

## Success Story

### Empowering Purna Pharmaceuticals with Advanced Data Management and Compliance

Improved alarm management efficiency, streamlined tracking operations, and integrated multiple vendor platforms seamlessly.

## Purna Pharmaceuticals

|                      |                |
|----------------------|----------------|
| Location:            | Belgium        |
| The project started: | June 2022      |
| Go-live Date:        | February 2023  |
| Industry:            | Pharmaceutical |

**PURNA**  
PHARMA

### Customer Business

Purna Pharmaceuticals, founded in 1986, is an independent Belgian company specializing in contract services for developing and manufacturing of non-sterile, semi-solid and liquid pharmaceutical products. Purna Pharmaceuticals is committed to meeting GXP standards, ensuring quality and compliance while also addressing specific customer requirements. The site is next to GMP compliant also FDA inspected.



### Executive Summary

Pharmaceutical producers face significant challenges in data management and compliance processes. Ensuring data integrity, security, and regulatory compliance are critical aspects of their operations. Addressing these challenges requires pharmaceutical producers to invest in robust data management solutions that streamline processes, ensure compliance, enhance data security, and facilitate seamless integration.

Purna Pharmaceuticals has positioned itself as a leading provider of liquid and semi-solid formulations, specializing in these formulations as its main focus. The company's primary goal is to deliver top-notch medications of the highest quality, while ensuring affordability, catering to both urgent requirements and disadvantaged communities. Their expertise and competitiveness lie in the design and operation of production lines specifically tailored for the manufacturing of liquid and semi-solid formulations.

Over the years, Purna Pharmaceuticals has built a strong reputation for its excellence in producing high-quality pharmaceutical liquid and semi-solid formulations.

However, Purna Pharmaceuticals faced several challenges in their data management and compliance processes. Recognizing the challenges of improving data management, Yokogawa, a trusted provider of industrial automation solutions, stepped in to offer a transformative solution to streamline Purna Pharmaceuticals' operations, ensure data integrity, and meet customer audit requirements.



Photo courtesy of Purna Pharmaceuticals

## The Challenges and the Solutions

Purna Pharmaceuticals was faced with aging of previous manufacturing data management system. If a communication problem occurred between the SCADA and the dataloggers or controllers, manual data collection from controllers and devices was necessary to prepare comprehensive data and reports. Data management tasks, such as generating comprehensive reports, were time-consuming. Purna Pharmaceuticals also needed to ensure that their data lifecycle complies with Good Manufacturing Practices (GMP), and their systems are validated and compliant with FDA 21 CFR Part 11 and PIC/S Data Integrity Guidance. Additionally, Purna Pharmaceuticals is required to submit data for product quality assessment to their customers and undergo customer audits.

Under the leadership of Mr. Wim van den Dries, the Technical Services Manager, and the Quality Assurance team led by Mrs. Reytiens, Purna Pharmaceuticals continuously strived for operational excellence and customer satisfaction. They recognized the need to design, implement, and maintain robust procedures and protocols for Quality Assurance, ensuring compliance with GXP standards, including SOPs, CAPA, and Work Instructions.

Yokogawa understood Purna Pharmaceuticals' challenges and proposed an innovative solution to transform its data management and quality assurance practices.

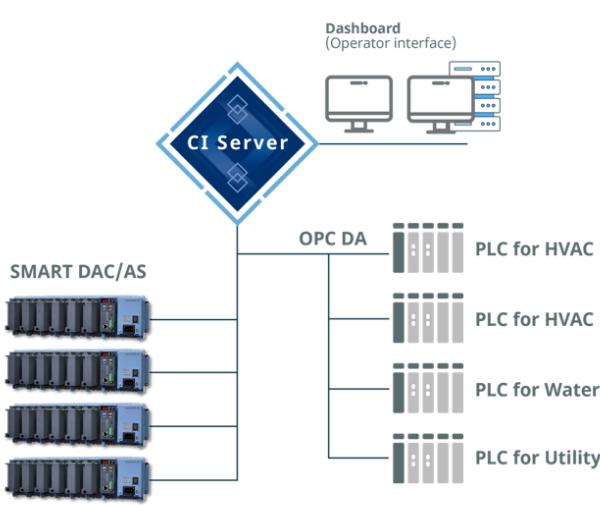
Yokogawa's solution addressed Purna Pharmaceuticals' needs with an architecture comprising the CI Server and SMARTDAC+ systems. This setup offered a centralized platform for environmental monitoring, pressure, temperature, humidity control, and PLC utilities. It provided a secure and compliant data storage and maintenance environment, meeting GMP, FDA CFR Part 11, and PIC/S Data Integrity Guidance requirements. On demand custom features were also developed with Purna Pharmaceuticals along the way to further add value to the solution.

