Alcon Puts Strong Focus on Validation for the Production of Eye-Care Products

Significantly Faster Response Times with Historian and High Performance Trend Analysis

Originally founded in 1947 by pharmacists Alexander and Conner, Alcon has grown to a world-wide pharmaceutical vision-care manufacturing and research company with over 10,000 employees. By expanding to multi-national production facilities and through continuous investments in research and development, Alcon has established a leadership in the eyecare field.

Alcon Belgium provides production facilities for specialized eyecare products. The production is organized into four divisions, each with very strict requirements for the automation layer. The pharmaceutical industry has always been subject to strict regulations. Production of medication and health care products must take place under the most severe registration rules, in order to comply with the regulating authorities. Following the trend for more automated production processes, the FDA has formulated an electronic definition of process tracking in the form of 21 CFR Part 11.

What does 21 CFR Part 11 mean in practice?

In an attempt to structure and guide line the continuous replacement of the current paper work flow in production processes, the FDA has formulated a set of definitions for electronic signatures and work-in-instructions. Working in a validated production environment basically means enforced security in combination with an extended audit trail. Every single change to the production system needs to be captured, recorded and archived into a closed and secured database.

"With the Proficy Historian product the response times are 20 to 30 times faster than with the traditional trending tools"

— **Dirk Steeman, Automation Manager, Alcon Couvreur, Belgium**

How to apply to these rules

Implementation of a validated electronic tracking system requires a structured approach from the bottom up, Alcon has adopted an object oriented control layer approach, starting with the organization of standard building blocks in the PLC. Each sensor value goes through a number of standard function-blocks to calibrate, check alarm boundaries and calculate before it reaches its final value. Set points and calibration can only be changed by authorized personnel and are checked continuously within the PLC.

Every non-conformity and deviation is automatically reported through the standard SCADA system iFIX from GE Digital to a central database from which daily reporting takes place. Authorization is enforced through out the entire system using the seamless integration-of security within iFIX and Microsoft Windows®.

SUMMARY

COMPANY
Alcon Couvreur, Belgium

SOLUTIONS
Production Management
- Process Visualization
- Process Validation
- Plant Information

PRODUCTS
- iFIX
- Proficy Historian

BENEFITS
- High performance trend analysis
- Integrated security complement to 21 CFR part 11
- Low cost plant Historian
- Secure base for reporting
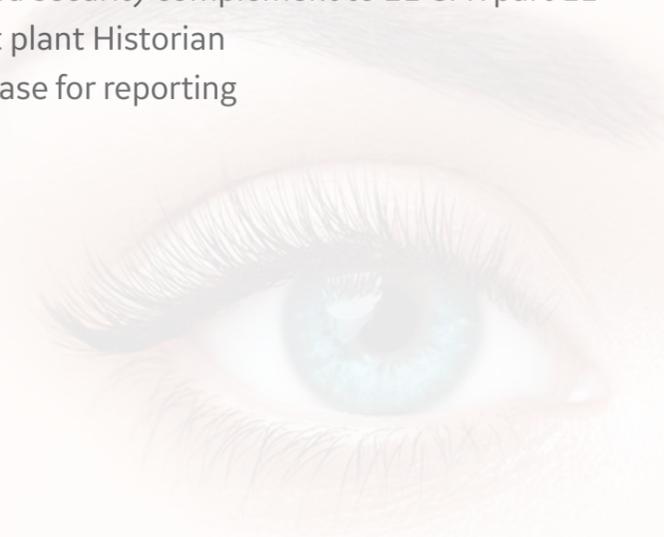
Validated Applications

From a hardware point-of-view, the network infrastructure is physically split into an administrative and a production network. The production-network itself is split into a part for validated applications and a part for non-validated applications. The validated applications deal with the continuous monitoring of the environmental production room condition (temperature, pressure, humidity, etc) and manufacturing equipment status. Within the validated-dated part no changes can be applied without the explicit authorization of the internal validation department, again enforced by the system. The use of standard building blocks both structures and simplifies the validation process.

