

Transformative Science Coupled With a Unique KojoX™ Operational Ecosystem - The Keys to Achieving Unparalleled Flexibility in CHO Based Bioproduction

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Keeping pace with the surging global demand for medicines is one of the largest challenges facing the bioprocessing industry today. The dynamic growth and pace of change observed in novel monoclonal antibody formats plus cell and gene therapies emphasizes that biomanufacturing innovation is essential to deliver the scale, speed, and sustainability needed for the future. FUJIFILM Biotechnologies is revolutionising the bioprocessing industry – through our unique, globally harmonized operational ecosystem termed **kojoX™** that brings our partners flexibility and unmatched speed to market. While harnessing transformative science and innovation via strategic partnerships with world leading universities and through Fujifilm's Innovation Center of Excellence at the Bioscience and Engineering Laboratory (BSEL) near Tokyo in Japan - ultimately working to the end goal of making the life changing therapies of tomorrow more accessible and affordable.

A Holistic Approach to Biomanufacturing

To truly meet future requirements, the biopharmaceutical industry needs to rethink how we design, manage, and scale Chinese Hamster Ovary (CHO) processes. Fragmented improvements focused on a one or two discrete process steps to a more comprehensive, holistic approach that has the agility, flexibility and speed to adapt to uncertain and fluctuating manufacturing demands - one that integrates bioprocess science (the bioprocesses themselves), technology (the physical equipment and facilities), and governance (the management of the bioprocess with artificial intelligence (AI)). By embracing this systems-level transformation, resilient, responsive, and future forward biomanufacturing ecosystems can better serve CDMO partners and their patients.

Be Confident in IND Readiness With the ApolloX™ Platform

Starting from a DNA sequence, our proven ApolloX CHO cell line expression platform enables modular, risk-based development strategies that can accelerate IND readiness (Figure 1), providing both speed and product quality for CHO expressed biotherapeutics including multi-specifics and more novel antibody formats [1].

Whether clients utilize our ApolloX standardized components or require more customized development, FUJIFILM Biotechnologies has the expertise to ensure optimized outcomes. This includes advanced expression vector design, high-throughput screening, robust analytical development, and customizable purification strategies that are focused on achieving high productivity and product quality. For more complex molecules we provide tailored process development solutions and have shown that for some bi-specifics adapting our standard mAb production and purification platform conditions results in a scaleable, manufacturing ready process [2].

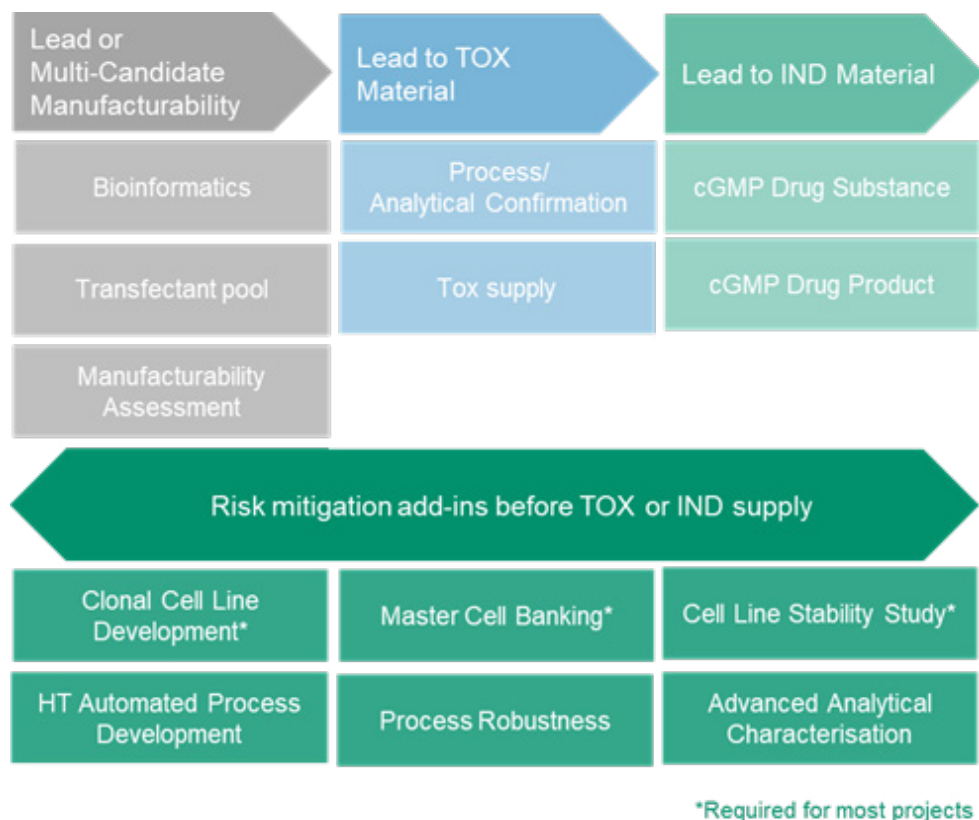
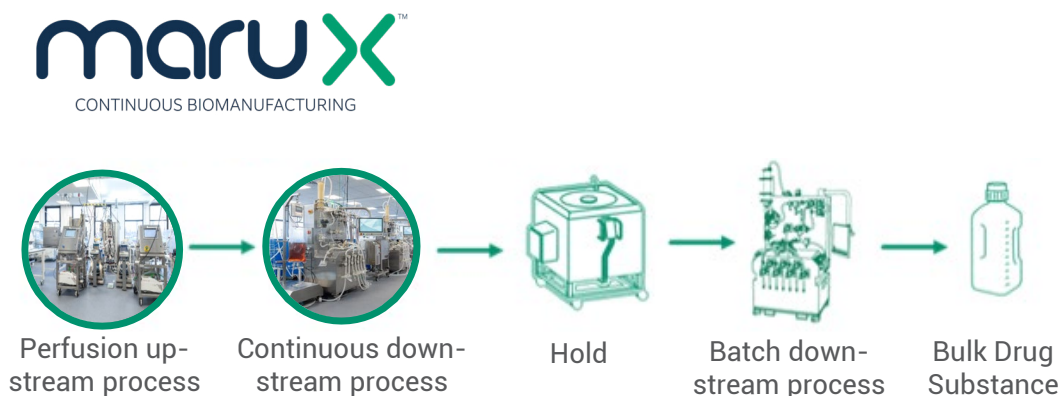


