FUJIFILM Diosynth biotechnologies

White Paper

Unlocking Agility and Efficiency in Biomanufacturing - the Standardized, Modular kojoX™ Platform

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The biopharmaceutical industry continues to face inefficiencies, bottlenecks, and challenges in scaling and technology transfer. FUJIFILM Diosynth Biotechnologies is transforming the sector with kojoX, a standardized yet flexible modular biomanufacturing system designed to accelerate timelines, improve scalability, and enhance quality while reducing costs and environmental impact. By aligning processes, equipment, and digital systems across a global network, kojoX ensures seamless technology transfer, de-risks supply chains, and provides the agility biopharma companies need to deliver innovative therapies to patients faster and more reliably than ever before.

Adapting to a Rapidly Evolving Biologics Landscape

The biologics market is experiencing unprecedented growth, and existing production capacity will soon be insufficient to meet the growing demand (Figure 1). To stay ahead, the industry must invest proactively — not only to accommodate projected market expansion but also to prepare for unexpected surges in demand. Recent events, such as the COVID-19 pandemic and the explosive rise of GLP-1 receptor agonists, have underscored the critical need for flexible, scalable manufacturing solutions.

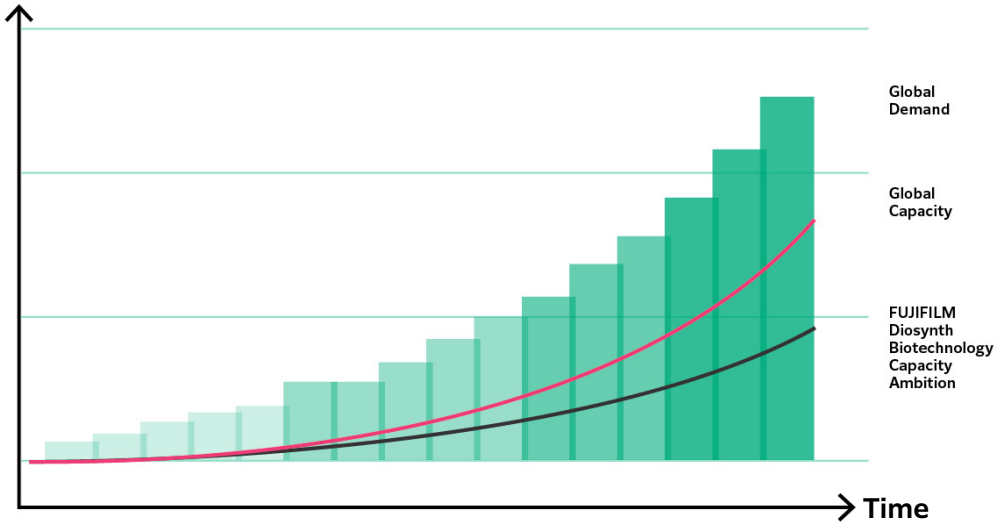

Figure 1. *Predicted global demand and production capacity for medicines*

Ensuring supply continuity requires a dual approach: expanding capacity while strengthening manufacturing redundancy across the global network. Manufacturers must build in agility to support seamless scale-up, scale-out, and technology transfer across sites. However, they also face increasing pressure to accelerate development timelines, ensure regulatory compliance, and reinforce supply chain security. Traditional biopharmaceutical manufacturing models, with their fragmented and often inconsistent approaches to process development and technology transfer, struggle to keep pace with these evolving expectations. To future-proof operations, companies must embrace standardized yet flexible frameworks that optimize efficiency without sacrificing quality.

By integrating a modular, standardized operating philosophy across global facilities, manufacturers can significantly reduce the inefficiencies and bottlenecks that have long plagued drug development. The next generation of biologics production will require seamless interoperability across scales and geographies — ensuring that therapies can be developed and delivered faster, more reliably, and with greater resilience against supply chain disruptions.

KojoX: A New Era of Standardized, Modular Biomanufacturing

As the pace of biotherapeutic drug development accelerates, an increasing share of manufacturing is being outsourced to contract development and manufacturing organizations (CDMOs). While outsourcing can offer cost and time efficiencies, manufacturing still suffers from persistent bottlenecks and inefficiencies — particularly when processes are transferred between CDMOs or even between sites within the same CDMO organization.

