Standardized Automation for Vaccine Production at the NVI

Strategic Pharma Project

Trends in Process Instrumentation

Compact Process Control: Simatic PCS 7 Box
Sensors are the eyes and ears of production and form the basis for every process control system. Siemens uses its extensive automation know-how to turn new technological developments into innovative solutions for the process industry.

At present, virtually every new bioreactor is instrumented and automated device-specifically. The NVI was looking for an alternative and, together with Siemens, created a detailed and comprehensive user requirement specification that will form the basis for all future bioreactor projects at NVI.

At Reckitt Benckiser in Ladenburg, Germany, Simatic PCS 7 has considerably increased productivity, while Simatic IT ensures greater transparency and availability.
Dear Readers!

Setting new standards and “knowing what’s possible tomorrow” – that’s the slogan of Hanover Fair 2004. An important milestone in this respect is the integration of Interkama+, the leading international fair for process automation, which is being held together with the Factory Automation fair in Hanover from April 19 to 24. This means that process and factory automation are being presented together for the first time on a single international platform.

Siemens will be presenting its extensive and integrated portfolio of solutions, systems, and products for the process and manufacturing industries together on one stand. With the uniform Totally Integrated Automation platform and the integrated interfaces to the IT world, solutions and systems from Siemens provide the ideal technology environment for creating genuinely integrated automation solutions and the optimization of industrial processes – across all industries and processes. As a result, manufacturers can more easily identify and exploit potential for rationalization and increase the productivity of the entire production chain. This is in keeping with Siemens’ declared goal for its customers – the slogan of the company’s exhibition stand is “Increase your productivity.” Using the chemical and pharmaceutical industries as two examples, the stand offers demonstrations of how innovative products and solutions contribute to an increase in process and plant productivity.

Productivity and quality are critical, especially in the pharmaceutical industry. Siemens not only provides products and solutions for the pharmaceutical industry but is also actively involved in the development of new technologies. Two current projects in the Netherlands, which we present in this issue of Process News, provide evidence of that commitment. I hope that these and the many other projects from different regions of the world will be an inspiration as you seek to improve your own processes.

Anton S. Huber
Member of the Group Executive Management
Siemens Automation and Drives
Modernization of the world’s largest phenol plant at INEOS Phenol

INEOS Phenol is the world’s largest manufacturer of phenol and acetone, with production sites in Gladbeck, Germany; Antwerp, Belgium; and Mobile, Alabama, USA. In the course of the company’s history, the Gladbeck site has experienced significant development. The capacity of the plants at the beginning of production in 1954 was a relatively modest 8,000 tons of phenol and 5,000 tons of acetone. Today, Gladbeck is the largest phenol plant in the world, with an annual capacity of 630,000 tons of phenol and 390,000 tons of acetone.

When INEOS was looking for a partner to modernize the existing process automation system for the entire factory, the company first performed an extensive comparison of various control system suppliers. Simatic PCS 7, though facing strong competition, was able to establish itself as the winner. The INEOS order includes replacement of all the installed control technology on the entire site, with about 8,000 I/Os, and the merging of two measurement stations.

One of the critical factors in the contract award, aside from INEOS’s previous positive experience with Siemens in low-voltage projects, was the fact that PCS 7 is a modern, innovative, and efficient control system that is based on future-safe standards. The integrated safety technology and the high system availability due to redundant solutions were also decisive. In addition, PCS 7 offers the possibility of replacing installed control technology during ongoing operation – allowing the Gladbeck plant to continue to operate without interruption.

Siemens wins contract for process analysis at Linde-KCA-Dresden

Linde-KCA-Dresden is building a new turnkey polypropylene plant for Slovnaft, near Bratislava in the Slovakian Republic, with an annual capacity of 255,000 tons of homopolymers and random and impact copolymers. Completion of the plant is planned for 2004.

Linde-KCA-Dresden was looking for a reliable analysis system to monitor the individual process steps. Siemens was able to beat some strong competitors to win the process analysis contract and will supply an analysis house with several Maxum edition II process gas chromatographs. To be able to transport the samples quickly from the expansive plant to analysis, both primary sample preparations in the field and secondary samples at the analysis house have been implemented in the plant. In addition, the analysis house is also networked with the process control system.

