

## New process control system

### Optimization of revalidation expenditure through the use of the ProLeiT Plant Direct iT process control system

Pharmaceutical production plants are subject to strict regulations for the qualification of technology and the validation of manufacturing procedures. That means the corresponding requalification and / or revalidation expenditure is necessary in the case of every change to a running plant. It is the aim of every operator to minimize this in term of time and costs.

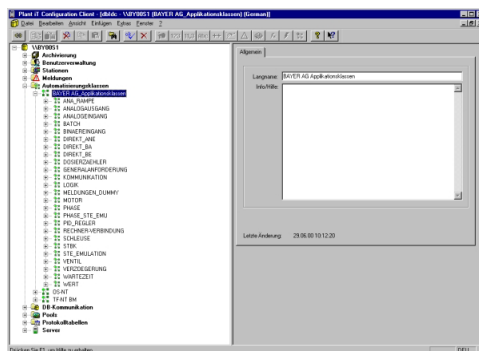
Bayer AG was confronted with the task of replacing the obsolete operator control and monitoring system in one of its agent plants, whereby the subordinate control level and the superimposed system for the recording of batch data were to remain unchanged. The by-pass had to take place with production running at high capacity. After intensive enquiry by its process control engineering (PCE) specialist department, Bayer AG decided to install the innovative process control system (PCS) Plant iT from ProLeiT AG within this complex project. The properties of this PCS and the project procedure plan drawn up mutually by Bayer and ProLeiT were the guarantor for the successful completion of the project in 2001 whereby the stipulated ancillary conditions of minimal requalification expenditure and shortest possible installation duration were met.

Bayer is a chemical-pharmaceuticals corporation which is represented in almost every country of the world by around 350 companies. At the Wuppertal / Elberfeld site the pharmaceuticals corporation is pursuing among other things an agent manufacturing business for a very high-revenue broad-spectrum antibiotic. This agent is subsequently being processed into an actual drug in various pharmaceutical forms. A sales market for Bayer for this agent among others is the USA. The Food and Drug Administration (FDA), the American regulatory body for food and drugs, has compiled strict regulations in order to permanently ensure quality of pharmaceutical products. Included is a validation obligation for the drug manufacturing process. Validation means „establishing documented evidence which provides a high degree of assurance that a specific process consistently produces a product meeting its predetermined specifications and quality attributes“. In order to

be permitted to sell the product on the American market, compliance with the validation regulations, for which the operator of the plants is responsible, must be demonstrated to the authority.

This environment placed Bayer AG before a great challenge in the planned displacement of the existing operator control and monitoring system. A revalidation of the entire manufacturing process was to be avoided. The running agent production was to be little affected in the by-pass phase. A complex task lay ahead.

After a comparative system choice by Bayer PCE technical planning, ProLeiT AG of Herzogenaurach was commissioned to replace the existing operator control and monitoring system (which also undertook coordinating functions between the subordinate controllers) with ProLeiT Plant iT and install a new and efficient network. The revalidation expenditure and the installation times were to be kept as low as possible.



A deciding factor for the pharmaceutical corporation in addition to the appropriate system properties was the contractually regulated promise with regard to long-term maintenance and development of the system.

#### Advantages of system architecture

The software specialists from ProLeiT in Herzogenaurach used the Plant Direct iT component from the ProLeiT Plant iT system family: an open, component-based process control system. It consists of servers and

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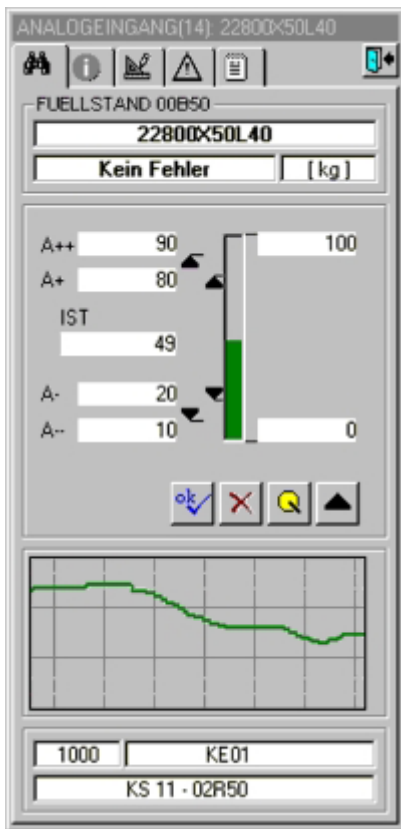


<b>Company:</b>	Bayer HealthCare AG
<b>Sector:</b>	Pharma
<b>Location:</b>	Elberfeld
<b>Country:</b>	Germany

operator stations based on PC's and subordinate SIMATIC S7 controllers.