A significant portion of the delays in bringing new therapies to market stems from the challenges associated with technology transfer and process scale-up. Each transition requires translating procedures from one facility's framework into another's framework, often with variations in equipment, documentation, and methodologies. The absence of universal industry standards and modular processes further compounds these inefficiencies. To address this, the industry must shift toward a more industrialized approach — one that standardizes the way manufacturing frameworks are structured and how critical parameters are defined while still allowing for necessary process-specific flexibility within a controlled design space.

As a leading global CDMO, FUJIFILM Diosynth Biotechnologies executes technology transfers and has recognized the benefits of modularity in driving efficiency. With the introduction of the kojoX system, FUJIFILM Diosynth Biotechnologies is raising the bar for industrialization in biopharmaceutical manufacturing. This uniform operating philosophy applies a modular framework across sites, scales, modalities, and product life cycles — delivering the capabilities, capacity, speed, flexibility, and consistency that customers need to bring life-changing medicines to the market faster.

Breaking biomanufacturing into interchangeable, standardized modules enables greater flexibility while ensuring seamless process scalability. This modular approach mirrors principles seen in other industries, such as automotive and electronics manufacturing, where efficiency is maximized through common platforms while still allowing for customization. By structuring bioproduction processes in a similar way, manufacturers can reduce duplication, accelerate decision-making, and ensure consistency at every stage — from early development to full-scale production.

Standardized, Modular, and Digital: The Future of Drug Production

The kojoX ecosystem enhances agility across the biopharmaceutical supply chain, reinforcing the end-to-end service offering. This includes seamless support from preclinical and early-phase development through late-stage clinical programs, commercial approval, and life cycle management. Customers benefit from a fully integrated framework that spans drug substances, drug products, and finished goods — covering assembly, labeling, and packaging.

A key advantage of kojoX is the availability of lab-scale equipment that is nearly identical to full-scale manufacturing systems, ensuring process development is directly scalable. Customers can work with single-use bioreactors (up to 5,000 L) and stainless-steel bioreactors (20,000 L), all aligned within a unified operational framework. By maintaining practically identical configurations across scales, we eliminate process drift, de-risk scale-up, and ensure that data generated during early development remains fully relevant as a program advances toward commercialization. All manufacturing data - starting from cell-line development through to commercial production - is stored in and shared via a centralized data cloud, ensuring transparency and continuity across sites.

Modularization within kojoX is implemented across three key functional areas: processes, equipment, and procedures.

- Processes are structured to create customer-specific frameworks that streamline technology transfer and ensure rapid deployment across biomanufacturing sites.
- Equipment configurations follow a standardized yet flexible approach, enabling fit-for-purpose modules that deliver fast, low-risk, and well-characterized solutions.
- Procedures are modularized to support high-quality cGxP execution, grounded in deep industry expertise.

At the core of this system is a commitment to digitalization. Digital tools underpin all unit operations, providing real-time data access and end-to-end process visibility. This digital backbone enhances transparency and consistency across the global network, facilitating facility design, capacity expansions, scale-up, technology transfers, and regulatory documentation. Embedding digital solutions throughout biomanufacturing operations, ensures that customers benefit from a highly efficient, predictable, and scalable production environment.

A Comprehensive and Flexible Biomanufacturing Network

While the greatest benefits of our kojoX system are realized by customers who leverage its end-to-end capabilities — from gene sequencing and cell line development through commercial production, post-approval process optimization, and reformulation — clients at any stage of the drug development life cycle can realize significant efficiencies and time savings. With a global, interconnected network FUJIFILM Diosynth Biotechnologies provides a streamlined alternative to the traditional patchwork CDMO model, which often suffers from internal constraints and operational inefficiencies. The kojoX network mitigates the risks associated with relying on a single-location mega-scale manufacturing approach, which can introduce bottlenecks and vulnerabilities in supply security.

