pharma's almanac
NICE INSIGHT'S CONTENT COMMUNITY

Future-Proofing a Volatile Supply Chain Through Modular Biomanufacturing

Rasmus Pedersen, Ph.D., Associate Director, Process Technology
FUJIFILM Biotechnologies

John Stewart, Vice President, kojoX Strategy
FUJIFILM Biotechnologies

Peter Skals, Head of Global Sustainability
FUJIFILM Biotechnologies

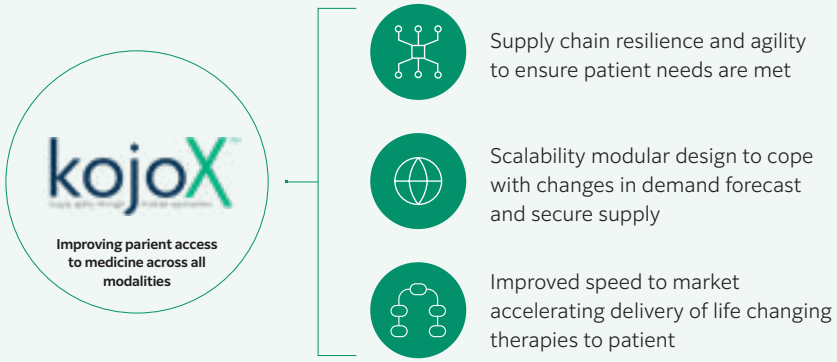
Biopharmaceutical supply chain volatility is at an all-time high, even as drug companies increase their reliance on outsourcing. To navigate this complexity, contract development and manufacturing organizations (CDMOs) must prioritize robust sourcing strategies and proactive vendor management. The kojoX ecosystem created by FUJIFILM Biotechnologies is transforming biologics development and manufacturing by integrating modularization and standardization, mitigating supply chain risks while enhancing flexibility, scalability, and resilience. Through continuous innovation, strategic investment, and long-term partnerships, kojoX is reshaping the industry, ensuring a more agile and future-proofed biomanufacturing ecosystem.

Navigating Supply Chain Volatility in an Unpredictable World

Over the past five years, the pharmaceutical industry has faced an unprecedented level of supply chain volatility, driven by a convergence of global crises. The COVID-19 pandemic exposed vulnerabilities in international supply networks, while subsequent geopolitical conflicts – including the Middle East crisis and the ongoing war in Europe – have further strained the industry. At the same time, natural disasters and economic instability continue to disrupt global logistics, raw material sourcing, and regulatory landscapes, underscoring the need for more resilient and future-proofed supply strategies.

Compounding these challenges is a global shift toward economic nationalism and as such, many pharmaceutical companies are reassessing their supply chain dependencies. Meanwhile, major industry moves – such as Novo Nordisk's acquisition of Catalent to secure internal manufacturing

Figure 1: kojoX – A transformative global bioproduction ecosystem that provides agility, speed and scalability across the product life cycle for biologics and advanced therapies



capacity – have demonstrated how well-funded organizations can reshape the contract development and manufacturing market, increasing competition for limited resources and capacity.

In this evolving landscape, companies are racing to develop strategies that reduce exposure to supply chain risks while ensuring uninterrupted access to critical materials, components, and equipment. No single organization can operate an entirely self-sufficient supply chain. Biopharmaceutical manufacturing requires a vast and interconnected vendor network. As a result, effective sourcing strategies and proactive vendor management have become top priorities for ensuring operational continuity and long-term stability.

The Outsourcing Paradox: Increased Reliance Amid Rising Volatility

Despite increasing supply chain volatility, biopharmaceutical companies continue to expand their reliance on outsourcing. While biologic drugs were once predominantly manufactured in-house to safeguard intellectual property (IP), the landscape has shifted. Recombinant proteins and monoclonal antibodies (mAbs) have become increasingly commoditized, lowering IP-related risks and making CDMOs a more attractive option for production.

However, this shift toward greater outsourcing presents a significant challenge – the biopharmaceutical market is experiencing unprecedented growth, and demand is set to outstrip available production capacity. To remain competitive and reliable partners in the supply chain, CDMOs must proactively invest in expanding capacity to prevent bottlenecks that could delay drug development and commercialization.

