

# Pharmaceutical Manufacturing Solutions

Bio Industrial Automation and  
Business Process Digitalization

# Pharmaceutical Success Starts with a Strong Foundation



## Rising to the Challenge of Helping Customer-Partners Achieve Well-Being

Patients need high-quality, affordable treatments. Compassionate pharmaceutical experts seek to deliver medicines that address patients' needs wherever they are and as soon as possible.

Pharmaceutical companies continue to co-innovate with Yokogawa to create pharmaceutical manufacturing solutions that deliver safe and reliable medicines.

Together, we apply digital transformation (DX) and manufacturing advances that lead to compliance with regulatory requirements, embed quality in the process, and speed time to market.

In every interaction, our goals parallel those of our co-innovating customer-partners.

### Optimized Operations

Pharmaceutical companies succeed when they deliver high-quality medicines on time to patients. To achieve their goals, companies must increase efficiency and reduce costs by optimizing operations — often requiring data digitalization and smooth integration among systems.



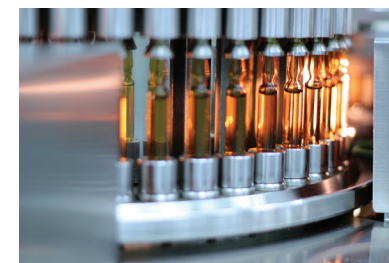
In other words, the entire factory must function as one harmonious system, and a cycle of continuous improvement must be established to support that system. In order to realize a smart factory, it is important to consider optimizing the factory as a whole with goals that include envisioning and implementing a system that leverages the strengths of the customer as well as the process.

### Consistent Quality



Assuring quality requires dedication — managing large amounts of data, maintaining data accuracy and accessibility, and upholding conformance to regulatory requirements.

To support the goals, Yokogawa delivers organization-wide tools, workflows, searchability, and user-defined access. Teams can visualize progress while managing deviations and product quality review efficiently.



Pharmaceutical companies seek to accelerate the development process. Yokogawa offers a complete solution that links the chemistry, manufacturing, and controls (CMC) areas with

other areas of the facility. Using Yokogawa solutions, customers reduce the lead time from development to production.

### Time to Market Acceleration



**Accelerate Automation and Optimize Operations**



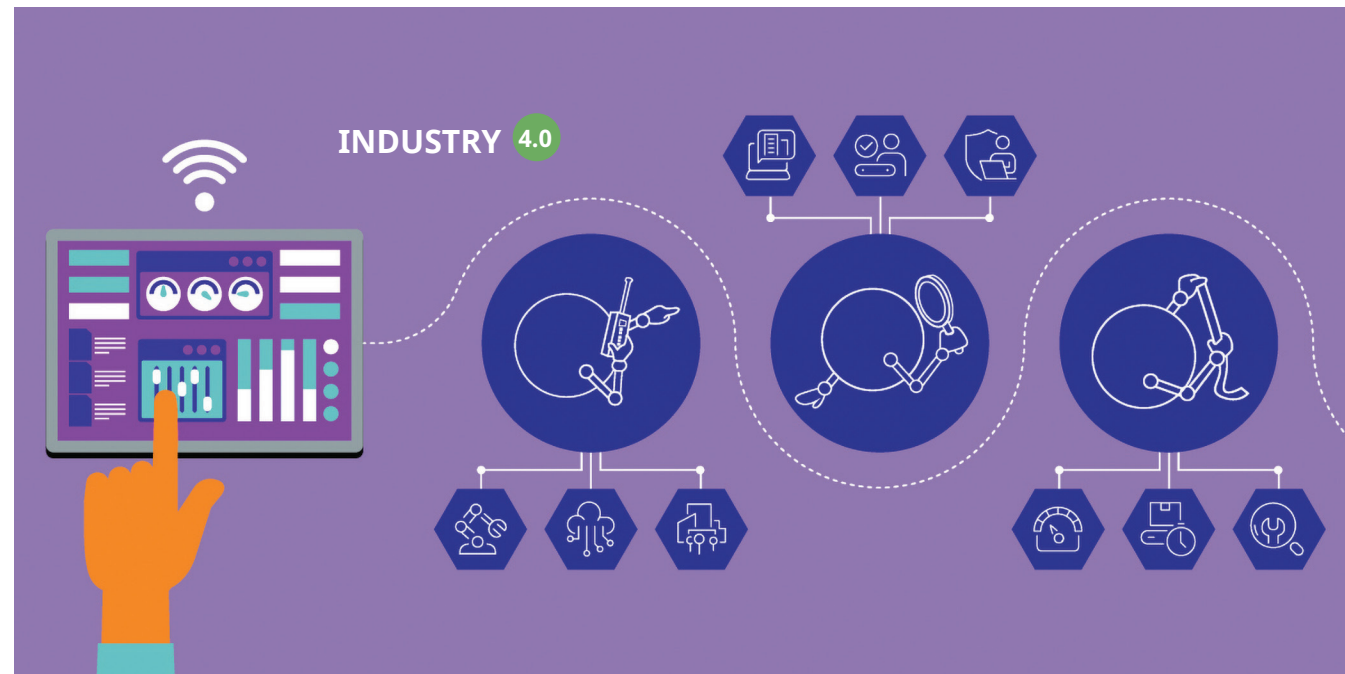
# Our Dedication to Manufacturing Excellence