Process analysis has a firm grip on a complex application

Dow Olefinverbund GmbH, a subsidiary of the US company Dow Chemical, of Midland, Michigan, commissioned a new pilot plant for modification of ceramic filters at its Schkopau site in November. Siemens won the contract to build an analysis container with a Maxum edition II process gas chromatograph, an oxygen laser, and an FTIR spectrometer for the process analysis. This solution allows the complex sample flows of the plant to be analyzed reliably. The sample preparations and the analyzers are installed in separate rooms.

The analysis house is networked with the process control system so that the operating personnel in Schkopau are always informed about the current analysis values.
Tailor-made Simatic PCS 7 course for bulldozer drivers

A LBA-Holzkontor Brandenburg GmbH provides fuel processing for a power station near Berlin that is controlled completely by Simatic PCS 7. Company management decided to hold a Sitrain Simatic PCS 7 training course to ensure that the employees were familiar with the functions and operating options of the system and able to exploit optimization potential. This was not a straightforward task, because initial interviews revealed that the basic knowledge of the participants varied greatly.

The employees are bulldozer or forklift drivers who prepare the fuel – old timber such as old furniture, railway ties, or tree roots – for burning. The Sitrain trainer gladly accepted this challenge, however, and every employee was trained to operate the belts, shredders, and silos from the terminal. The type of teaching and the joint performance of practical exercises motivated both the trainer and the participants, making this individually designed course a huge success.

Siemens outfits a sugar refinery in Turkey

Siemens has received an order from Konya Seker, the largest private sugar producer in Turkey, to equip a new sugar refinery in Cumra with automation and energy technology. The total value of the contract amounts to about 8.1 million euros.

The production facility is taking shape on a greenfield site 50 kilometers south of Konya in the highlands of Anatolia. It is the only greenfield sugar refinery being built in Europe at the moment. Designed to handle 12,000 tons of sugar beet per day (corresponding to around 1,700 tons of sugar), the plant is expected to go into production at the end of 2004.

The Siemens project team is made up of both German and Turkish employees, guaranteeing a good level of local service. Under the terms of the contract, Siemens will be supplying a turbo set for energy production, the drive and control technology, and the complete field instrumentation, networked by Profibus PA. The Simatic PCS 7 process control system will be used throughout as the control system for automation and energy production.

Siemens automates LIFE at B. Braun in Melsungen

The Leading Infusion Factory Europe (LIFE) in Melsungen will be the largest facility of its kind in Europe. Production is scheduled to begin in October 2004, when B. Braun will begin producing different versions of the innovative Ecoflac plus infusion solution container for the global market. LIFE will almost double the previous production of infusion solutions in Europe. To supply international markets at competitive prices and open up new markets, B. Braun is relying on optimized production processes and a new generation of production technology.

Against fierce competition, Siemens and its partner, Lang und Peitler, won the contract to provide automation of the package unit controller (PUC), including linking the PUC to the MES level. The project involves the coordination of about 70 package units from 10 different suppliers and will employ the Simatic PCS 7 V6 process control system. Siemens modified the existing qualification and validation system with B. Braun in advance, based on the latest GAMP 4 regulations. Siemens is not only managing the project and writing the specifications but is also supplying and configuring all the hardware and software – and is responsible for the qualification and commissioning of the entire PUC system as well.
Current trends and developments in process instrumentation

Portfolio for the Future

Sensors play a fundamental role in process automation: they are the eyes and ears of production, and the information they provide forms the basis for every aspect of process control. For this reason, in the late 1990s Siemens considerably expanded its range of process instrumentation equipment by investing more in research and development and also by making specific acquisitions. Siemens is now able to offer a comprehensive range of equipment, from flow and filling level through weighing technology, gas chromatography, and spectrometry, as well as an extended gas analysis system. Siemens also uses its extensive automation know-how to turn new technological developments into concrete solutions for the process industry.

Process automation systems are becoming increasingly complex, particularly with the emergence of digital fieldbuses and powerful MES software packages. In order to be able to offer a complete portfolio of modular automation solutions, it is necessary to have the know-how to develop the most important systems and components synchronously in the same direction. This necessity was the impetus behind the strong consolidation process over the last 10 years, from which Siemens has emerged as a major provider of automation solutions.

Reliability par excellence

Magnetic-inductive (MID) flow meters are the most commonly used electronic flow meters, thanks to their accurate and reliable measuring results and simple installation, commissioning, operation, and maintenance. They are suitable for the flow measurement of almost all electrically conductive liquids, including slurries, pastes, and pulps. Temperature, pressure, viscosity, and density have no influence on the measuring result.