One of the standout features of Yokogawa's solution was its user-friendly interface, allowing operators to navigate effortless. With a single click, operators could access comprehensive reports, including alarm history with acknowledgment reasons and parameter change history. The solution enabled automatic periodic report generation, reducing the time and effort required for data management.

Transitioning to Yokogawa's solution was a seamless process for Purna Pharmaceuticals. There was "zero" impact on existing wiring, ensuring a smooth integration without disruptions to their operations. The solution's native integration capabilities with multi-vendor systems and platforms further simplified the implementation.

Yokogawa's prompt support and training, provided by their local office, impressed Purna. Their flexibility and quick responses to product requests solidified the partnership, demonstrating Yokogawa's commitment to customer satisfaction.

## SUCCESS CASE



### PROJECT PROFILE

- Leveraged Yokogawa recorders' install base
- Migration of 3rd party SCADA
- Application: Environmental Monitoring System (EMS)
- Customer: CDMO (Contract Development and Manufacturing Organization)
- Location: Europe
- Status: Go-live

### CUSTOMER VALUE

-  **ENSURE DATA INTEGRITY**
-  **CENTRALIZED REPORT MANAGEMENT**
-  **CENTRALIZED REAL-TIME MONITORING**

## Customer Satisfaction

Yokogawa's commitment to customer satisfaction was evident through their prompt support, comprehensive training, and quick responses to Purna Pharmaceuticals' product requests. Purna Pharmaceuticals appreciated the partnership, as Yokogawa proved to be a reliable and flexible collaborator throughout the implementation phase.



Looking to the future, Purna Pharmaceuticals aims to consolidate production data and environmental monitoring data onto a single platform. Yokogawa's solution perfectly aligned with this vision, offering Purna Pharmaceuticals a comprehensive view of its operations. Moreover, the solution's capability to backfill data from SMARTDAC+ to the CI Server in case of communication loss ensured uninterrupted data continuity.

Thanks to Yokogawa's advanced data management solution, Purna Pharmaceuticals successfully overcame their data-related challenges. They achieved greater efficiency, improved compliance, and enhanced their position as a leader in the pharmaceutical contract services sector. Yokogawa played a crucial role in Purna Pharmaceuticals' success story, empowering them to deliver exceptional products and services while meeting the highest industry standards. This eventually led to Purna Pharmaceuticals successfully passing an FDA audit in early 2023, which now allows them to do business overseas as well.

In conclusion, Yokogawa's collaboration with Purna Pharmaceuticals exemplifies its commitment to delivering innovative solutions tailored to its customers' specific needs. By addressing Purna Pharmaceuticals' data management challenges and ensuring compliance, Yokogawa enabled Purna Pharmaceuticals to achieve new levels of operational excellence. Together, they set a new standard in data management, fostering a long-lasting partnership built on trust and success.



## Summary

- Purna Pharmaceuticals established itself as a preferred partner for major pharma multinationals in the contract services industry.
- Specializing in liquid and semi-solid formulations, Purna Pharmaceuticals aims to provide high-quality medicines at a reasonable price for urgent needs and the indigent population.
- Yokogawa proposed an innovative solution to streamline Purna Pharmaceuticals' operations, addressing consistent data management, manual efforts and compliance challenges.
- Yokogawa's solution, including the CI Server and SMARTDAC+ systems, centralized environmental monitoring, control and compliance with GMP and FDA regulations.
- The user-friendly interface and automatic report generation reduced time and effort for data management.
- The seamless integration of Yokogawa's solution had "zero" impact on existing wiring.
- Purna Pharmaceuticals appreciated Yokogawa's prompt support, training, and flexibility in responding to product requests.
- Purna Pharmaceuticals envisioned consolidating production and environmental monitoring data on a single platform with Yokogawa's solution.
- Yokogawa's solution improved data integrity, streamlined operations, and strengthened Purna Pharmaceuticals' position in the industry. This eventually led to their passing an FDA audit in early 2023.
- The collaboration between Yokogawa and Purna Pharmaceuticals demonstrated Yokogawa's commitment to cutting-edge solutions and setting new standards in the contract services sector.



### Contact:

**Yokogawa Belgium N.V.**  
Ikaroslaan 6, 1930 Zaventem, Belgium  
<https://www.yokogawa.com/eu/be>

**Yokogawa Europe B.V.**  
Euroweg 2, 3825 HD Amersfoort, The Netherlands  
P.O.Box 163, 3800 AD Amersfoort, The Netherlands  
<https://www.yokogawa.com/eu/>