## Optimized Operations

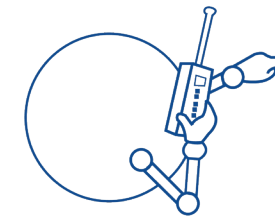
Data from areas such as the process, management, and supply-chain need to be shared across the organization in order to accelerate automation and optimization thus reducing down time and increasing efficiency — ultimately delivering high-quality medicines to patients. Well-designed solutions from Yokogawa gather and deliver data to the people and systems as needed throughout the organization.

To support and promote the interconnected factory, Yokogawa innovates products and solutions architecture to integrate digital technologies. These power tools assist end users to integrate measurement, control, and systems solutions with end-user workflows for an interconnected and automated factory. Throughout the product lifecycle, data is complete, consistent, and accurate.

Solutions can include Yokogawa field instruments, 21 CFR Part 11 compliant data recorders, the Centum VP and the CI Server to control manufacturing.



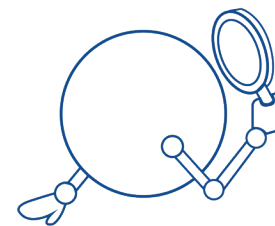
## Integration



Find efficient tools that enable access and analysis of data scattered across the company to arrive at well-informed decisions. Reduce shutdowns due to unexpected breakdowns while reducing unnecessary maintenance activities.

**Yokogawa's Solution** – An open environment helps plan daily work by synchronizing information across the company. FLEXSCHE production scheduler and eServ plant maintenance system enable improved response to ever-changing conditions: improved scheduling, visualizing conditions, decision-making, and more.

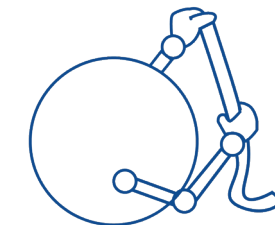
## Analysis



Reduce inefficiencies that lead to increased work hours and production losses. Improve process data analysis and avoid losses. Promote optimal control where products are made continuously, and multiple devices move simultaneously.

**Yokogawa's Solution** – Yokogawa solutions help improve batch processes to improve analysis and maintain quality. The Centum VP offers flexible, scalable batch management for centralized recipe and process management. The CI Server, a DX integrated information server, helps improve operational and production efficiency by promoting data and wisdom sharing.

## Measurement



Build a solid foundation with accurate, reliable measurements and secure electronic data recorders that comply with 21 CFR Part 11. Knowledge of sensing technology is fundamental to anyone involved in the industrial and engineering fields, and analytical sensors are the first key element in creating value.