Figure 1. Strategic workflow for IND-ready material. A modular & risk-based approach for IND readiness.

Scaling Bioproduction with MaruX™ Continuous Manufacturing

MaruX is a scalable and modular continuous manufacturing approach that enables efficiency and flexibility (Figure 2), the system brings a third dimension to our manufacturing options to scale-by-time, alongside traditional scale-up and scale-out. As ApolloX was designed to be manufacturing ready for batch and continuous processes, we can ultimately provide our partners with greater agility and control in scaling to efficiently meet global demands using any of the three manufacturing strategies (scale up, scale out or continuous) they choose to deploy.



Unparalleled flexibility

- **Equivalent Costs and Timelines:** Process development costs and timelines are similar to those of fed-batch methods.
- **Cost Reduction:** Offers up to a 28% reduction in Cost of Goods Sold (CoGs) compared to traditional single-use fed-batch processes.
- **Lifecycle Flexibility:** Provides flexibility to adapt to changing demand forecasts throughout the product lifecycle.
- **Industry Standards Compatibility:** Aligns with industry standards for continuous manufacturing, enabling the integration of fed-batch and continuous manufacturing processes.
- **SymphonX™ Technology:** Utilizes a single rig/flow path capable of handling all downstream processing steps, featuring advanced automation, customization, and buffer management for seamless continuous processing.

Figure 2. MaruX - a continuous biomanufacturing strategy with the flexibility to meet fluctuating demands for a multimodal pipeline.

Harmonizing Global Biomanufacturing Through KojoX

Through globally harmonized operations and the agility of one CDMO network our kojoX operational ecosystem unlocks the potential of advanced bioproduction platforms like ApolloX and MaruX. By standardizing facility design (equipment, process, quality systems) across our sites in the US, UK, Denmark, and Japan, FUJIFILM Biotechnologies provides agile, high quality bioproduction that overcomes capacity constraints and geopolitical risk. KojoX reduces regulatory burden [3] and drives faster technology transfer to deliver unmatched speed to market [4]. Together, these capabilities set new industry benchmarks that enable us to help our partners bring life-changing medicines to patients more quickly and reliably. In turn, our partners can be confident that through our capacity expansions (Figure 3), FUJIFILM Biotechnologies can scale in line with their needs.