The new MID Sitrans F Magflo MAG 8000 from Siemens is ideal wherever long lifespan and minimum service requirements are decisive criteria. The flow meter operates with an extremely effective battery that lasts six years and can therefore be operated without an external power supply – for example, as an external field device in the water supply. The measuring range covers three orders of magnitude so that the device encounters no problems with great fluctuations in flow. Since the device is designed with an IP68 degree of protection, the MAG 8000 can be installed without an additional enclosure directly at the base of the supply lines.
The greater complexity of the systems also has the result, however, of increasing installation and life-cycle costs. To counteract this trend, Siemens began, several years ago, basing its automation products and systems on as homogeneous and standardized a technology platform as possible: Totally Integrated Automation (TIA). Throughout the life cycle of a plant – from initial installation to maintenance and care – TIA leads to enormous savings.

To be able to exploit the advantages of TIA equally in all industries and processes but still offer specific solutions, Siemens is currently developing TIA into a universal technology platform that can easily be used as a basis for industry-specific development. With the consistent expansion of TIA, it seems clear that following the increasing decentralization of systems, self-organization and even virtual technology will find a foothold in automation.

**Unity in variety**

Despite the processes of consolidation and standardization on the manufacturer side, plants still usually consist of a mixture of devices from different manufacturers that are connected by and communicate via various interfaces. It is obvious that such a network of devices cannot be managed without efficient process instrumentation engineering. One example of such a manufacturer-independent tool is the Simatic PDM (Process Device Manager), an integrated part of the Simatic PCS 7 process control system, which can communicate with more than 700 devices from various manufacturers. The only precondition is a HART Device Description, which is usually available for any new device.

**Intelligent asset management**

Sensors are the basis of modern requirement-oriented asset management. Using sensors, a maintenance server can collect and display all the information necessary for maintenance. The MES-level asset management system can also be integrated via standardized interfaces. The product data and information required for maintenance are usually available directly – in most cases via the Internet. The processing and visualization of this information assumes that all components that supply and process information are networked – a requirement satisfied by TIA. One example of the advantages of intelligent asset management with the aid of status monitoring by sensors has been implemented by Siemens in the Pointek CLS 300 capacitive filling-level switch.

Maintenance becomes necessary when the limit switch is operated in caking media. The limit of wear may be reached and the switching function no longer guaranteed in the event of increasing encrustation. The degree of encrustation and the probable remaining life is calculated and displayed by the diagnostic station. Graduated maintenance messages can be generated with the aid of an operating-hours counter. The limit values at which alarm messages are transmitted can be adapted to user-specific maintenance intervals. As a result, the user knows when the sensor will fail without maintenance and is actively prewarned.

**Digital future**

Profibus has become an important communications standard in the world of automation in recent years and covers the entire process, from the control to the field level, with one protocol – and, with the Profibus PA variant, even as far as explosion hazardous areas of production. In

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**Series 6 “in situ”**

The 6 series analysis equipment family has been expanded by a new addition. The new LDS 6 laser diode spectrometer combines the compact, service-friendly design, the user-friendly operation, and the network capability of the 6 series with the well-known excellent performance data of the in situ laser diode gas analysis system, with which a number of IR-active substances can be measured.

The LDS 6 makes no compromises in performance: robust fiber-optic sensors, a self-calibration function, and the split-second cross-interference-free measurement provide accurate results even under extreme measuring conditions – for example, directly in hot flue gases.

**Do your mass**

The Sitrans F C measuring instruments determine the mass flow directly and with high precision using the Coriolis measuring principle. In addition, the devices also determine exact volumetric flow, density, fractional flow, and temperature. They are easy to install and are not sensitive to external vibrations.

All measuring sensors consist of a single tube without welding seams and can therefore be cleaned easily with CIP systems or steam.

The most compact example of the Coriolis-flow measuring instruments is the Sitrans F Massflow MASS 2100 DI 1.5. The mass flow meter can be connected with a single quick-release clamp and a single multipole connector – fast and low cost. The device can be installed and commissioned in just 10 minutes. The central block and the balanced pipe loops guarantee reliable long-term stability and eliminate influence from process conditions.
production plants that have both a process and a discrete production part, all the logistics can be operated with Profibus.

Although the majority of sensors installed today are still connected to the control system by a 4-20mA interface, a large number of newly installed devices are equipped with digital interfaces (or digital information can, as in the case of HART, be transmitted via the analog interface). Via digital communication systems such as Profibus, additional information – such as current device loads, failure probabilities, or information about the device status – can be transmitted to the master control system.