High Performance Data Historian

In their continuous search for process improvements, Alcon has adopted the Proficy Historian product. With a built-in 21-CFR-Part 11 compliancy the product is able to capture historical process values and store these into central archives. Historical values are often required for trend analysis and reporting by both the QA department and production personnel. The main reason for Alcon to purchase Proficy Historian was its tremendous increase in performance over the existing trending tools. Response times have increased enormously, while the impact on the existing installation is kept to a minimum. The sophisticated compacting functionality minimizes the required disk-space, which means for Alcon a disk-space requirement of only 0.5 MB for the recording of 30,000 tags per day.
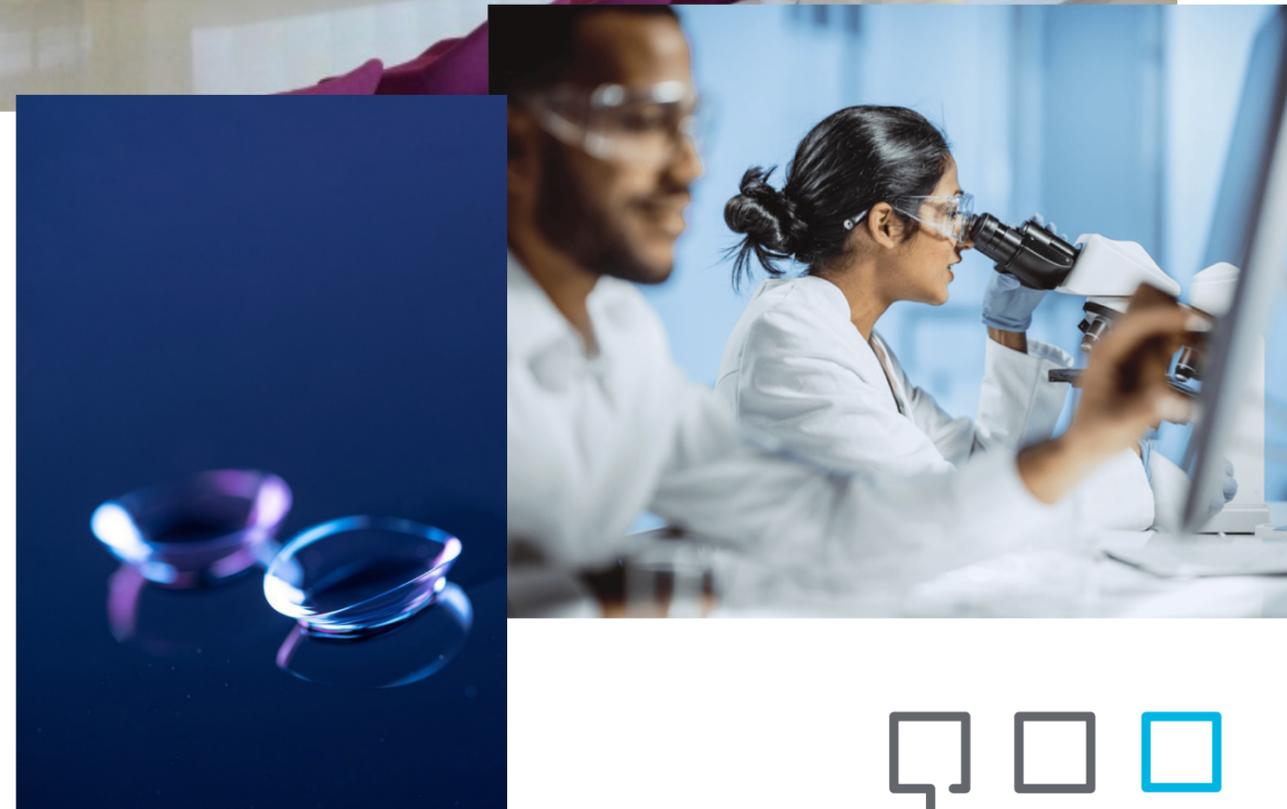
About GE

GE (NYSE: GE) is the world's Digital Industrial Company, transforming industry with software-defined machines and solutions that are connected, responsive and predictive. GE is organized around a global exchange of knowledge, the "GE Store," through which each business shares and accesses the same technology, markets, structure and intellect. Each invention further fuels innovation and application across our industrial sectors. With people, services, technology and scale, GE delivers better outcomes for customers by speaking the language of industry.

Contact Information

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