



# Lek Pharmaceuticals Solutions for Building Automation

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Saša Sokolić, Ph.D., Member of the Management Board,  
responsible for Sales and Marketing in Metronik

## Results

- Solution for HVAC control and supervision was developed, tested, and commissioned on-site within eight months
- Production flexibility increase due to automatic process adaptation in case of new production demands, or modification of clean-room functionalities
- Synergy of two complex requirements, high reliability and rich functionality, achieved by using highly reliable industrial equipment and appropriate control algorithms implemented at different levels
- Configurable PC application fulfills all regulatory requirements, as well as recommendations, for the pharmaceutical industry
- Solution provides a complete overview of energy use, and consequently, operational costs, assisting management in analyzing and optimizing energy usage to reduce operational costs

# Lek, a Sandoz Company, uses GE Digital's iFIX-based solution to control and monitor environmental conditions and energy usage

Founded in 1946, Lek is a part of Sandoz, one of the world's leading generic pharmaceuticals manufacturers. It operates as a global development center for products and technologies, as well as a global manufacturing center for active pharmaceutical ingredients and medicines. The company is also a competence center for vertically-integrated product development, including generic medicines along with pharmaceutical, and biotechnological active substances and anti-infectives, as well as development and manufacturing of biopharmaceutical products. It is the main supply center for the CEE, SEE, and CIS markets.

The OTO2 production plant is one of Lek's largest production sites in Slovenia, with specialized high-technology process equipment for producing generic drugs. Key product groups include antibiotics, treatments for central nervous system disorders, gastrointestinal medicines, cardiovascular treatments, and hormone therapies (for example AMOKSIKLAV, IBUPROFEN, KETONAL, LEKADOL, etc.).

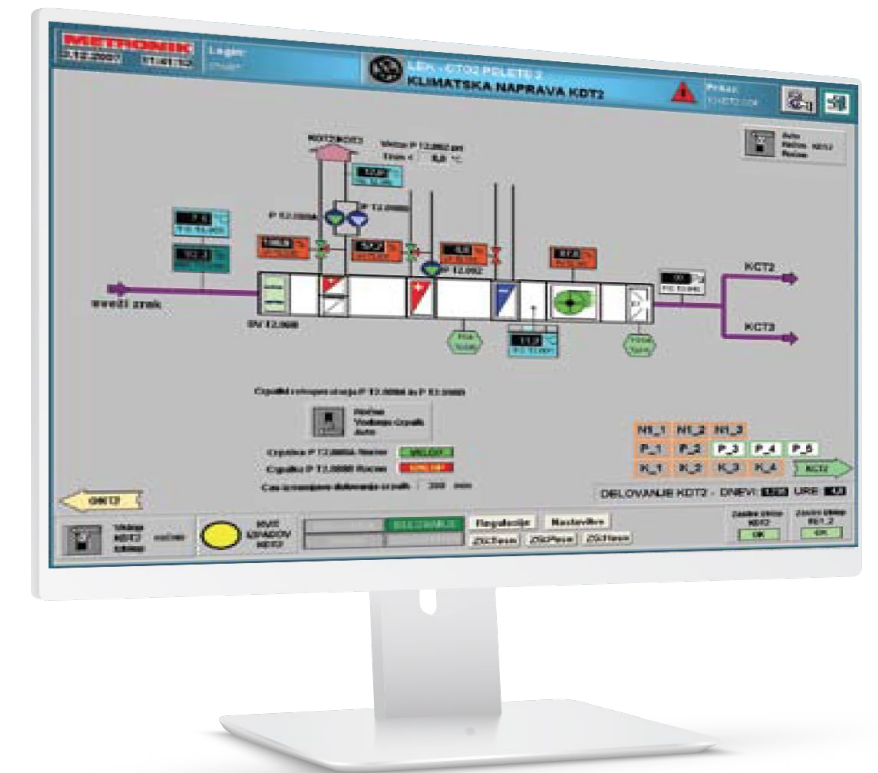
In recent years, Lek has been expanding, and has modernized its production capacity and strengthened its position inside the Sandoz group. Plant OTO2 follows high standards of sterility, safety, and quality to meet strict FDA approvals.

The production of pharmaceutical products requires specialized and controlled environments, where sterile conditions have to be maintained. Therefore, heating, ventilation, and air-conditioning systems (HVAC) are necessary for controlling these environments. A control system for HVAC is a critical factor, which affects the reliability of analysis results, experiments, and production systems. One of its most critical tasks is to prevent outside air from entering the facility.

Therefore, Lek required a validated and highly reliable building management system/environmental monitoring system (BMS/EMS) solution for HVAC control and supervision to provide precise, critical control of temperature, humidity levels, and airflow patterns at the OTO2 production site. The solution had to provide complete remote control of all HVAC systems, automatic adjustment of process parameters according to production demands, alarm management, efficient visualization, and trending, together with process data archiving and reporting.

Introducing the complete BMS/EMS solution for HVAC, Lek wanted to provide fully controlled conditions in OTO2 to enable effective production and energy management, increase the level of quality control, as well as increase flexibility and production adaptation to new demands.

Since plant and all production facilities have been designed according to GAMP<sup>1</sup> recommendations, the company's HVAC solution had to meet respective pharmaceutical regulatory requirements and recommendations.