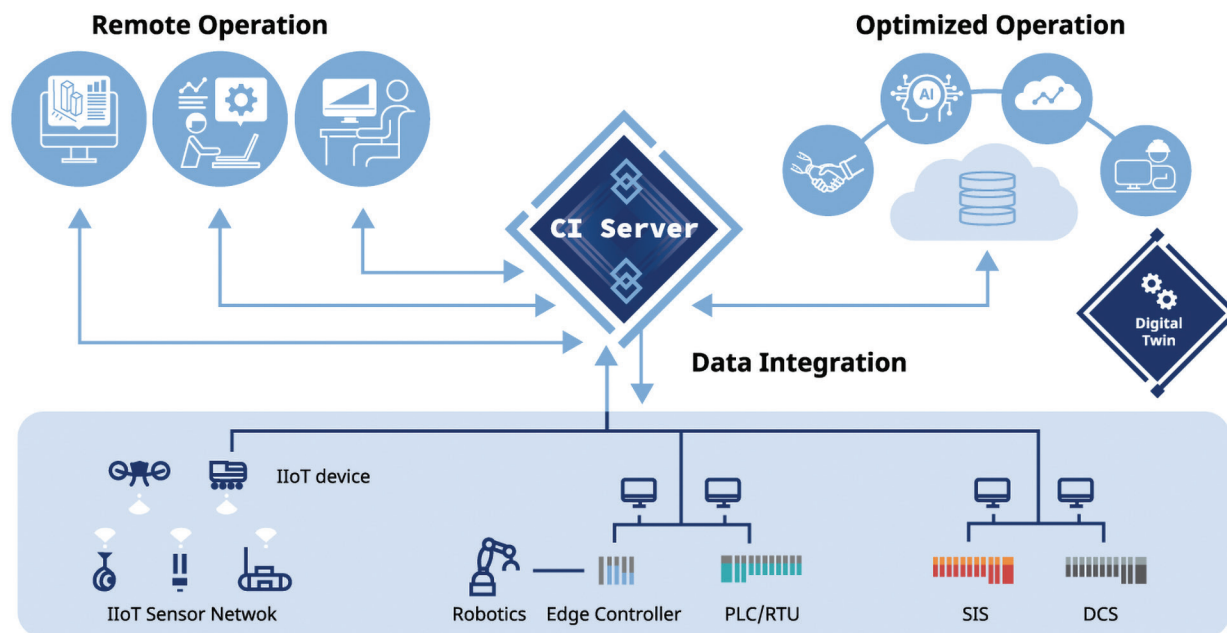
The challenge for the next stage of progress is to shift from mere sensing to making sense, which is the process of adding value to data. To further improve profitability and achieve sustainable operations, it is necessary to collect a wider range of sensor data that has been difficult to measure in the past, or to use highly accurate plant data that has not been used in the past.

**Yokogawa's Solution** – Optimizing operations begins with accurate and reliable measurements and recorders. Yokogawa instrumentation is known for quality, accuracy, and dependability. With Yokogawa PIMS, data becomes actionable information by providing a central database.

# Collaborate Across Multiple Plants and Teams

## Release the Power of Production Data with CI Server

Yokogawa's Collaborative Information Server (CI Server) can help integrate islands of operation. Monitoring and control activities are unified throughout plants and across multiple production sites by bringing together, for example, a DCS or controllers and an asset management system. Integration, remote operation, and data analysis form the strong foundation of optimized operation for pharmaceutical production sites.



## CI Server Brings Integration, Collaboration, and Optimization

- Unified management of production data from multiple facilities or systems that support standard protocols of OPC UA, OPC Classic, and Modbus — drivers of various vendors' controllers
- Remote operation, monitoring, and engineering
- Simple and secure connection with a wide variety of applications for data analysis to help ensure stable production and to enhance productivity
- Fully compliant with 21 CFR Part 11 and PIC/S Data Integrity ALCOA+ principles

# Visualizing Information That Ensures Production Efficiency

## Real-Time Decisions and Predictions

### Data-Driven Operation

The CI Server helps leverage a large amount of widely scattered data and shape it into meaningful information for optimizing operation and production efficiency.