At the same time, progress in microelectronics allows ever-greater computer performance in a confined space, with a simultaneous drop in energy consumption. Functions that were previously performed by the hardware and software of the control system are now often moved to intelligent peripheral components – for example, complex diagnostic and control functions. As a result, an increasing percentage of devices are equipped with their own intelligence. It is likely that within a few years only process instruments that communicate with the control level via a digital bus protocol will be available.

**Big performance “miniaturized”**

Another result of innovations in microelectronics is that complex technologies can be accommodated in increasingly compact devices, making them of interest for local application directly on site. One example is mass spectrometry, which for many years was performed only as a sensitive analysis process in large lab spectrometers. With the Quantra, Siemens has developed a compact, low-cost Fourier transfer mass spectrometer that can be used online in the process, thanks to increased computing performance and miniaturized physics. The same holds true for gas chromatography, which has been close to the process for longer but now for the first time, with the MicroSAM, can be installed directly in the plant without an analysis cabinet.

One application that demands extreme miniaturization of devices is the microreactor, such as is used in pharmaceutical production as a process variant. However, such plants have previously been constructed only in a laboratory environment and without professional automation technology. In a project sponsored by the German Ministry of Education, Science and Research, Siemens developed a prototype microreaction plant equipped with industrial automation technology in cooperation with other project partners.

**Basis of a successful strategy**

The expansion of the company’s portfolio for the process industry is a central component of Siemens’ business strategy. An important part of this portfolio is and will always remain sensors and devices for process instrumentation, which are undergoing continuous development and will be integrated into the Siemens system landscape even better in the future.

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**Find out more:**

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**High-tech for the process**

The Quantra is the world’s only FT-ICR mass spectrometer that is compact and inexpensive enough to be used in the daily process routine.

Quantra has an extremely good mass resolution, can identify substances with almost identical masses reliably, and has been designed for use in the harsh everyday industrial environment. It needs no external vacuum pump and requires only a permanent magnet rather than the superconducting magnets normally used.

**Small gas chromatograph with a big performance**

State-of-the-art microelectronics ensure that a whole process gas chromatograph can be accommodated within a space of just 25 by 23 centimeters. The MicroSAM includes all the components necessary for separating and detecting the measuring substances in a pressurized housing.
Simatic PCS7 Box is the latest variation of the PCS7 process control system and combines all the components of a classic control system in the compact structure of an industrial PC: process visualization and engineering system, fieldbus, and SQL-based archive system.

The powerful Win AC component Slot-416-CPU is used as an integrated hardware controller. The standard input and output modules of the distributed Simatic ET 200 systems are linked by the Profibus DP interface of the Slot-CPU.

Simatic PCS7 Box is designed for small process applications such as pilot plants, laboratories, or packaging units and is also ideal for process engineering companies. The system opens up totally new implementation possibilities because it offers a small footprint and eliminates the additional wiring usually needed between the automation system, the operating system, and the engineering system.

Everything on one PC
All control and monitoring tasks run on one PCI card in the PC with a dedicated power supply. Consequently, the automation solution runs independently of the main PC and will still work even if the PC fails or is switched off. PCS7 Box is a full-fledged control system with all the important properties of PCS7, such as compliance with 21 CFR Part 11, and it is compatible with the S88-compliant Simatic Batch and the S95-compliant Simatic IT.

Simatic PCS7 Box can, of course, be integrated into existing Simatic PCS7 systems. This allows established process control know-how to be used; there is no need to waste time and money creating new software or retraining operating personnel.

Flexible and expandable
Simatic PCS7 Box can be easily extended because it uses standard PCS7 components, allowing other hardware and software components to be added at any time. The decisive advantage for the user: If requirements change because a test system is to be expanded in a production plant, for example, this compact solution can be extended with further control system components.

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Control System on a PC: Simatic PCS 7 Box
Magic Box

From office applications to the plant floor, PCs have become ubiquitous in today’s production processes. So for small applications, why not just put a complete process control system on a PC and use technology that is already available? This is exactly what Simatic PCS 7 Box accomplishes.
Flexible Processing with Simatic PCS 7

Problem Solved

To meet the strict international requirements for the manufacture of pharmaceutical products, Hoffmann-La Roche pharmaceuticals in Grenzach-Wyhlen had to equip its solutions plant with a new process control system. Good teamwork and the user-friendly Simatic PCS 7 ensured a trouble-free migration.

Hoffmann-La Roche manufactures, packages, and sells pharmaceutical products, including sterile bulk solutions produced under clean-room conditions at the Grenzach-Wyhlen site.