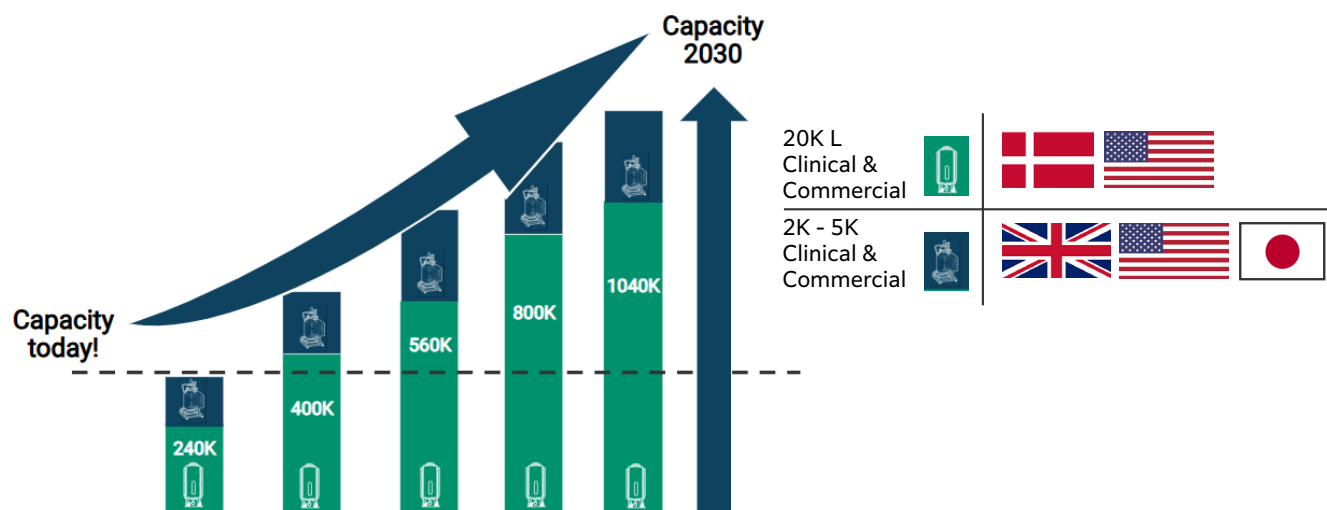


Figure 3. *KojoX ecosystem. Global network of harmonized, modular, and scalable biomanufacturing assets with the agility to scale.*

Enhancing Innovation Through Academic Collaboration

Our partnerships with leading academic institutions strengthen internal innovation and support the development of more advanced, efficient processes for CHO-based bioproduction. Our academic collaborations enable us to employ multi-omics, synthetic biology, and AI-enabled digital bioprocessing to achieve new levels of process control, efficiency, and scalability. For example, collaborations with the Universities of Edinburgh, Manchester, and York have enabled the application of engineering biology and a design-build-test-learn (DBTL) cycle to improve CHO cell systems. These types of academic collaborations allow us to continuously evolve our platform and deliver smarter, faster, and more predictable manufacturing solutions to the marketplace.

Engineering the Future: Bio-AI

Driving our Bio-AI strategy is Fujifilm's Innovation Center of Excellence at BSEL, which is dedicated to advancing bioproduction technologies that accelerate the delivery of life-changing medicines. By integrating decades of expertise across cell line development, media optimization, and process engineering with AI and process analytical technology (PAT), we are driving the digital transformation of biomanufacturing.

By combining in silico methods with a data-driven approach, we can optimize yield and product quality far faster than traditional engineering methods. For example, applying AI to media development has enabled up to 4x faster optimization timelines. This integrated, combinatorial approach delivers measurable gains in CHO productivity, more accurate batch forecasting, and faster production cycles.

Biomanufacturing for The Future

As global healthcare needs grow and evolve, FUJIFILM Biotechnologies is setting new standards for predictability, scalability, and speed in bioproduction. Powered by platforms like ApolloX and MaruX, and guided by the *kojoX* philosophy and global network of biomanufacturing sites our partners have already recognized that we are redefining how biologics are developed, manufactured, and delivered. This integrated, modular, and data-driven approach sets a promising trajectory for the future of biomanufacturing, aligns with our Partners for Life strategy, and unites our employees to a common purpose in our work - to help ensure that life-changing medicines reach the patients who need them most—faster, more reliably, and more sustainably.



About the Author

Leon Pybus is an **Associate Director** within the cell culture process development team at FUJIFILM Biotechnologies UK, where he leads project teams that deliver next-generation upstream solutions that improve and assist customers with the manufacture of therapeutic recombinant proteins. Leon holds a PhD from the University of Sheffield and has worked in the field of biotechnology for over 10 years.

About FUJIFILM Biotechnologies

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 United 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.

References

1. [Striking a Balance Between Speed and Quality to Deliver Next-Generation Therapeutics - FUJIFILM Biotechnologies](#)
2. [Application of Platform Approaches to the Development of Bispecific Antibodies - FUJIFILM Biotechnologies](#)
3. [kojoX™ in Action: Accelerating Regulatory Approvals - FUJIFILM Biotechnologies](#)
4. [kojoX™ in Action: Optimizing Regulatory Pathways - FUJIFILM Biotechnologies](#)