### Flexible Architecture

CI Server assists in scaling up or scaling down. In addition to the system configuration in an on-premises environment, CI Server can be used as a Platform as a Service (PaaS) that combines Yokogawa Cloud with software licensing and maintenance.

### Efficient Integration Toward Flexibility

Yokogawa employs Module Type Package (MTP) standards to help reduce engineering hours in highly adaptive, modular pharmaceutical plants. MTP provides plug-and-play simplicity through its standardized, non-proprietary descriptions of process modules. Users can increase production flexibility and shorten the time required to modify production lines.

### Informed Engineering

Engineering becomes more streamlined through the Module Type Package (MTP) standardized methodology, which simplifies integration of communication, services, PLCs, and other systems.

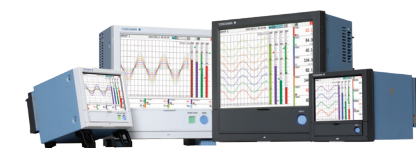
## Flow, Pressure and Temperature

Yokogawa is known in the pharmaceutical industry for its wide range of high-quality flow, pressure, and temperature transmitters.



## Data Acquisition

Yokogawa's recorder portfolio, is compliant with 21 CFR Part 11, and includes conventional chart and paperless recorders.



## Liquid and Gas Analyzers

Yokogawa offers a comprehensive family of sensors and analyzers for pH, conductivity, dissolved oxygen, humidity, liquid, gas density, and process gas chromatography.