The benefits of kojoX extend across all biopharmaceutical modalities, as its modular, standardized approach to process development is independent of molecule type and intended application. For instance, the ApolloX™ advanced mammalian expression system is specifically designed to enhance both quality and speed in the production of monoclonal antibodies (mAbs) and a diverse range of Chinese hamster ovary (CHO)-expressed molecules — including bispecific antibodies, Fc-fusion proteins, and non-Fc recombinant proteins. ApolloX (Figure 2) recombinant cell lines are biomanufacturing-ready, seamlessly supporting both fed-batch and continuous cultures, and delivering high performance as processes are scaled up or scaled out.

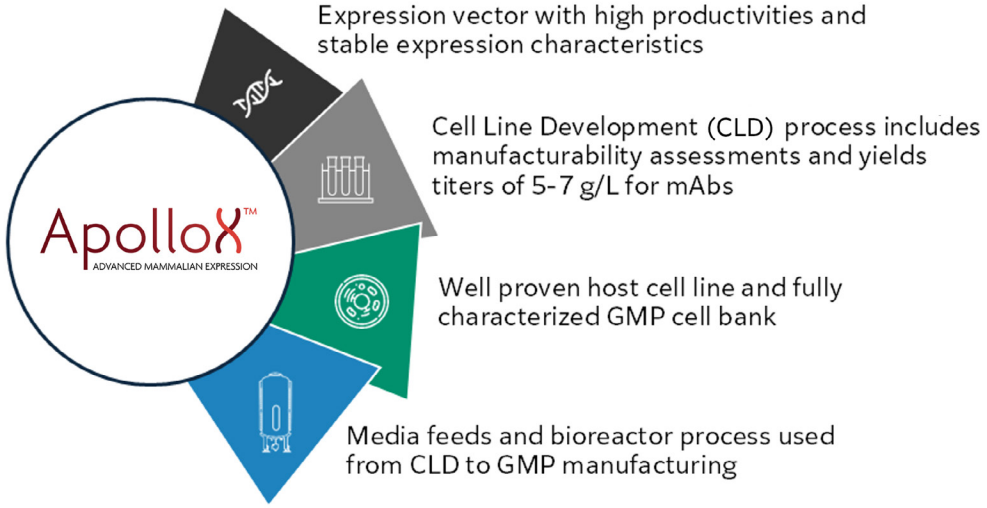

Figure 2. *ApolloX, enabling robust scale up from Cell Line Development to cGMP*

For customers with broad development pipelines, kojoX offers proactive capacity planning by working closely with them to forecast expected volume requirements and reserve network capacity up to a year in advance, preventing bottlenecks in scale-up. In rare cases where demand surges beyond projections, we also provide a build-on-demand model, ensuring continued supply continuity even in unforeseen circumstances.

For emerging biopharma companies, the kojoX system provides a fully integrated development and manufacturing solution without the need for physical infrastructure investment. Companies

can progress from early process development through first clinical batches, into late-stage and commercial production, and then scale down as necessary at the end of a product's life cycle — all while leveraging expertise in technology transfer to ensure seamless transitions between scales and sites. This approach eliminates the burden of excess capacity and infrastructure maintenance, allowing companies to focus resources on innovation and clinical advancement.

At the same time, established biopharma companies with blockbuster products can leverage our kojoX network to expand drug substance supply or access specific capabilities, such as fill-finish services. By offering a broad, modular suite of solutions, we ensure that companies of all sizes and at all stages of drug development can benefit from greater efficiency, flexibility, and scalability.

Streamlining Scaling and Technology Transfer with kojoX

FUJIFILM Diosynth Biotechnologies is committed to addressing technology transfer and scaling challenges through kojoX, marrying the modular biomanufacturing system with one of the largest capacity expansions in biopharmaceutical history. By replicating manufacturing capabilities across our global network, we have created modular production units that can be seamlessly combined and adapted to support the unique needs of each customer. Standardization is implemented not just within the same scale, but across scales, ensuring uniformity in framework automation setup, processes, and, in many cases, equipment. This harmonization enables faster and smoother technology transfers between our global network of sites, while also simplifying scale-up and scale-out based on project requirements.

With kojoX, all documents, processes, and automation systems follow a standardized design, allowing for easy deployment across multiple facilities. This alignment eliminates variability, reduces administrative burdens, and accelerates transitions from development to manufacturing. By ensuring consistency in equipment, automation software, and procedural frameworks, we have dramatically shortened technology transfer timelines, enabling uninterrupted knowledge flow and rapid process implementation.