A prominent attribute from the viewpoint of application software is pre-defined technological classes in which recurring, similar automation tasks are processed (e.g. motor control, valve control). Decisive for this project was the possibility of being able to develop own project-specific classes according to the same concept on the basis of the supplied modules. By means of these re-usable objects which only have to be tested functionally once and from which through parameterisation the instances are provided which control a concrete process control object, the engineering expenditure is significantly reduced. The upgrade ability of the solution is ensured by ProLeiT.

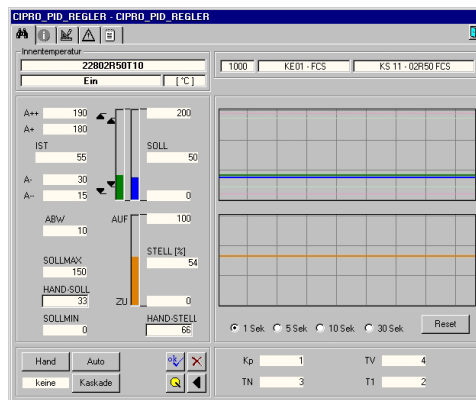
This architecture allows standardized communication between the existing controllers of the field device level and the Plant Direct iT process control system to be constructed on a cyclical and result-governed way by means of modern network technologies.



### Solution structure

The existing AEG A500 control level was retained and the ProLeiT PCS with SIMATIC S7-400 are used here as linking units for the transmission of data to the operator stations of the Plant Direct iT process control system.

An important aspect was the securing of reliable and efficient communication between the 18 existing AEG A500 controllers, the 3 new SIMATIC S7-400 linking units, the server, the workstations and the superimposed Electronic Batch Recording System. The system in its final configuration possesses three bus systems: a PLC bus on the field device level, implemented as SINEC-H1-Bus; and a standard system on Ethernet / TCP / IP basis in the ProLeiT system. In addition, a third bus exists which connects the ProLeiT system via communication tables to the already existing Electronic Batch System. The communication of the new PCS with the existing base functions elements (the smallest validated software modules on the field device level) in the AEG A500 control level was implemented in the form of ProLeiT classes. Project-specific, modular, re-usable ProLeiT classes emerged which run as kind of mirror modules to the A500 in the linking units (SIMATIC S7-400). In addition, all vertical communication tasks were realized by means of such classes.



### Project procedure planning

First of all the exact procedure of the by-pass and the requirements of the new system were described together with the client in a specification phase lasting three months. In the final phase of the specification a complete Plant Direct iT test system was constructed in the MSR laboratory at the Elberfeld plant which was complemented with A500 controllers by Bayer. The most important classes and process graphics were already installed here and could be subjected to primary tests.

The test system served initially as a fundamental performance test of the new system in communication with the existing controllers. On the other hand, it was used in the configuration phase for software tests and operator training. A further task of the test system is the loading of all changes (i.e. updates and upgrades of the system) onto this system first for in-depth testing before release for use in the productive system is issued.

### The project process contemplated the following steps:

- A very detailed plan was compiled including risk analysis and disaster plan
- In a Factory Acceptance Test (FAT) lasting several weeks and split into several sessions, the factory approval took place in Herzogenaurach after Bayer approved delivery of the system.
- The Site Acceptance Test (SAT) after successful on-site installation of the system contained the necessary functional checks for the approval for production by ProLeiT engineers and the Bayer AG process control engineers.
- The first product runs as verification of the validated procedure with the new

PCS were accompanied by ProLeiT engineers whereupon the final acceptance took place and the system was handed over to the operator.

For the conversation, the ProLeiT AG engineers implemented a temporal and systemic concept of conversion planning stages. This approach was supported by the modular structure of Plant Direct iT, whereby the individual modules (e.g. subsystems) can be selectively activated. The installation permitted the parallel operation of the system being substituted and the new process control system: this facilitated some activities during qualification and would have provided the client with the possibility of securing production via the old system in the event on an error (which did not occur).

The entire concept, engineering and project management and the great and close cooperation with the client's experts were the guarantee for a timely and high-quality handover of the system to Bayer AG.

### Conclusion

This project has directly shown that keeping to the strategy of renovation with optimised revalidation expenditure and shorter installations duration, an efficient PLC-based process control system such as ProLeiT Plant Direct iT - building on hardware components of the market leader - is the means of choice. The free upgrade ability of the system by project-specific classes for a client which, as here, encapsulates and emulates already existing functionalities, appeared as the deciding asset of the ProLeiT solution. In this way a concept and a library of classes comparable with industry toolkits emerged, which can be used in similar projects. In addition, there is the advantage that the system expansions can in future also be directly and smoothly undertaken by the ProLeiT system controllers. In this way, the project is an example of a successful capital-securing migration.