This issue is particularly critical for small- and mid-sized pharma companies, which often lack in-house manufacturing capabilities and depend entirely on CDMO partnerships. For these companies, the functionality, stability, and resilience of their CDMO's supply chain is directly tied to their ability to bring therapies to market. Without robust investments in capacity, infrastructure, and supply-chain agility, CDMOs risk becoming bottlenecks rather than enablers in the evolving biopharmaceutical manufacturing ecosystem.

kojoX: Strengthening Supply Chain Resilience Through Modularity

The kojoX operating ecosystem by FUJIFILM Biotechnologies serves as a unified operating philosophy, leveraging a modular approach across sites, scales, modalities, and product life cycles to ensure unmatched flexibility, speed, and efficiency in biopharmaceutical manufacturing (Figure 1). By breaking biomanufacturing into standardized yet adaptable modules, kojoX enables customizable, scalable production that can be adjusted within a controlled design space. This integration of modularity and standardization accelerates decision-making, improves consistency, and enhances overall operational efficiency.

Beyond optimizing biomanufacturing itself, kojoX is designed to fortify the entire outsourcing process – from raw material procurement to final product delivery. By ensuring interoperability across raw material suppliers, equipment, technologies, and production sites, kojoX enables seamless adjustments in response to supply disruptions, ensuring on-time, in-full delivery regardless of geopolitical risks or market shifts.

With technology and scale no longer a barrier, FUJIFILM Biotechnologies has built a highly adaptable global network capable of maintaining output levels despite external uncertainties. To further reinforce supply chain agility, we actively collaborate with strategic suppliers and service providers whose advanced tools and technologies align with kojoX's modular, integrated vision. By fostering a seamless, interconnected operational framework, we ensure that our six global sites function as a single, unified campus – offering customers the benefits of a harmonized, highly responsive manufacturing ecosystem.

Future-Proofing Biomanufacturing with a Standardized Global Network

At its core, kojoX is built on an open, flexible, and uniform global network, designed to support cross-region, cross-scale, and cross-technology production. While FUJIFILM Biotechnologies operates as a single organization, our expansive footprint – with facilities in the United States, Europe, and Japan – ensures dual-supply capabilities, strengthening supply-chain security and manufacturing resilience. By maintaining process and equipment uniformity across sites, kojoX enables seamless scale-up and technology transfer, helping customers navigate the growing complexities of pharmaceutical bioproduction.

In addition to the expansion projects currently planned, we offer on-demand expansion capabilities, allowing customers to rapidly scale manufacturing in response to market needs. For example, a four-pack of 20,000 L bioreactors can be brought online within approximately 18 months, either at a FUJIFILM Biotechnologies facility or, if appropriate, on-site at a customer's location.

This unparalleled speed and scalability stem from kojoX's standardized facility and equipment design philosophy. By relying on validated, proven system architectures, we

eliminate the need for lengthy conceptual and base design phases, significantly reducing project complexity and risk. While FUJIFILM Biotechnologies remains a CDMO, not a construction company, its deep expertise in managing large-scale capital projects enables customers to de-risk facility expansions and accelerate time-to-market.

Beyond capacity-building, kojoX also helps biopharma companies navigate evolving regulatory landscapes. With increasing industry emphasis on continuous bioprocessing and local manufacturing requirements, our harmonized global platform ensures compliance with shifting regulations while benefiting from broader regulatory harmonization.

The effectiveness of this scalable, synchronized model is already evident – FUJIFILM Biotechnologies recently supported a client by establishing two equivalent but separate production streams within a single site – achieving approval from the U.S. Food and Drug Administration (FDA) in just one month. Looking ahead, we anticipate that this level of regulatory efficiency will soon extend across multi-site production strategies, enabling our customers to dramatically streamline development and manufacturing operations across global locations.

Integrating Synergistic Technologies for Next-Generation Biomanufacturing

kojoX integrates a suite of proprietary, synergistic technologies that enhance efficiency, scalability, and quality for biopharmaceutical development and manufacturing. One such innovation by FUJIFILM Biotechnologies is ApolloX™, our advanced mammalian cell line development platform that provides an optimized starting point for process development. ApolloX is designed for seamless scalability, functioning across both single-use and stainless-steel bioreactors, making it adaptable to a wide range of biomanufacturing scales.

