



WHITE PAPER

Prioritizing Data Security through Digital Transformation in Biomanufacturing

Authors: **John Atkinson**, Global Head of Information Security Office,
FUJIFILM Biotechnologies

Digital transformation is reshaping biomanufacturing, and FUJIFILM Biotechnologies is at the forefront with its modular kojoX™ platform. By integrating advanced digitalization solutions and prioritizing data security, FUJIFILM Biotechnologies is accelerating drug development while reducing costs and ensuring consistency across its global network. Through a focus on innovation, transparency, and security, FUJIFILM Biotechnologies is aligning its operations with the future of the biopharmaceutical industry, setting new standards for efficiency, reliability, and regulatory compliance.

Harnessing the Power of Digitalization

Drug developers face dual pressures: reducing both the cost and time required to bring new medicines to market while managing the increasing complexity of drug modalities. Automation and digitalization have proven to be key components in addressing these challenges, as evidenced by their successful implementation in sectors like automotive and advanced manufacturing. The shift toward Pharma 4.0 — a concept heavily promoted by regulatory agencies like the U.S. Food and Drug Administration (FDA) — marks a pivotal movement in the industry. Most pharma companies are well into their digital transformation journeys, aiming to boost efficiency, productivity, and quality while driving down the costs tied to drug discovery, development, and manufacturing.

In this evolution, digital tools are helping companies streamline processes, reduce human error, and enable real-time data analytics across various stages of development and production. With automated systems, developers and manufacturers can make faster decisions, ensure consistency, and create more agile production models, ultimately supporting faster time-to-market without compromising safety or compliance. As the landscape evolves, those that fully integrate digital solutions will be better positioned to meet rising market demands and regulatory expectations.

Digitalization Amplifies New Data Security Challenges

In the biopharmaceutical production industry, digitalization encompasses several critical aspects: Laboratory Information Management Systems (LIMS), online sensors for process monitoring and control, centralized data collection and storage in the cloud, and big data analytics. These tools span the full spectrum from research and development through commercial manufacturing, supporting more efficient operations and faster decision-making.

Effective data security hinges on thorough risk assessments conducted before implementing any digitalization solutions and requires ongoing vigilance throughout the digitalization journey.

However, with these advancements comes a heightened need for data security. As digitalization expands, so do the potential threats — ranging from lone hackers to organized crime syndicates and even state-sponsored cyberattacks. Each of these actors may have various motives but share a common goal: exploiting vulnerabilities in the healthcare sector. The challenge becomes even more complex in manufacturing, where some legacy systems cannot be updated as frequently as desired, leaving pharmaceutical companies exposed to potential breaches. Malware and ransomware attacks that compromise sensitive data or intellectual property and cripple key systems remain the biggest concerns, with the threat of data theft looming large over the industry.

Balancing Innovation and Security with Smart Risk Assessments

Effective data security hinges on thorough risk assessments conducted before implementing any digitalization solutions and requires ongoing vigilance throughout the digitalization journey. These assessments help identify potential vulnerabilities and ensure that necessary safeguards are in place to protect sensitive data and systems. A robust change control process is also essential, with every new digitalization project being reviewed by a data architecture board and a change advisory board. Additionally, staying aligned with the latest regulatory guidelines concerning emerging technologies is crucial for maintaining compliance and security.

kojoX is a groundbreaking global operating biomanufacturing ecosystem that provides customers with the flexibility, speed and capabilities to meet dynamic market demand..

Subject matter experts (SMEs) who are familiar with both the company's existing processes and the planned digitalization initiatives should lead these evaluations. They must balance the need for innovation with the responsibility of minimizing risks. The key is to adopt an evolutionary approach — where human oversight acts as a check on machine performance and outcomes until sufficient data supports full automation. This ensures that digital solutions are applied strategically, minimizing the introduction of vulnerabilities while allowing for continuous innovation.

KojoX: Harmonizing Biomanufacturing for Speed and Flexibility

FUJIFILM Biotechnologies has implemented a groundbreaking operating philosophy, which we call kojoX, to accelerate biopharmaceutical development while reducing associated costs. "Kojo" is a Japanese word with two meanings – 'improvement' and 'factory'. The kojoX platform is a modular approach to bioproduction

manufacturing designed to work across different sites, scales, modalities, and product life cycles, giving customers the flexibility, speed, and capabilities they need to meet market demand. By breaking down biomanufacturing into interchangeable modules, FUJIFILM Biotechnologies can tailor solutions to meet specific customer requirements while maintaining both speed and flexibility. Through kojoX, the increased standardization of internal processes, equipment, and software enables quicker decision-making and enhances operational consistency and efficiency. Ultimately meaning that our partners can leverage the network to bring life changing medicines to the market faster.

