

Saving Money, Saving Time

IN PHARMA OPERATIONS



This is a **comprehensive system** that allows employees to view data across production facilities **in real-time.**

A pharmaceutical company with global operations recently received a warning letter for failing to properly investigate a batch failure. Among the potential consequences: any pending drug applications listing the affected facility may be stalled. Of the worries that keep pharmaceutical executives up at night, receiving such a letter is high on the list.

With the clock ticking, company personnel took stock of what they faced. Their blockbuster medication was manufactured in an ecosystem involving three countries. One facility produced a carrier polymer, a second the active ingredient, while the third facility — where the violation was cited — produced the finished product. Was the problem really at that facility, or upstream at one of the others? The answer, of course, was in the data, which was disparate and came from different parts of the world. Moreover, this company's data was mostly in paper form, and the few electronic files on hand were not contextualized. The organization faced a daunting task, with its billion-dollar-a-year product — and other products and business — at risk.

But the story did not have to play out this way. This company could have identified the source of variation in real-time with the right data infrastructure. This is a comprehensive system that allows employees to view data across production facilities in real-time. Such a system collects and contextualizes data from all sources: process, material, in-process control, quality/LIMS, building management systems and smart sensors like IoT and PAT in a trustworthy, easy-to-access platform.

AN INFRASTRUCTURE APPROACH

A holistic data infrastructure removes the barriers of finding, capturing, converting and organizing operational data, enabling operators and engineers to model enterprise-wide operational intelligence while reducing complexity and cost. With a data infrastructure, assets can be readily analyzed and compared, and analytics can be used for better long-range capital planning and utilization. A unified view enabled by a data infrastructure also makes it possible to shift

from scheduled or run-to-failure maintenance to condition-based or predictive maintenance. All of this paves the way for improved operational efficiency and greater uptime across a facility or enterprise.

As the organization directly benefits from developing models to support and predict asset health, process efficiency, resource management and product quality, regulatory reporting and compliance are also simplified through the end-to-end visibility.

INSTEAD OF...

Disparate Data

Each system "speaking" in different languages, vendor specific formats

Distributed Assets

Mobile and fixed equipment across the organization

Siloed Decision-Making

Manual reporting using out of date information from small subsets of the organization

Site-specific KPIs

Disparate goals across sites that result in poor overall visibility

Inflexible Systems Requiring Customizations

Solutions that require constant coding to maintain customizations as the needs of the business change

Scheduled Maintenance

A reactive strategy where capital is tied up in spare parts inventory and critical repairs are performed upon failure

WHAT COULD BE...

United Data

Getting all the data in one place

Unified Assets

Creating an enterprise model of that data

Democratization of Data

Giving people access to data for decision making

Overarching Business Goals

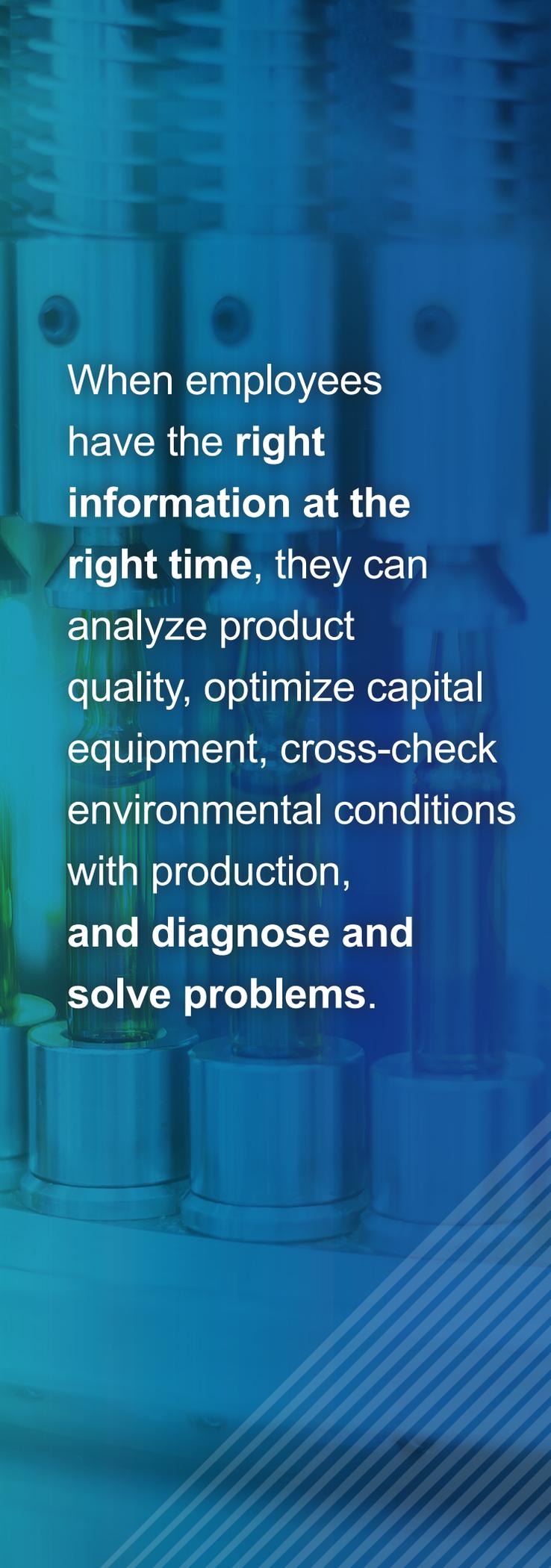
Share data, collaborative analysis and standardized KPIs drive the entire business forward