One of the most critical advantages of kojoX is its ability to mitigate supply chain volatility.

Additionally we are advancing our MaruX™ platform, a fully automated continuous manufacturing system featuring 500 L single-use perfusion bioreactors capable of sustaining high-density cell cultures. MaruX integrates with our SymphonX™ platform, an automated, modular, and highly customizable downstream purification platform, which is currently undergoing testing with clients and will be on-line for cGMP manufacturing starting in 2027. By streamlining both upstream and downstream operations, our in-house innovation has the potential to revolutionize bioprocessing – dramatically reducing facility footprint and capacity requirements while simultaneously enhancing quality, lowering production costs and increasing speed to market for our biopharma customers.

Beyond our technological innovations, FUJIFILM Biotechnologies brings more than two decades of industry experience to the automation and modularization of biomanufacturing. By embedding automation into every stage of production, kojoX ensures "right-first-time" execution, minimizing human intervention errors and producing robust, repeatable, and highly consistent processes. This fusion of scientific expertise, digital automation, and modular design is fundamental to our mission of transforming biopharmaceutical manufacturing for greater efficiency, reliability, and scalability.

To further enhance capacity and flexibility, FUJIFILM Biotechnologies is investing nearly $9 billion in capacity expansion projects worldwide.

Shaping the Future of Biopharmaceutical Manufacturing

The biopharmaceutical industry is undergoing a profound transformation, and this evolution will only accelerate over the next 15–20 years. CDMOs are no longer just outsourcing partners – they are becoming true innovation drivers, playing an active role in the development, optimization, and commercialization of novel drug candidates.

At the same time, globalized biomanufacturing networks are expanding access to life-impacting therapeutics, ensuring that patients worldwide – regardless of geography – can benefit from cutting-edge therapies. As regulatory harmonization pro-

gresses and supply chains become more interconnected, the ability to implement equivalent, high-quality processes and digital enablement tools across multiple regions will be a key differentiator for the most advanced CDMOs.

With its kojoX framework and continuous manufacturing expertise, FUJIFILM Biotechnologies is positioned at the forefront of this transformation, offering scalable, efficient, and flexible solutions developed by some of the most experienced teams in the industry. By leveraging modularity, automation, and real-time data integration, we ensure that both novel and commoditized biologics can be manufactured and distributed efficiently – maximizing patient access and minimizing production bottlenecks.

Looking ahead, our globally standardized approach may enable us to become the sole manufacturer of certain molecules for select clients, or even multiple clients, offering unparalleled efficiency, consistency, and scalability. As the industry continues to evolve, CDMOs that embrace innovation and global integration will play an ever-larger role—not just in manufacturing, but in shaping the future of biopharmaceutical development itself.

Revolutionizing Biopharma Production: From Factory to Fully Integrated Network

For decades, the largest pharmaceutical companies have dictated their own manufacturing standards, leading to fragmentation, inefficiencies, and inflated drug production costs. The lack of standardized facility designs and processes has made it difficult to transfer manufacturing between companies and sites, adding complexity, delays, and unnecessary financial burden to the industry.

The kojoX framework represents a fundamental shift in how biomanufacturing is approached. By combining modularization and standardization across a globally integrated network, FUJIFILM Biotechnologies eliminates inefficiencies while reducing costs and accelerating development timelines. With alignment across scales and technologies, kojoX ensures:

- Built-in redundancy for enhanced supply chain security
- Seamless scalability to meet evolving production needs
- Expedited regulatory filings to approval timelines through harmonized global processes
- Faster, lower-risk technology transfers between sites
- Reduced environmental impact through optimized resource utilization

By combining modularization and standardization across a globally integrated network, FUJIFILM Biotechnologies eliminates inefficiencies while reducing costs and accelerating development timelines.

More than just a manufacturing philosophy, kojoX fosters transparency and collaboration, ensuring open communication between FUJIFILM Biotechnologies, our vendors, and customers. This commitment to partnership illustrates we are fully focused on building long-term, trust-based relationships rather than traditional contractual-based relationships which are purely transactional.