Modernization according to strict regulations

The solutions plant in Grenzach, completed in 1998, consists of two preparation tanks and transfer pipes to feed the solutions through a filtration unit into two mobile storage tanks. The plant is cleaned and sterilized by an integrated CIP/SIP system. Because the existing process control system no longer met the increasingly stringent cGMP (current Good Manufacturing Practice) requirements and the rising demands of company operation, Hoffmann-La Roche decided to upgrade the process control technology in 2002.

The company chose the Simatic PCS7 process control system, based on convincing references from within the pharmaceutical industry as well as on the efficient and flexible programmability of the system. The fact that Siemens would assist Hoffmann-La Roche in complying with the cGMP regulations and was able to offer excellent local support were also points in Siemens’ favor.

The PCS7 process control system (with the Simatic Batch package) controls and enables the visualization of all processes in the system. The management information system MIS-Light archives the process data and the Simatic Advanced User Administrator ensures uniform access control in accordance with the strict regulations of the Food and Drug Administration FDA and the European Medicines Evaluation Agency EMEA.

In automatic operation mode, the basic functions of the Simatic Batch package automatically execute, control, and log all batches. The automation solution also allows manual operation of the plant, enabling the operator to start basic functions without using recipe management. An additional revision mode has also been implemented, allowing every individual unit to be operated from the operator screen.

Start on schedule

Production began on schedule after qualification of the plant – due in large to the close and cooperative partnership of all those involved at Hoffmann-La Roche and Siemens.

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Innovation in the Balance

“Innovation is the lifeblood and the driving force of the pharmaceutical industry, as well as a key to any improvement in medical care. For over 100 years, Europe has been a powerhouse of pharmaceutical research and innovation. In 2002 alone, research-based pharmaceutical companies have been investing nearly 20 billion Euro – almost a fifth of all industrial research and development in Europe.”

Yet, Europe’s pharmaceutical industry faces a series of challenges in the near future, states Brian Ager, Director General of the European Federation of Pharmaceutical Industries and Associations (EFPIA). “Although it remains one of Europe’s best performing high-technology growth sectors, the research-based pharmaceutical industry in Europe has gradually seen a steady transfer of its research and development activities to the US, where policies and market conditions are more favorable to pharmaceutical innovation.

The ability of European companies to fund increasingly costly research and development is declining under economic, technological and regulatory pressures. New medicines are too often perceived as a cost, or a threat to healthcare systems, rather than an investment and a benefit.

Costs put restraints on innovation

At the research stage, it has become harder and more costly to get promising new medicines through the pipeline to market. The rise of biotechnology and our expanding knowledge of genetics has expanded the possibilities of creating new solutions for treating and preventing diseases, but made the task more complex. Due to the growing sophistication of products and the complexity of regulatory requirements it now takes an average of twelve to thirteen years to turn a new promising compound into a marketable medicinal product. Each new medicine costs in the range of 600 to 900 million Euro to develop. Half the medicines that reach the final stage of clinical trials stumble at that hurdle. Only three out of ten marketed medicines produce revenues that match or exceed average research and development costs.

The escalating cost of research and development and the huge risks involved – since success is in no way guaranteed or proportional to the huge amount invested – make individual companies highly vulnerable. The ongoing restructuring and consolidation of the pharmaceutical industry through mergers and acquisitions is primarily a response to the need to secure industry’s long-term competitiveness in a global, highly complex and increasingly competitive environment.

European Union initiative addresses industry concerns

The widespread concern caused by the diminishing competitiveness of the European pharmaceutical industry has lead the European Commission to put forward a package of practical proposals for enhancing innovation and provision of medicines in Europe.

EFPIA is part of the process and fully supports the stated objective to help the European-based pharmaceutical industry regain its competitive edge and continue to make a valuable contribution to public health and the European science base.”

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NVI and Siemens develop a standard for bioreactor instrumentation, analysis and automation

Long-term Cooperation

At the moment it’s all part of the daily routine for every biotech company: virtually every new bioreactor is instrumented and automated device-specifically. This practice has led to the development of isolated solutions that are difficult to integrate into an overall concept, despite the fact that both the processes and the equipment are very similar for the majority of applications. The Nederlands Vaccin Instituut (NVI) was looking for an alternative to this time- and cost-intensive procedure and partnered with Siemens to create a detailed and comprehensive user requirement specification that will form the basis for all future bioreactor projects at NVI.
NI, headquartered in Bilthoven in the Netherlands, is a state-owned institute responsible for guaranteeing the availability of all vaccines required for government vaccination programs. In addition, NVI also has its own large research department. Consequently, a wide variety of processes are run in Bilthoven in a number of different bioreactors – from small tabletop bioreactors up to fully automatic bioreactors with a capacity of several hundred liters.

