position to take the lead on adopting disruptive manufacturing technologies, unless their pharma partners explicitly ask for it.

It is branded pharmaceutical companies, particularly those with deep pipelines, broad portfolios, and longer investment horizons, that are leading the charge. These companies have the resources and strategic incentive to build new facilities around continuous platforms. They also benefit most from the ability to accelerate development, secure supply chains, and reduce environmental impact — all while maintaining control over sensitive intellectual property and product quality.

As more ICM systems are installed and demonstrate measurable success, CDMOs will be next to follow, eager to support their pharma clients with faster, more cost-effective solutions. Generics will eventually join the wave, likely once off-patent products originally produced on ICM platforms require replication. But for now, the reshaping of pharma manufacturing is being spearheaded by innovators with the vision, and the capital, to make the first move.

Policy and Investment Must Match Innovation

While regulatory agencies are already proponents of continuous processing, they are continuing to take further steps to support the wider transition from batch to continuous manufacturing that is needed to galvanize significant reshoring of drug production to the United States and Europe. This active regulatory support for innovative technologies like CONTINUUS' ICM platform — supported further by evolving governmental interest outside of regulatory agencies — will help to ensure such solutions are not perceived as too risky.

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Financial support for installation of ICM systems by not only big pharma, but also small and emerging companies bringing novel therapies to market, is also needed to strengthen domestic pharmaceutical manufacturing capabilities. The combination of financing and an established regulatory framework are essential to supporting measurable reshoring of drug production.

Regulatory agencies, particularly the FDA, have taken important steps to promote continuous manufacturing: programs like the FDA's ETT and the AMT Designation are helping to facilitate and promote broader adoption of novel platforms like CONTINUUS Pharmaceuticals' ICM system. This helps ensure that advanced technologies are seen as reliable, approvable, and scalable to overcoming industry inertia.

Equally important is financial support. Even with its long-term economic advantages, the upfront CapEx required to build and validate an ICM-based facility can be a barrier, particularly for small and emerging companies developing novel therapies. Public investment, whether through direct funding or loan guarantees, can play a pivotal role in enabling these companies to invest in both domestic production and transformative technology. Supporting large pharmaceutical firms alone will not be enough to secure resilient, diversified manufacturing capacity.

To incentivize end-to-end domestic production, U.S. reimbursement models should be updated to recognize and reward manufacturers that use domestically sourced processes and components. This could include mechanisms such as pricing differentials, procurement preferences, or eligibility for federal contracts. Without aligning reimbursement incentives with supply chain resilience goals, the economic case for reshoring, particularly for high-volume, low-margin products, may remain too weak to drive widespread industry change.

Encouragingly, Congress is increasingly recognizing the urgency of strengthening domestic pharmaceutical manufacturing, not just as an economic issue but as a national security imperative. Lawmakers from both parties, including Senators Elizabeth Warren and Tom Cotton, have highlighted the risks of U.S. dependence on foreign drug and API suppliers, especially in the context of defense readiness. This bipartisan concern is beginning to translate into action, including support for innovative FDA initiatives that could accelerate reshoring. One promising example is a recently announced priority review voucher program, which, while still under development, could potentially be applied not only to full drug applications but also to CMC packages that meet specific criteria, such as bolstering domestic manufacturing capacity.

Although the operational details of the voucher program remain sparse, its early framing is encouraging. Notably, one of the criteria outlined — "increasing domestic drug manufacturing as a national security issue" — aligns directly with reshoring initiatives like the ICM platform. If properly implemented, this kind of regulatory prioritization could become a powerful lever for incentivizing investment in advanced domestic production. However, it will also demand

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significant resources within the FDA and careful oversight to avoid politicization or unintended delays in other review pathways.

Reshoring drug substance (API) and drug product manufacturing is only part of the equation. A truly secure pharmaceutical supply chain must also encompass KSMs and other key ingredients. While many of these materials are technically simpler to produce than multi-step APIs, relying on overseas sources still introduces vulnerabilities, particularly when supply chains are concentrated or poorly diversified. Without meaningful domestic capacity for upstream inputs, geographic risk can persist in different parts of the value chain.

Ultimately, it will take more than innovation alone to solve the reshoring challenge. The combination of proactive regulatory alignment, strategic financial support, modernized reimbursement schemes that reward domestic production, and full-spectrum supply chain planning is necessary to restore pharmaceutical sovereignty and resilience in the West.

Reshoring Is a National Health Imperative

The continued reliance of the United States and Europe on China and India for the supply of KSMs, APIs, and FDFs has created a persistent vulnerability in global healthcare systems. Whether the next disruption comes in the form of a pandemic, geopolitical conflict, or economic leverage, the risk to patient access and public health is real — and growing.

This is not a hypothetical concern. It is a strategic failure decades in the making. Today, the consequences are clear: nearly every citizen in the United States and Europe depends, in some way, on foreign-produced medicines that may not be reliably available in a crisis.

Addressing this problem will require more than political rhetoric. It demands a sustained, coordinated, and forward-looking effort across sectors and administrations. Reshoring must be seen not just as an economic initiative or a geopolitical countermeasure but as a matter of national health security.

But it cannot be reshoring as usual. Attempting to replicate traditional manufacturing models domestically will only reproduce their inefficiencies at a higher cost. The only viable path forward is reshoring with innovation—leveraging new technologies like ICM to create a domestic pharmaceutical infrastructure that is faster, more flexible, more sustainable, and ultimately more resilient.

The journey will be long. But the critical steps must be taken now to ensure a secure and resilient future.