

## Migration of the process control system to Simatic PCS 7 at Janssen Pharmaceutica

# Added Value

In just three weeks, Siemens installed and commissioned a new process control system at the liquids and creams plant of Janssen Pharmaceutica in Beerse, Belgium. Detailed preparation and an experienced project team were the decisive factors in completing this challenging project – and the entire validation and qualification of the new system – in this tight time frame.

**T**he Beerse L&Cr liquids and creams plant produces a wide variety of products for treating diverse disorders and infections. The Beerse site comprises pilot plants, secondary units, and research and development facilities. The L&Cr plant produces about 50 different products and processes 5,000 orders per year.

Batch production in the multipurpose facility goes through several stages and is equipped with a clean-in-place system. Water, raw materials, and bulk ingredients are mixed in a boiling vessel and a processing unit. Then they are transferred to holding and buffering tanks before the semi-finished product is transferred to the secondary unit for finishing and packaging.

### A new core

The existing process control, based on Simatic S5 controllers and the Coros LS-B supervisory system, had not undergone a major upgrade in 12 years, and some system components were approaching the end of their service life. Consequently, in 2003, Janssen Pharmaceutica decided to modernize the system and replace the automation level with a new solution. The company also wanted the new system to provide possibilities for future expansions and upgrades, as the frequency of control system upgrades is expected to rise. Additionally, the new system was to be capable of linking with the higher-level manufacturing execution system (MES) and enterprise resource planning (ERP) system.

The major challenge for the system migration, however, was the very tight time frame for the conversion. The production shutdown period was not to exceed three

weeks to avoid the risk of running out of market stock. Consequently, choosing the right partner for this project was crucial.

Janssen wanted to keep the existing remote I/O devices in place and replace only the automation and operator systems. As Siemens had supplied the existing process control system, Janssen invited Siemens to participate in the tender. After extensive considerations, Janssen Pharmaceutica decided that Simatic PCS 7 Version 6 would be the best solution for the plant at Beerse.

### Detailed study for smooth transition

Planning was everything during this project, as Janssen Pharmaceutica senior project manager Kris Buys confirms: “It is

## Project highlights

- ▶ Migration of process control system for multipurpose batch production facility
- ▶ Tight time frame of only three weeks for the migration

essential to work out a detailed project execution plan and project qualification strategy, including documentation, and that all work during the shutdown be planned exactly in order to be able to complete the factory acceptance test.”

In the second quarter of 2004, Siemens performed a detailed project study. The project team defined the functional specifications, software and hardware design, and coding and internal testing. This study also included the user requirement specifications, a detailed validation plan, and a





### Local operation is enabled by Simatic Panel PCs

risk and 21 CFR Part 11 assessment. Siemens was also responsible for the detail engineering, including GxP and business-criticality analysis, evaluation of various solutions and migration approaches, and updating and finalizing the user requirement specifications and the final tender document.

In mid-2005, the execution phase of the new solution implementation was initiated. Siemens took on the engineering of the new system hardware, including installing



### In the liquids and creams plant, about 50 different products and 5,000 orders per year are processed in multistage batch processes

to make sure there would be no problems during the real shutdown.

#### Experienced partners

All systems were up and running before the final project deadline of August 1, 2006. This success was made possible by the excellent preparation and good team effort, as Kris Buys recalls: "The shutdown period was very intense. During one weekend, the team took the old system out and put all the new systems in, so we had an operational system for the testing and qualification procedures after just one weekend. And the result was very positive: after the system went into operation, we did not have even a single major incident. This was, of course, due to the excellent combined preparation of Janssen and Siemens."

The project team from Siemens also included individuals who had already implemented the old Simatic S5 / Coros LS-B system and who were familiar with both the plant and the control system. "For us, this was a major added value," says Buys. He was also quite impressed with the qualification and validation support: "Siemens provided us with a very good qualification file that was very defensible with the FDA – which, of course, is very important." ■

#### Find out more:

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## New system architecture

### ► Production

- 1 batch Server + batch API for CIP scheduling
- 1 redundant PCS 7 server with 250,000 variables (in use: +/- 170,000)
- 1 engineering station (unlimited license)
- 1 redundant domain server
- Simatic Logon/Electronic Signature

- 19 PCS 7 clients
- 8 OS clients
- 11 Panel PCs
- 6 AS 417 stations

### ► Test Station

- 1 PCS 7 server/batch server
- 2 AS417 stations
- 1 Panel PC
- 1 OS client

and commissioning the system on-site in Beerse, and was also responsible for the operator training. Siemens also provided validation support and compiled the documentation for qualification and validation.

To mitigate the risks associated with the migration, Siemens performed a pretest of the new system during the Christmas break. The new PCS 7 system was connected to and tested with all types of I/O devices