KojoX eliminates operational variability and communication bottlenecks that can delay scale-ups or technology transfers. By harmonizing production through standardized development and manufacturing processes, we also minimize our environmental impact. With kojoX, our partners have access to a network of possibilities, from early development to scalable commercialization, enabling access to manufacturing capacity quickly, removing the need for their own investment in infrastructure expansions. The platform's global network allows for seamless scaling (both up and down) and ensures rapid adaptation to changing market demands.

A key element of kojoX is the integration of digitalization solutions into every unit operation. This ensures transparency, consistency, and support for facility design, capacity expansion, tech transfers, and uniform manufacturing across locations. In addition, the platform streamlines product development and regulatory documentation, making it easier for customers to meet regulatory requirements while accelerating time to market.

Building a Secure Data Framework in the kojoX Ecosystem

Within the kojoX system, data security is achieved through the standardization of all IT platforms and security protocols across our global network. By utilizing uniform tooling, network layers, and setups, FUJIFILM Biotechnologies simplifies the protection and maintenance of its systems and customer data. This standardization not only enhances security but also streamlines global operations, making it easier to monitor and safeguard critical information.



A core element of the *kojoX* philosophy is the use of equivalent equipment trains and processes at different facilities. This approach allows each suite to be digitalized and automated consistently, with data being centralized for a highly interconnected and secure network. Regardless of location, this system supports rapid technology transfers, while separate data layers ensure the appropriate segregation between enterprise and manufacturing information, minimizing risks.

Before any new digitalization or automation projects are introduced, comprehensive risk assessments are conducted. These assessments focus on the potential impact on Good Manufacturing Practice (GMP) compliance and evaluate risks related to external threats. Policies are established, and essential documentation is prepared to support these new technologies. FUJIFILM Biotechnologies has created an escalation system and alert mechanism to ensure that any issues can be swiftly triaged for senior leadership and addressed. With access to top-tier IT and quality experts, we are well-equipped to bring the *kojoX* vision to life, ensuring both security and operational excellence.

Building the Future

FUJIFILM Biotechnologies is on a mission to become the leading and most trusted CDMO in the world. Through our 'Partners for Life' vision, that is underpinned by three core pillars — people first, industry transformation, and unprecedented delivery FUJIFILM Biotechnologies are redefining how global partnerships are built on trust and transparency.

While leveraging our *kojoX* framework to implement consistent digitalization and AI systems across our global network, our teams diligently monitor new advancements in data security technologies. Our ultimate aim is to ensure continued investments in leveraging all available technological applications that ensure cyber resilience for us and our partners. FUJIFILM Biotechnologies recognizes that these are critical steps towards achieving our Partners for Life vision in terms of building trust, so that our partners accept and view us as an extension of their own organizations.

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: www.fujifilmbiotechnologies.fujifilm.com.

About the Authors



JOHN ATKINSON

Global Head of Information Security Office

John Atkinson is part of the FUJIFILM Biotechnologies global IT team, serving as Global Head of Information Security Office (GHISO). As GHISO, John has been instrumental in the creation of the Information Security Office, ensuring FUJIFILM Biotechnologies has an information security strategy aligned with organizational goals and regulatory compliance. John joined the company in 2020 as Application Manager, progressed to Head of IT for the UK, then GHISO when IT transitioned into a global organization. Before joining our global organization, John worked within the Chemical industry for 27 years with a number of large companies including ICI, DuPont, Lotte Chemical, Mitsubishi Chemical and Venator.

Partners for *Life*

"Partners for Life" represents a transformative approach to development and manufacturing, emphasizing relationships founded on trust and transparency — founded in people-centric values, transformative science and innovation, and unprecedented delivery.

CDMO
LEADERSHIP
AWARDS 2024

**Contact us to discuss
your science.**

USA

College Station, Texas
3940 Fujifilm Way
College Station, TX 77845
+1 979 431 3500

Holly Springs, North Carolina
100 Biotechnology Avenue
Holly Springs, NC 27540

**Research Triangle Park,
North Carolina**
101 J Morris Commons Lane
Morrisville, NC 27560
+1 919 337 4400

Thousand Oaks, California
2430 Conejo Spectrum Street
Thousand Oaks, CA 91320
+1 805 699 5579

DENMARK

Hillerød
Biotek Allé 1
3400 Hillerød
+45 7741 6000

UNITED KINGDOM

Teesside
Belasis Avenue
Billingham, TS23 1LH
+44 1642 363511

JAPAN

Tokyo
R7 Building, 7-12-2 Roppongi
Minato-ku, Tokyo 106-0032
+81 3 6871 7736



FUJIFILM Biotechnologies

fujifilmbiotechnologies.fujifilm.com



MKT-0161-WP-Rev02
© 2025 FUJIFILM Diosynth Biotechnologies.
All Rights Reserved.