Lab-to-production platform
The automation system used in these bioreactors, however, was no longer state of the art. Moreover, NVI also wanted to create the possibility of setting up all plants and processes on a uniform automation and instrumentation platform to improve the efficiency of the processes, shorten implementation times, and simplify validation. At the same time, NVI was looking for a way to link research and production in a more tightly integrated network and implement a common lab-to-production platform. The long-term aim of all these measures was to reduce the overall production costs, as vaccines must be produced in large quantities and as inexpensively as possible.

For the implementation of the standardization plans, NVI decided to work in close cooperation with Siemens from the very start to achieve a tight integration of biotechnology and automation experience. Siemens had already proven its expertise in the automation of biotechnology projects on other occasions – the Simatic PCS7 process control system, for example, has been in successful use for some time in media preparation at NVI. NVI was also impressed by Siemens’ involvement in such a prestigious project as Parametric Release (see page 14). Thijs Veerman, general director of NVI, confirms: “When an automation provider like Siemens is involved in a long-term project such as Parametric Release, we can be sure that that company is serious about its commitment to biotechnology.”

Pilot plant exploits the advantages of standardization
Within this year, NVI will be implementing the user requirement specification (URS) resulting from its close cooperation with Siemens in a new plant. The S4 category – the highest security level – pilot plant is to bring to market maturity a process developed on a laboratory scale, resulting in the production of a new kind of vaccine against pertussis. All the components of the plant have been built and automated for NVI according to the URS – and the advantages of the standardization already appear to be paying off. The function and design specifications for the Simatic PCS7 control system for the pilot plant were compiled within a few weeks, so construction – along with the almost simultaneous implementation of the control system – can commence in April. Because Siemens had proved to be an extremely knowledgeable and experienced partner in the initial collaboration, NVI also chose Siemens to provide the control technology and introduced Simatic PCS7 as a standard for the first time. The pilot plant is scheduled to begin production this fall.

Separation of process and equipment
The joint interdisciplinary project team of NVI and Siemens first analyzed all the various existing bioreactors at NVI, including those used in media preparation, and compiled a list of typical processes and tasks. The bioreactors were divided into typical modules with corresponding parameters, and then the instrumentation and control strategies for the respective modules were defined and determined.

However, to be able to divide the process into standardized modules, it was absolutely essential to create a strict separation between the recipe (and thus the process-technical control) on the one hand and the equipment used for it on the other. This approach enables a typical bioreactor to be set up without any reference to a specific application; the recipe
used by the bioreactor contains the application-specific instructions. This separation, which complies with the S88 recommendations, is being implemented at NVI as part of the standardization project.

**Typical tasks**

A batch process in biotechnology consists of a series of several typical process steps. First, the bioreactor must be sterilized, along with the connected systems, unless they are separated from the bioreactor by the appropriate sterile filters. Then the nutrient media are added and the reactor is inoculated with the cell culture. This is followed by the cultivation phase. In some processes, the medium is changed and reinoculated with a second culture. At the end of the process, the cultures or the desired products are harvested.

Various parameters must typically be monitored and controlled during the process – for example, temperature, pH value, or dissolved oxygen.

**Modular, generic, reusable**

The results of the joint analysis were evaluated and recorded in an extensive user requirement specification (URS). This URS will form the foundation for instrumentation and automation specifications of all future bioreactor projects at NVI and will also be used in the conversion of existing systems. The documentation of the modularization and standardization phases also provides the basis for later validation of the equipment. Every single module possesses the appropriate validation documentation, from the URS to the test results, in addition to the algorithm and instance-specific parameters. This object-oriented method means that only Installation Qualification (IQ) is necessary for validation when the modules are reused – an enormous savings in time and costs.

The URS describes a library of equipment modules and the corresponding control strategies. Different bioreactor types and different processes and applications – in both research and production – have been taken into account.

Thijs Veerman was especially impressed by Siemens’ customer-oriented approach to the project. “We did not want a highly complex and infinitely powerful solution,” he said, “but rather a system that would support us in the effective reduction of our production costs. The Siemens team did not simply try to sell us their products – they helped us to find the simplest way to meet our requirements. This showed us that Siemens understood our situation.”