One Flexible Infrastructure

A centralized infrastructure that consolidates applications and scales as the business grows

Condition-based or Predictive Maintenance

Predict and fix failures before they occur while only buying the right parts at the right time



When employees have the **right information at the right time**, they can analyze product quality, optimize capital equipment, cross-check environmental conditions with production, and **diagnose and solve problems.**

When employees have the right information at the right time, they can analyze product quality, optimize capital equipment, cross-check environmental conditions with production, and diagnose and solve problems.

For the pharmaceutical company now holding a warning letter, this could have given operators the knowledge needed at the time of production to make decisions on the spot. It could have armed them with the ability to understand quality and performance during the manufacturing process. With such a system in place, the warning letter would likely never have been sent in the first place — because the company would have been operating to manage risk and ensure quality using real-time data for secure and reliable actions.

FOUR PILLARS OF SUCCESS

Once this holistic data infrastructure is implemented within an organization, it becomes a foundation for building four pillars of a successful and stress-free pharmaceutical manufacturing operation.

PILLAR 1: REGULATORY COMPLIANCE.

The pharmaceutical industry is bound by a variety of regulations. The proliferation of information, the increasing number of ways to capture it, and the speed at which it can be transmitted places a premium on data integrity. When data fall short of standards, an organization can expect a warning letter from the FDA or other regulatory action that can cause delays in operations and can even be a serious threat to the entire business.

Compliance efforts are shifting and becoming more proactive than reactive, meaning that the traditional process validation is becoming continuous. The traditional three reference runs or batches are now being complemented with every single run, batch and lot, including all of the parts material, process and quality data. Information should continuously be reported as Continued Process Verification (CPV). The trustworthiness of the data is highlighted with Data Integrity guidance's which form the foundation for the digitalization enabling Pharma 4.0.

FOUR PILLARS OF SUCCESS



Pillar 1:
**REGULATORY
COMPLIANCE**



Pillar 2:
**RECORDING
AND REPORTING**



Pillar 3:
**KNOWLEDGE
MANAGEMENT**



Pillar 4:
**OPERATIONAL
EXCELLENCE**

PILLAR 2: RECORDING AND REPORTING.

Ensuring batch consistency is important, but it only takes a pharmaceutical company partway down the path to market. Having the right kind of automated reporting system can help reduce manufacturing time and increase production. Electronic batch recording (EBR) usually comprises a very large number of pages per batch, making it difficult and costly to investigate these data to understand the potential impact on patient safety and critical quality attributes (CQA). A digital infrastructure can help by implementing a rules-based system that allows for “review by exception.” There is no need to look at a report unless there is a violation of predetermined specifications. What’s more, such a platform can tie seamlessly into an organization’s corrective and preventive actions, further streamlining operations, reducing production time and increasing throughput.

PILLAR 3: KNOWLEDGE MANAGEMENT.

The time to market for a particular drug typically takes eight to 10 years, and time seems to increase

as a drug progresses from the discovery phase through clinical trials to commercialization. Pharmaceutical companies are increasingly adopting a “quality by design” (QbD) approach to gain and use more information about a molecule in real time, speeding and improving the process. They are adding measurements to their manufacturing data sensors, improving their knowledge of how to run equipment and making closer observations of exactly how a material is produced inside the equipment.

PILLAR 4: OPERATIONAL EXCELLENCE.