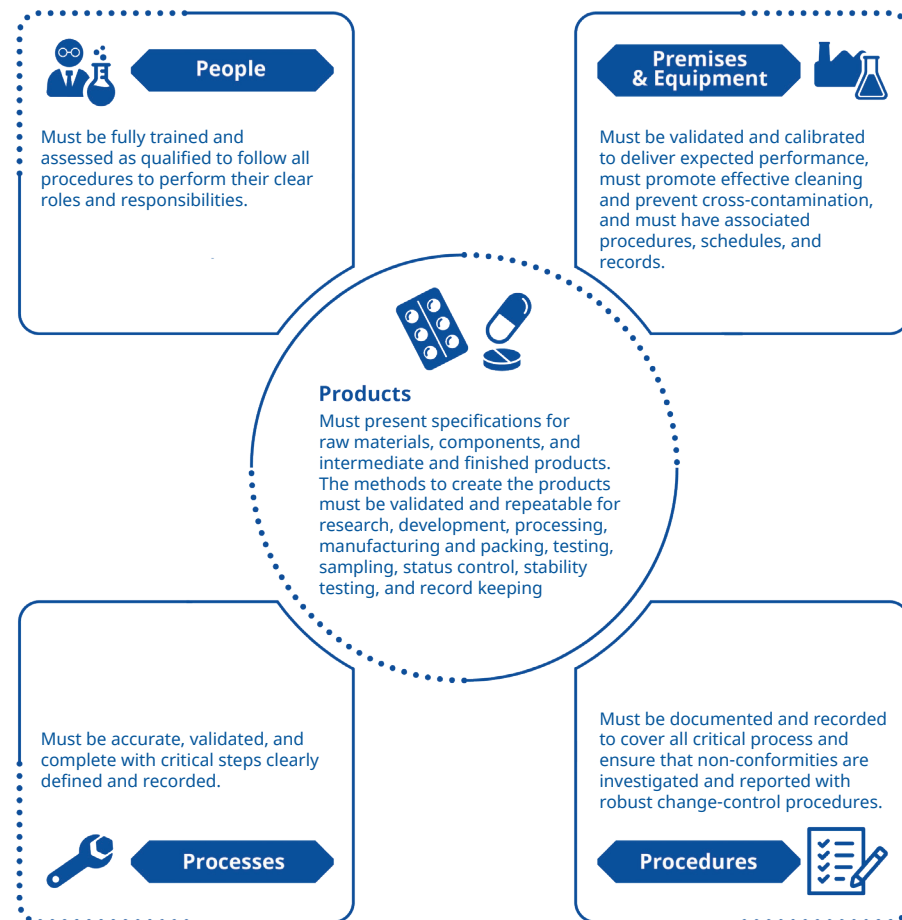


# Quality is Key

## Securing Product Quality with Data Integrity

Yokogawa solutions support quality groups as they manage large amounts of data, maintain data accuracy and accessibility, and uphold conformance to regulatory requirements. Yokogawa understands that quality procedures must be performed per the standard operating procedures (SOPs) regardless of individual experience and knowledge. When reliable processes and good practices are in place, success follows.

With these goals in mind, Yokogawa innovators work with pharmaceutical customer-partners to put in place controls that prevent mistakes. Keys to quality include minimizing human errors, preventing contamination and deterioration of pharmaceutical products, and using a proven system designed to manufacture products as defined in the approval document.



Yokogawa solutions are built on the five Ps of current good manufacturing practices (cGMP). These five pillars, are embedded into Yokogawa solutions. To make the specified products, people must have a system for the required procedures to accomplish the required processes using the defined premises and equipment.

## OpreX™ Laboratory Information Management System Systematic Management of Overall Quality Control Operations

OpreX Laboratory Information Management System (LIMS) supports management of quality and improves test-data quality through automation of data collection, calculations, specification judgment, and form creation.



- Improve product quality while complying with regulations
- Standardize and automate analysis and testing
- Improve organizational efficiency by linking with other systems
- Compliant with 21 CFR part 11 and more

**Automatic collection of analysis data** - Prevents transcription errors and tampering and uses online verification, approval, and acceptance of test results data.

**Standardization and verification of workflow** - Supports standard workflow for quality control such as test acceptance, instruction, approval of test results, and factory-shipment decisions.

**Collaboration among systems** - Enables collaboration with ERP and production management systems to share and use quality data on a company-wide level. This standardizes operations and complies with regulations.

## OpreX™ Environmental Monitoring System Environmental Monitoring Compliant with Pharmaceutical Regulations

The OpreX Environment Monitoring System (EMS) collects data all day every day and stores it to monitor the environment in areas such as manufacturing, quality control, and storage. The system uses Yokogawa's paperless recorders that comply with GMP, QMS, and other regulatory requirements and can be installed in locations around a plant.

**Data Integrity** - Meets ALCOA+ requirements.

**Data Collection and Long-term Storage** - Long-term data storage in recorders (21 CFR Part 11 compliant).



**Real-Time Data Monitoring** - Alerts team to out-of-range conditions in real time.

**Centralized Management of User Logins** - EMS active directory enables efficient management of usernames and passwords.

## OpreX™ Laboratory Information Management System

### Serving A Customer-Partner Committed to Quality:

Otsuka Pharmaceutical Co., Ltd

Since its founding in 1964, Otsuka Pharmaceutical has been committed to a holistic approach to the health and well-being of people and are striving to create innovative, thoroughly-original pharmaceutical and nutraceutical products. The company has established a headquarters for Product Safety and Quality Assurance to strengthen measures related to product quality and safety and to deliver special products to the market. Yokogawa proudly partners with Otsuka to help maintain consistent quality.