Scaling is also significantly more efficient with kojoX. The distribution and sizing of bioreactors across the network allows for exponential increases in production volumes, ensuring capacity expansion at unprecedented speeds. Additionally, we can secure product approvals simultaneously at multiple sites across different regions, providing customers with unparalleled flexibility and efficiency in navigating global regulatory requirements.

- Scaling-out is as simple as running the same process in additional production lines — whether within the same facility or at another site designed to near identical specifications. This ensures that regulatory requirements remain streamlined, as we can document and verify that the manufacturing lines are either identical or sufficiently compatible to enable rapid process validation.

- Scaling-up is pre-engineered from the outset. The kojoX approach prioritizes scalability at the earliest stages of process development, ensuring that if a therapy becomes a blockbuster, it can be seamlessly transferred to a 20,000 L bioreactor without requiring process redesign or redevelopment. All media, raw materials, and process conditions are chosen to deliver equivalent performance across scales, minimizing risk and assuring supply chain security as the drug progresses from clinical development to commercialization.

By maintaining alignment across scales, sites, and technologies, FUJIFILM Diosynth Biotechnologies accelerates scalability while de-risking supply chains. The built-in redundancy within our global network provides agility, ensuring supply resilience even in the face of disruptions. Additionally, broad regulatory experience across the full product life cycle expedites approvals, further reducing barriers to commercialization.

Beyond scalability, kojoX plays a central role in optimizing process efficiency and improving productivity to achieve our environmental target of reducing energy and water consumption, and cutting waste generation by 50% by 2030. In addition to supporting sustainability through efficiencies gained, kojoX also eliminates bottlenecks that traditionally hinder technology transfer and scale-up. Through our kojoX ecosystem, we provide customers with a fully integrated, global modularity framework that ensures they have everything they need to efficiently develop, manufacture, and commercialize life-impacting treatments.

Transforming Biopharma with a Scalable, End-to-End Solution

FUJIFILM Diosynth Biotechnologies is committed to a "Partners for Life" mission - prioritizing people, transformative science and innovation, and unprecedented delivery performance. Beyond individual transactions, we take a holistic approach, supporting clients across their entire portfolio and throughout the full value chain of drug development. Whether by mitigating risk, overcoming supply chain challenges, or optimizing scalability, we ensure that customers can focus on their ultimate goal: delivering lifesaving and life-changing medicines to patients who need them.

Through kojoX, we are eliminating operational inefficiencies and documentation barriers, ensuring manufacturing consistency, accelerating regulatory filings, and reducing environmental impact. By leveraging a standardized yet adaptable approach, our customers benefit from:

- Alignment across scales and technologies, enabling rapid scalability and de-risking of supply chains
- Expedited regulatory filings, driven by extensive experience across the entire product life-cycle
- Supply chain agility, redundancy, and resilience, with seamless technology transfers across an integrated global network
- Optimized process efficiencies and improved productivity

Beyond infrastructure, kojoX represents a cultural shift in how biomanufacturing is approached. By removing traditional hierarchies and empowering both employees and customers, FUJIFILM Diosynth Biotechnologies fosters a mindset of continuous improvement and operational excellence. Rather than reinventing processes for each project, proven solutions are encapsulated into reusable modules that seamlessly support multi-site, multi-product operations — without compromising the unique needs of individual clients and therapies.

With this new level of global modularity, kojoX is not just enhancing efficiency — it is transforming the way biotherapeutics and advanced therapies are developed, manufactured, and delivered. By providing customers with everything they need to advance treatments from concept to commercialization, FUJIFILM Diosynth Biotechnologies is redefining what's possible in biopharmaceutical manufacturing — and ensuring that medicines are delivered to the market faster and more reliably than ever before.

About the Authors

John Stewart, Vice President KojoX Strategy, serves as part of the Global Strategic Business Services group at FUJIFILM Diosynth 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 for FUJIFILM Diosynth 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 Diosynth 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.

About FUJIFILM Diosynth Biotechologies

FUJIFILM Diosynth 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 Diosynth 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: www.fujifilmdiosynth.com.

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