**An excellent basis for further projects**

The additional process and biotech expertise that Siemens gained from this project will benefit future projects as well. Negotiations are currently under way with other companies about modularizing and standardizing their bioreactor processes on the basis of the equipment modules.

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Totally integrated quality assurance for vaccine production

**Parametric Release**

Quality tests are obligatory at the end of every production run – whether the products manufactured are automobiles or pharmaceuticals. These quality tests are particularly significant in the pharmaceutical and biotechnology industries. At present, it is extremely difficult to get real-time information about the processes in the bioreactor. It is not possible to ascertain whether a process took place according to specifications, whether the reactor was reliably sterile, whether the media were free from contamination, or whether the end product was manufactured to the required level of quality. This information is only available much later, after testing. A representative sample must be taken from the finished batch and examined in the laboratory – and possibly even in animal experiments – at great expense.

These examinations often take a few days to several weeks to complete. They are not only a considerable cost factor but is also prone to errors, as the tests can only determine a condition that is already a thing of the past when the tests are completed. Until now, biotech companies have taken great care to ensure that only perfect products leave their production plants (Bio Capacity Shortage). If there is the slightest doubt that a batch may not be up to standard, it is rejected. In view of the current market changes in the health sector, however, many biotech companies are asking themselves whether they can still afford waste rates averaging 30 percent, and how they can cost-effectively guarantee the high quality of their products in the future.

The U.S. Food and Drug Administration has taken up this subject in its initiative promoting a scientific and risk-based method in pharmaceutical production. In an initial draft of a future directive, the FDA suggests a quality assurance system that is already built into process planning and is totally integrated with the whole production environment. The basic idea is to control the entire manufacturing process so that only products of perfect quality can be produced.

The core of this FDA initiative is the process analytical technology (PAT), with which process states can be measured and evaluated online during the process.
Siemens has adopted this initiative and has already implemented it in a PAT solution for bioprocesses. This enables the process to be mastered in such a way that the end product achieves the required quality reliably and reproducibly. Parametric release – unlike the release of products after quality tests – is now based on proof that process specifications have been fully satisfied.

Interdisciplinary cooperation in the Netherlands

Prompt batch release based on process information – parametric release – is an important topic in the pharmaceutical industry. One of the companies currently pursuing this goal is the Nederlands Vaccin Instituut (NVI). In a four-year project, the institute is working with Siemens and fermenter manufacturer Applikon to research a solution that should largely replace expensive laboratory tests. The parametric release (PaRel) project, due to last four years, is also sponsored by the Dutch government. One aim of the PaRel project is to further develop near-infrared spectroscopy so that it can be used as an instrument for in-line bioprocess monitoring. In this way, constant compliance with process specifications can be guaranteed.

A prerequisite for parametric release is the availability of a detailed functional process model and PAT measurements. Both provide information about the parameters that could influence the process and allow conclusions to be drawn about quality-relevant process information. The PaRel project can use the results of the user requirement specification (URS) at NVI for this.

The final step is to assess the current state of the process (from the process model and the PAT process information, using a mathematical correlation) and to be able to forecast further developments in the process. This makes it possible to measure quality-relevant deviations and take appropriate action without laboratory examinations.

Promising results

Research and development work on the analysis and mathematical modeling is still in progress, but initial results already look very promising. The next step planned by NVI is to implement online acquisition of the process quality parameters and evaluation by PAT fingerprint technology within the year.

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Founded in 1980, Cosmed’s original mission was medical device sterilization. When the company moved from the New York area to larger facilities in Newark, New Jersey, its focus expanded to sterilizing spices. Since then, Cosmed has built new facilities in nearby Linden, New Jersey, and Baltimore, Maryland, they have also opened sterilization plants in Texas, California, Illinois, Nevada, and Rhode Island.

In 1995, Cosmed began thinking about integrating process controls into other data streams flowing into that facility. At the time, separate vertical production-related systems each generated printed reports, data which was manually entered into other systems. Cosmed contends with a multitude of information streams, including incoming customer orders, recipes which direct how sterilizing equipment should operate when processing specific target products, reports with historical data showing how specific sterilizers were or are operating moment-to-moment in Cosmed plants, and business information from Cosmed’s front office.

Cosmed established objectives including reports that the new system should generate; system inputs/outputs; alarms; cross-application integration, and others. “We are a small privately owned company looking for inexpensive ways to manage our business,” Operation Vice President David Howe notes. “We wanted to keep the solution as simple as possible using off-the-shelf technology.”