## OpreX™ Environmental Monitoring System

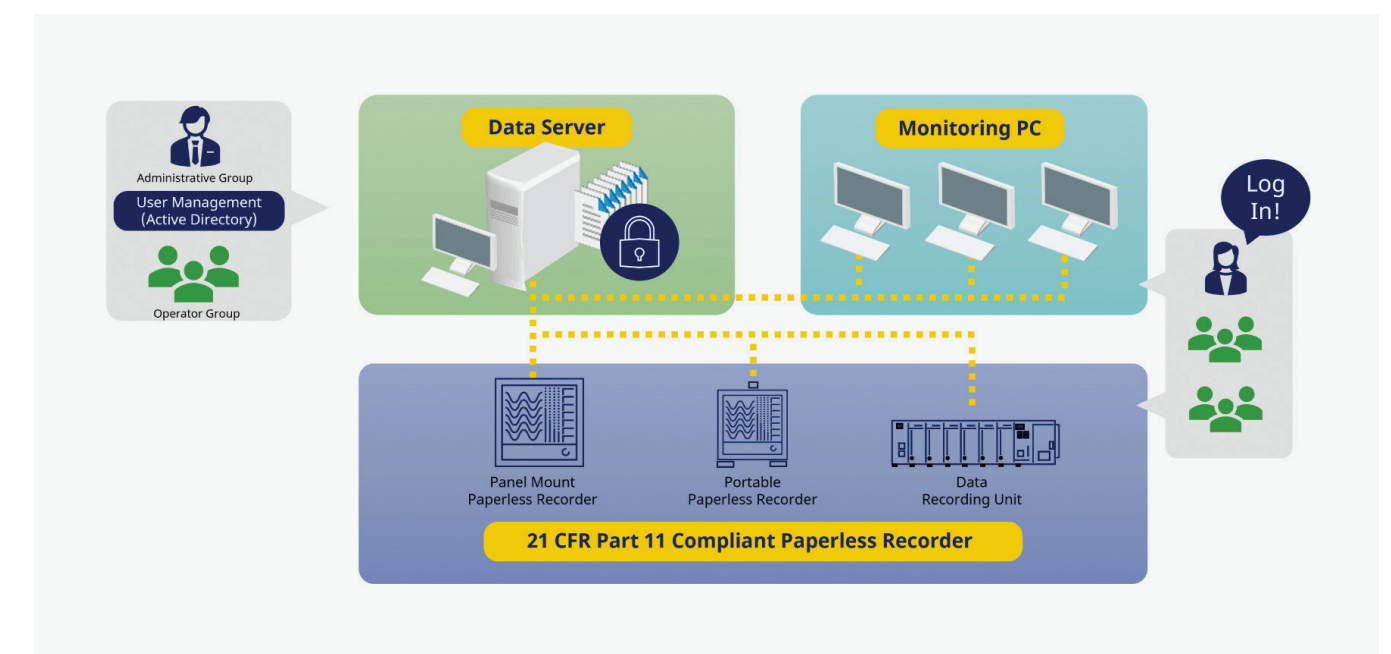
### Model the Pharmaceutical Industry with Reliable Data Management:

Foundation for Biomedical Research and Innovation at Kobe FBRI

Kobe FBRI supports the practical application of medical care using therapeutic cells and the development and clinical application of cell therapy. They must maintain aseptic conditions from initial collection of cells to their processing. The temperature and humidity inside the facility and the temperature inside the liquid nitrogen freezer must be monitored. In addition, the oxygen concentration in the facility must be monitored for the safety of workers.

They needed an environment that complies with GMP standards in terms of manufacturing control and quality control. Strengths such as these influenced Kobe FBRI's decision to choose Yokogawa:

- The robust system of data collection — compliant with 21 CFR Part 11 — meets ALCOA+ requirements and prevents raw data from being compromised.
- Data tampering protection and login functions are standard.
- Kobe FBRI recognized Yokogawa engineers' expert CSV knowledge.
- Specific functions required by Kobe FBRI could be incorporated smoothly into the design requirements.
- Data can be centrally managed and monitored by simply switching screens for each temperature control range.





# Improving Lives Through Swift Response and Accelerated Time to Market

Because pharmaceuticals support well-being and the quality of life (QOL), the mission of pharmaceutical manufacturers is to satisfy unmet medical needs and continuously create and deliver innovative drugs to patients — as safely and swiftly as possible.

Co-innovating with our customers, Yokogawa strives to help them meet their mission by providing technologies such as digital twins and by simplifying data sharing among labs, clinical trials, and manufacturing processes.