The long-term vision for kojoX is to connect our global network of sites into a single, seamless biomanufacturing ecosystem – effectively operating as one global factory. Once fully realized, this harmonization will allow regulatory authorities to accept that our processes are equivalent across geographies, potentially eliminating the need for redundant performance qualification batches in multiple locations – saving clients millions of dollars per project and enabling faster time-to-market.

We foresee a future where kojoX develops to extend beyond its own network, integrating into a broader ecosystem of companies supporting biologic drug development at every stage of the life cycle.

Looking even further ahead, FUJIFILM Biotechnologies envisions kojoX evolving into a fully integrated biopharma ecosystem, where all our customers, suppliers, and manufacturing partners – from raw material providers to equipment manufacturers and component suppliers – are fully integrated into a shared value stream. The ultimate goal? A seamless, highly efficient, and transparent network where the right materials and technologies are always available at the right time and place.

Taking this concept even further, we foresee a future where kojoX develops to extend beyond its own network, integrating into a broader ecosystem of companies supporting biologic drug development at every stage of the life cycle. While this level of industry-wide connectivity remains years away, it represents the ultimate vision for a truly aligned, future-proofed biomanufacturing model.

About the Authors

John Stewart
Vice President, KojoX Strategy
FUJIFILM Biotechnologies

John Stewart, Vice President KojoX Strategy, serves as part of the Global Strategic Business Services group at FUJIFILM Biotechnologies. His responsibilities include the execution of the Company's novel kojoX Strategy. John is an executive with 30 years' experience in the pharmaceuticals industry with a background in international multi-site leadership of both small molecule and biologics manufacture and supply networks and with responsibility for internal and external manufacturing of clinical and commercial stage biologics.

Rasmus Pedersen
Associate Director of Process Technology
FUJIFILM Biotechnologies

Rasmus Pedersen, Associate Director of Process Technology for FUJIFILM Biotechnologies at the site in Hillerød, Denmark. Rasmus has over 20 years of experience in strategic modular approaches in the life sciences and across various other industries. He is now part of the development and rollout of the kojoX modular operating philosophy, the expanding integrated global manufacturing network. Before joining FUJIFILM Biotechnologies, Rasmus spent 15 years as a consultant specializing in modularity and complexity management. He holds a Ph.D. in modular platforms and an M.Sc. in Mechanical Engineering from the Technical University of Denmark.

Peter Skals
Head of Global Sustainability
FUJIFILM Biotechnologies

Peter Skals serves as the Head of Global Sustainability at FUJIFILM Biotechnologies. He has global responsibility for leading the company's sustainability initiatives, Partners for the Planet, supporting Fujifilm's Sustainable Value Plan 2030. He has over 15 years of experience in improving company sustainability programs, developing and executing a sustainability strategy, setting SBTi targets, CSRD Reporting, ISO 14001 & 45001 certifications, CDP reporting, stakeholder communication, as well as legislation and change management. He holds a M.Sc. in Environmental Engineering and an advanced degree in strategic management and leadership (HDO) from Copenhagen Business School.

About FUJIFILM Biotechologies

FUJIFILM Biotechnologies, a subsidiary of FUJIFILM Corporation, is a world-leading contract development and manufacturing organization (CDMO) for the development and manufacture of biologics, advanced therapies, and vaccines. The company operates a global network with major locations in the Unites States of America, the United Kingdom and Denmark, offering end-to-end services including drug substance, drug product, and finished goods services. It is also building a new manufacturing site in Holly Springs, North Carolina, USA, scheduled to be operational in 2025. FUJIFILM Biotechnologies has over thirty years of experience in developing and manufacturing drug substance of recombinant proteins, monoclonal antibodies, vaccines, among other large molecules, viral products and medical countermeasures expressed in a wide array of microbial, mammalian, and host/virus systems. We have drug product filling capabilities to support both clinical and commercial demands. Our finished goods services, supported by more than 15 years of experience, can accommodate commercial products for more than 65 countries around the world. The company offers a comprehensive list of services from cell line development using its proprietary pAVEway™ microbial and ApolloX™ cell line systems to process development, analytical development, clinical and FDA-approved commercial manufacturing.

For more information, go to:
biotechnologies.fujifilm.com