*HVAC system visualization*



*Trends of the process variables: temperatures (fresh air temperature, temperature behind refrigerator, etc.) and valves*



# Integrated control provided

Lek turned to GE Digital's solutions provider Metronik, a leading systems integrator for process control and automation for the pharmaceutical industry in the Eastern European region. Formed in 1990, Metronik has 17 years of experience providing more than 1,000 air-conditioning units automated, commissioned, and validated on more than 50 different production sites. The company, headquartered in Ljubljana, Slovenia, with offices in Zagreb, Croatia, Belgrade, Serbia, and Sofia, Bulgaria, employs more than 50 engineers for its project teams.

Metronik delivered a flexible, high-powered, integrated BMS/EMS solution for HVAC system in Lek's production plant OTO2 based on proven industrial equipment, such as GE PLCs, and iFIX from GE Digital to assure accurate and reliable control.

The GE PLCs come from a family of controllers, I/O systems and specialty modules designed to meet the demand for versatile, industrial solutions—helping businesses gain a sustainable advantage. With its single overall control architecture, this controller has been the PLC of record in more than 200,000 applications, such as high-speed packaging, material handling, and complex motion control.

With the power of leading technologies and patented techniques, GE Digital's iFIX is the ultimate tool for visualization, automation, and in delivering analytics to drive the lowest possible total cost of ownership. The software provides a comprehensive monitoring, analysis, control, and distribution of their plant-wide data. With applications in industries including pharmaceuticals, biotech, consumer packaged goods, food and beverage, oil and gas, water, waste water, power, and others, iFIX is the right HMI or SCADA solution for any automation environment.

“The environmental conditions have a strong impact on product quality in OTO2. Therefore, we had to establish a system to adequately control these environmental conditions,” said Aleš Dolenc, Lek, Technologist Energetics Department. “Together with Metronik, an integrated EMS/BMS solution for HVAC was deployed for the production plant. It enables flexibility of the production process, as well as more consistent and controlled HVAC system operation and maintenance, while eliminating the need for paper records.”

The main task of the Metronik solution is to provide precise control over environment parameters and conditions in clean rooms by implementing control algorithms for temperature, humidity, and pressure. Changes in production demands are handled automatically by special control algorithms embedded in the PLC blocks. They are used to facilitate automatic control of output process values based on predefined set-up values, as well as provide a very fast response, and consequently, production adaptation in a very short time.

The solution enables rich graphical visualization of processes, conditions, and sensor values in real-time. All key parameters, such as alarm boundaries, PID loops, and production parameters can be accessed through SCADA. Power-users have the option to define two-level alarm settings for GMP (Good Manufacturing Practice)<sup>2</sup> and non-GMP parameters. Two modules running in real-time process data collection and an archiving module are incorporated into the solution, as well as a module for maintenance support, including fault diagnostics for all HVAC installation. All key data are stored into the Oracle relational database, and can be used for analysis and reporting.



# Results achieved

The high-powered EMS/BMS solution combines the accurate control of heating, ventilation, and air-conditioning systems, as well as EMS solutions. It is used to monitor and control the critical and non-critical parameters coming from plant technologies.

“Our GMP compliant HVAC solution combines the environmental parameters monitoring functionalities (EMS), with the central building management system (BMS),” said Saša Sokolić, Ph.D., member of the management board responsible for sales and marketing in Metronik. “Production flexibility increases have been realized due to automatic process adaptation in case of new production demands, or when the functionalities of existing clean rooms are changed.”

Efficient visualization, alarming, and fault diagnostics for all HVAC equipment and installations in OTO2 provides plant personnel with efficient support for monitoring in real-time, and maintenance support in case of unacceptable or dangerous situations.

The validated Metronik solution fulfills the requirements for paperless HVAC system management, and complies with pharmaceutical regulations. And, the integrated BMS/EMS solution delivers lower TCO and maintenance of the complete HVAC system in OTO2.

“The Metronik engineering team has the knowledge and experience for implementing complex BMS/EMS building management systems for pharmaceutical production facilities,” said Lek’s Dolenc. “Efficient visualization, alarm, and fault diagnostics for all HVAC equipment and installations provide efficient support for real-time monitoring and maintenance support.”

“A synergy of two requirements—high reliability and rich functionality—was achieved by using the [GE Digital] industrial equipment and appropriate control algorithms implemented at different levels,” concluded Metronik’s Sokolić.

<sup>1</sup> GAMP (The Good Automated Manufacturing Practice - GAMP Guide for Validation of Automated Systems in Pharmaceutical Manufacture). Metronik system is designed, developed and commissioned according to GAMP 5 based project life cycle approach: User Requirement Specification, Quality and Project Planning, Specifications (Functional, Configuration and Design), Risk Assessment, Design Reviews, Software Production/Configuration, Test strategy and testing, User documentation and training, system support and maintenance operation, GMP relevance, 21 CFR Part 11 relevance.

<sup>2</sup> GMP is a term that is recognized worldwide for the control and management of manufacturing and quality control testing of foods, pharmaceutical products, and medical devices. Metronik system provides visualization and monitoring of the critical process data in compliance with good manufacturing practices—so called GMP critical parameters. CFR Part 11 relevance.





## About GE

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