## Chemistry, Manufacturing, and Control (CMC)

### Promote Continuous Quality and Yield Improvement

CMC assists during design formulations by analyzing the relationships among numerous parameter settings and the qualities associated with them. When yield-loss or quality anomalies occur at a plant, their causes can be evaluated based on the relationship between process data and quality.

By linking the closely related CMC and manufacturing analysis information, Yokogawa users can significantly reduce the work-hours required for the technology transfer from the CMC to the plant and can improve the efficiency of the manufacturing process.



## OpreX™ Informatics Manager

### Achieve Laboratory Informatics – Connecting from R&D Lab to Manufacturing, Quality Control and Quality Assurance

OpreX™ Informatics Manager is an integrated laboratory information solution that not only digitizes research notes of each laboratory, but also connects R&D laboratories, life sciences production departments, quality control departments, and quality assurance departments through project management and document management functions. By providing subscriptions through cloud services, we reduce our customers' operational costs and workloads, and enable management including performance management of various users with this software alone.

Optimizes R&D lab operation by:

- Integrating lab management including experiment data and resource/task management
- Enabling wide data access in the cloud



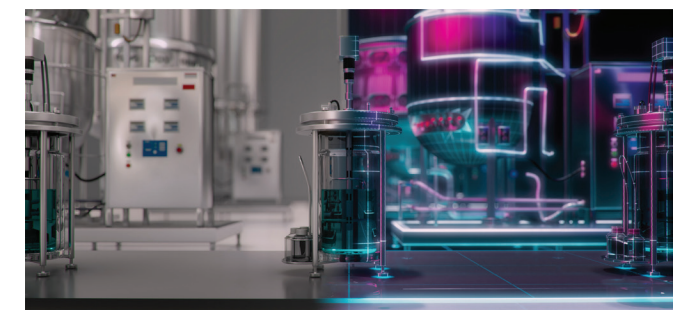
## Insilico Digital Twin Factory



### Accelerate Time-to-Market, Mitigate Risks, and Capitalize on the Value of Data

Yokogawa's Insilico Biotechnology uses the power of digital twins to provide software solutions for predictive biomanufacturing. Digital twins can be used for real-time monitoring and control of processes such that deviations are detected early and prevented.

Biopharma users can predict the performance of cell culture processes in virtual experiments, and they have been able to replace up to 50% of the experiments during process development, scale-up, and process characterization.



