

CASE STUDY: BIOPRODUCTION

Solution: Gateway solutions
Country: France
Company: Genzyme
Summary: 30 Anybus Communicators allow communication between different industrial devices and Genzyme's central SCADA. Communication is handled over Ethernet or Profibus.



The effects

- ✓ Compatibility with several networks.
- ✓ Re-usable for future network connections.
- ✓ Lowered costs.

Genzyme monitors 50,000 SCADA points with Anybus Communicator

The company, which is a world leader in biotechnology, is creating a new polyclonal antibody production site. This is an innovative production facility: the process has been automated as far as possible, to reduce human error in the many stages of the process (separation, purification, filtration, ultrafiltration, haemadsorption etc.). This involves being able to interface with a battery of very mixed laboratory equipment, which was not initially designed to communicate with fieldbuses. Genzyme has used about thirty HMS Anybus Communicator gateways, to enable consistent SCADA management across all the devices in use. Benefits are as much in terms of quality as in production costs.

The Lyon bioproduction site extends over an area of 22,000 m², and produces a selective immunosuppressant which is used to prevent and treat organ rejection during organ transplants (Thymoglobulin®). This drug is also used in haematology in cases where the transplanted cells react against their host in bone marrow transplants. The active agents in this drug are anti-human thymocyte immunoglobulins, obtained from the purification of a serum, which is used as the raw material. The immunogenic base consists of thymocytes (Thymus cells), a natural source of T cells. The development of this site has involved investment worth 115 million euros.

"Quite apart from the quality of the product, we found that technical support was there whenever we needed it."

Alexis Ducancel
Automated Systems officer
Genzyme

"Genzyme is currently using labour-intensive production methods at the Sanofi Pasteur site, Marcy. With the new site, we're hoping to optimise the process so as to reduce human error to the absolute minimum. This highly sequential batch process involves more than 780 production stages. There are many sources of error. Automating a process such as this has required a lot of close work with the equipment involved when deciding how the system should behave. This has avoided the need to re-think the entire ergonomics of the building and production equipment, whilst still resulting in a true revolution in the way the production process works. To achieve this, we specified more than 4,000 parameters and 13,000 alarms, enabling us to master every stage of production," explains Alexis Ducancel, Genzyme's Automated Systems officer.

Bioproduction: a series of complex processes

Unlike traditional chemistry, production based on living cells involves many different complex and expensive stages. The production cycle for a recombinant protein requires an industrial

infrastructure which is suited to large-scale production involving several stages staggered over several months. Each stage is subject to numerous quality controls. Tests to ensure the absence of viruses and contaminants are performed throughout the production cycle. At the end of the line, the purity and action of the protein are also checked.

The production of this drug involves many complex stages, punctuated by a succession of technical and quality assurance tests. The production process can be broken down into four main stages:

- The collection of the immunoglobulins, which is done by injecting human tissue into rabbits.
- The purification of the immunoglobulins to remove undesirable proteins (particularly anti-erythrocyte antibodies), by haemadsorption
- The chromatography stage consists of anion exchange through the use of an ion exchange resin. Impurities are captured by the resin, whilst the immunoglobulins, which are not negatively charged, are eluted. This stage is checked using spectrophotometry and electrophoresis.
- The precipitation stage is intended to eliminate the last remaining impurities. The purified immunoglobulins are pasteurised (60°C for 10 hours). This solution is freeze-dried before being sealed into vials.

“In this process we can, for example, program in the settings for the centrifuges (speed, temperature, working time etc.). These values can be changed in the SCADA to take the specific requirements of the current production batch into account. Readings are taken at every stage and sent back to the SCADA. This enables us to put a very precise traceability process in place. In particular, this means that the workload for the quality assurance teams is significantly reduced, which is an advantage in cost terms,” adds Alexis Ducancel.

The Lyon site, like the Marcy site, will receive FDA and AFFAPS approval. “Naturally, we chose HMS, because we felt that no other company has standard solutions available to return data from a very mixed set of equipment which has not necessarily been designed for connection



to fieldbuses. We have 28 centrifuges, pH-meters, balances and so on. The interface protocols vary: serial or ASCII for example. The 30 Anybus Communicators on site send the data back over the Ethernet or Profibus to the central SCADA.”

Anybus Communicator: the solution for integrating Serial equipment into an industrial communication network

The Anybus Communicator series of gateways for connection to industrial Ethernet/Fieldbus makes it possible to network devices which were developed for use in a serial network. The Anybus Communicator can connect most products with an RS-232/422/485 serial interface to an industrial Ethernet or fieldbus. It performs an intelligent conversion between the serial protocol and destination network. This conversion is configured using the “ABC Config Tool” software. The network configuration, once completed, can be re-used for all networks supported by the Communicator.

“Quite apart from the quality of the product, we found that technical support was there whenever we needed it,” concludes Alexis Ducancel.

Around fifty employees are now in place at the Genzyme production site, where initial production batches are being run to validate the production process. Full production should start in late 2011, once the AFSSAPS certifications have been obtained. The total number of staff should then rise to 270.

Learn more on www.anybus.com or www.genzyme.fr



Anybus Communicator Gateways

Anybus Communicator can connect almost any automation device with a serial communication interface to fieldbus and industrial Ethernet networks. The Communicator performs an intelligent conversion between the serial protocol of the automation device and the chosen industrial network.