Pharmaceutical companies are becoming more and more data-driven to maximize operations, improve quality, and shorten production time. Something that once took several weeks to complete now takes a few days, and in some cases just a few hours. Energy management is optimized. Maintenance processes are streamlined via condition-based or predictive maintenance.



A biotech firm is expected to reduce test result wait time by **50%**, batch exceptions by **70%** and batch review time by **more than 70%**.

SUCCESS ILLUSTRATED

How does a single source of the truth look in practice? [Multiple pharmaceutical firms](#) have seen significant improvements using OSIsoft's PI System as a real-time data infrastructure.

A biotech company is using OSIsoft's PI System to help it deliver treatments at a fraction of the typical cost of biologics manufacturing. How? By building a strong foundation with common context across business areas — from batch execution to equipment utilization to resource consumption.

TREATMENT AT A FRACTION OF THE COST

Capturing a single source of the truth helped the company use its data more easily and effectively. It has also enabled it to synchronize critical business processes, including global and site applications. The biotech firm is expected to reduce test result wait time by 50%, batch exceptions by 70% and batch review time by more than 70%. It is also expected to lower production costs by 80% compared with typical biopharma operation costs for this type of monoclonal antibody.

BATCH-TO-BATCH COMPARISONS

In another case, a different global biopharmaceutical company could not necessarily depend on getting to a single source of the truth quickly. In 2008, it operated with a paper system and no batch context. This made it difficult to correlate streaming data with batch stages, and there were no batch-to-batch comparisons. The company wanted to change that, and it started by outlining specific goals:

- Guarantee access to accurate, verified data.
- Allow scientists to analyze experiments in under 10 minutes.
- Consolidate tribal knowledge and redundant spreadsheets in favor of scalable enterprise solutions.
- Drive a paradigm shift from single data points to streaming data visualization.

None of these objectives would have been possible without batch contextualization. With more than 300 sources of information across research and development, as well as multiple physical servers and stand-alone systems, this was no easy task. But the OSIsoft PI System was up to the challenge. By 2016, the company had created a virtual infrastructure with the PI System serving as its hub. Moreover, batch context was no longer operator dependent. Additionally, the inclusion of PI Notifications now meant that R&D no longer needed to be staffed 24/7. Every notification and alarm was now chronicled. The new system facilitated remote monitoring, event escalation and excursion analysis. Perhaps most important of all, the company gained peace of mind.

QUALITY ASSURANCE

Lastly, a top 10 pharmaceutical company was seeking to create a global PI Solutions Store for its biologics operation to quickly enable modern and effective operations underpinned by data for Industry 4.0 applications, use of AI and ML, maintenance optimizations, use of AR and VR etc at the same time as meeting regulatory demands and increase compliance.

Already an OSIsoft customer, the company looked to the organization to align, standardize and accelerate deployment of its PI System in parallel across several

manufacturing sites. A collaborative and governance supported, multi-site approach was used to develop and publish a business solution using OSIsoft tools and pre-qualified, documented modules. This tactic:

- Functionality and performance were defined once and deployed in parallel at different sites.
- Reduced downtime needed for on-site qualification.
- Employed a proven approach — already used for environmental monitoring systems (EMS) deployment.
- Offered a standard solution for all compliance issues.

Success was achieved through a strong partnership and involvement at local sites to define the scope and budget. The company achieved a 60% reduction in local qualification efforts.

KNOWLEDGE IS THE PRODUCT

All three of these companies improved their collection and use of real-time data by utilizing data as a key asset. Over time, they came to view knowledge as a key product. And they understood that their knowledge is only as good as the data it is built upon and the infrastructure that analyzes it. For these organizations, making those connections paved the way to better data, higher quality and more efficient operations.



These companies were able to **improve** their collection and use of **real-time data** when they realized their product is not just the pharmaceuticals they manufacture.

ABOUT OSISOFT

OSIsoft's PI System is one of the world's most widely-used technologies for the Industrial Internet of Things. The PI System captures data from sensors, manufacturing equipment and other devices and transforms it into rich, real-time insight that people use to reduce costs, dramatically improve overall productivity, and create new products and services.

Some of the world's largest organizations — including over 1,000 leading utilities, 90% of the largest oil and gas companies and more than 65% of the Fortune 500 industrial companies — rely on the PI System for critical processes and decisions. Worldwide, the PI System manages over 2 billion sensor-based data streams.

To learn more, please visit www.osisoft.com.