**Accelerated timelines and reduced costs**



**Increased capacity**



**Improved process performance**



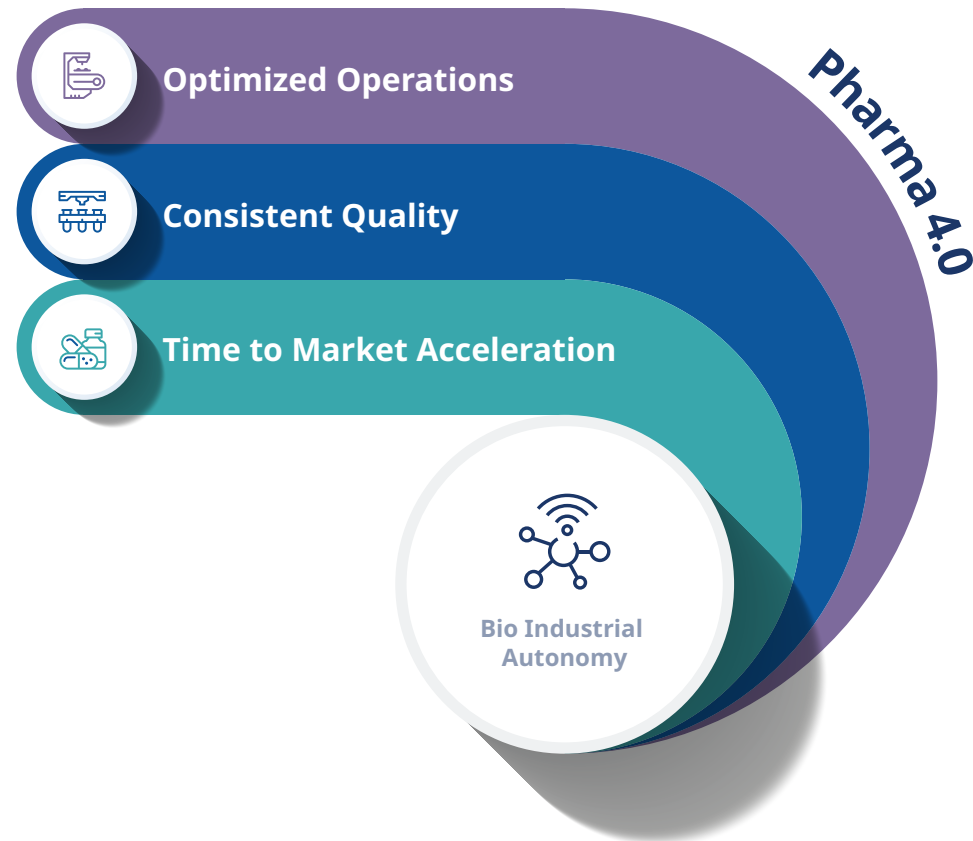
**Turning data into strategic assets**

## Lifetime Commitment to Customers

### Yokogawa's LIFE Business Vision to Bio Industrial Autonomy

Yokogawa commits to long-lasting relationships with customers. Through co-innovations and continuous support, we pursue the highest quality processes and tools so that our clients can deliver much-needed pharmaceuticals to patients.

By fulfilling social responsibilities, helping our customer-partners meet regulations, and consistently moving toward the Yokogawa Life Business Vision, we and our customers contribute to global harmony.



## Lifetime Partnership Provides Lifetime Value

### Yokogawa LIFE Business Vision to Bio Industrial Autonomy

#### Regulation

- Reform operations through digital transformation to optimize operations while complying with regulatory requirements.
- Help customer-partners meet the critical dual goals of industry profits and the growing costs of quality-assurance compliance.
- Proudly provide high-quality support for customer-partners' business activities by using knowledge and experience in IT, in operation, and in control technology.

#### Our Vision

- Co-innovate with customer-partners as they produce safe and reliable medications accessible to all patients.
- Ensure a stable and efficient supply of high-quality, safe pharmaceuticals.
- Move toward autonomous manufacturing.

#### Social Responsibility

- Help customer-partners deliver safe and reliable medicines even as disruptive societal changes, such as COVID-19, occur.
- Work proactively toward sustainability to conserve ecosystems and become carbon neutral throughout supply chains.



#### LIFE Business Vision

We will lead the world in advancing "Bio Industrial Autonomy", and contribute to a future embracing global harmony.





# Other Pharmaceutical Publications



## The Road to Realizing Pharma 4.0

By leveraging our extensive knowledge and experience in IT, operation and control technology, we aim to build an advanced improvement cycle that is useful to all management levels, and eventually achieve Pharma 4.0 together with our customers.

**WATCH HERE**

## Life Business Vision

Bio Industrial Autonomy is creating an environment where we as humans can focus on doing the things we do best. Watch the following video for more information.

**WATCH HERE**

## Success Story Collection

Gain a comprehensive understanding of Yokogawa's Pharma 4.0 solutions, production waste elimination, measurement reliability, successful process applications, and more.

**DOWNLOAD**

BU-L-20230816-01

Yokogawa Corporation of America  
12530 W. Airport Blvd.,  
Sugar Land, TX 77478  
[www.yokogawa.com/us](http://www.yokogawa.com/us)

Yokogawa Canada, Inc.  
Bay 4, 11133 40th Street SE,  
Calgary, AB T2C 2Z4  
[www.yokogawa.com/ca](http://www.yokogawa.com/ca)

Yokogawa de México, SA de CV  
Urbina No. 18  
Parque Industrial Naucalpan  
Naucalpan de Juarez, Estado de México  
C.P. 53370  
[www.yokogawa.com/mx](http://www.yokogawa.com/mx)