Simatic IT improves supply chain visibility and turnaround times

Managing Process Information

Since they first installed Simatic IT in one of their facilities, the sterilization expert Cosmed has seen a dramatic decrease in numbers – numbers they are very happy about: Nonconformity rates where decreased by an order of magnitude and product turnaround times shrank from several days to just 24 hours. That is why Cosmed is more than just content with the new MES solution and has already implemented Simatic IT in other sites.
State-of-the-art yet low cost technology

To enable Cosmed to accomplish all its objectives, Siemens has installed Simatic IT Framework, designed to provide full support for existing industrial standards, and offer a highly customizable, scalable, component-based approach. The first implementation of Simatic IT was completed in 1999 at Cosmed’s Texas facility.

Simatic IT creates secure Internet links, which enable customers to enter orders, browse schedules, and review performance data from their own business workstations. Customers receive automatic email notification when loads are received, sterilized, and shipped. “We now quantify and codify production processes for specific customers in an electronic database and push that information across channels provided by the Simatic IT Production Suite,” David Howe explains.

Implementing the Simatic IT based solution was also one of the most cost effective ways to solve Cosmed’s integration task. Had it adopted high-end alternative systems, Cosmed would have required ISDN connections at all its factories, spending hundreds of thousands of dollars for engineering, installation, and operation. “To put up this system,” Howe says, “Cosmed is now paying less than $500/month per connection, as little as $50/month, and we can connect to the VPN using a software client for outside connections rather than requiring a connection appliance.”

Process Improvements Cut Costs, Reduce Liability

Today Cosmed directly enters recipes into the system without using intermediate forms and procedures. In the past, new processes were designed in a word processor in a format which was understood by the customer. Once the design was accepted by both parties the process was translated into a recipe by a staff engineer.

Any error in the engineer’s input could result in an expensive process failure. With the recipe designed in a format which can be understood by a layman, Cosmed eliminates the liability of reentering the process into the system after it has been accepted by all parties.

“That is a major improvement for us,” David Howe says. “Our typical product sterilization process involves receiving, preconditioning, sterilization, aeration, and shipping,” David Howe explains. “Until we applied Simatic IT, we manually moved product from process to process, which was labor-intensive and time-consuming. Now we simply move the product into a single mammoth process chamber, capable of accommodating trailer-loads of products, and we apply Simatic IT ‘on top’ of the entire process. Products stay in one place while the Siemens system executes each process step there, as the recipe directs. We continually optimize the process we use around the recipes, focusing on minimizing nonconformities, minimizing downtime, and eliminating redundancy. Before being changed over to the new system, our facilities experienced non-conformity rates of about one percent. Cosmed facilities using Siemens Simatic IT are experiencing nonconformity rates that are a full order of magnitude lower.”

Turnaround has also changed dramatically. “Our old system guaranteed Friday delivery for products received Monday for processing. Now, advance-scheduled products received Monday are out of our plants within 24 hours.

And although we could perform parametric release before, Simatic IT now measures process performance with such depth and issues such complete management reports that our customers feel a greater sense of comfort now that they can rely on the results.”

Integrated compliance

Following the first Simatic IT application, Cosmed has retrofitted Simatic IT into other facilities. In addition to filling and managing the supply chain, Simatic IT enables Cosmed to access historical data concerning any process performed at any time since the system was introduced. Since the system provides full support for existing industrial standards and ensures precise execution of all process recipes, data it stores constitutes proof of compliance with FDA and other regulations.

Right now, Cosmed and Siemens are in the process of defining the upgrade of the existing applications scheduled this year.

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Largest ever fail-safe project in Denmark

Fail-Safe Pharma Expertise

The Danish engineering company Novo Nordisk Engineering chose Siemens to supply the largest ever Fail Safe system in Denmark. The system is installed at one of the world’s largest insulin factories, owned by the pharmaceutical company Novo Nordisk, in Kalundborg.

Over a period of 36 months and with continuous planning, the Danish engineering company Novo Nordisk Engineering has built an enormous insulin factory, containing complete production lines from raw materials to finished bulk products. Insulin is used to treat diabetics. The factory was built for Novo Nordisk, Denmark’s largest pharmaceutical company. Novo Nordisk has invested DKK 2.5 billion in the factory, known colloquially as IBP (Insulin Bulk Plant).

IBP is the most sophisticated factory of its kind and is four times the size of conventional insulin factories. The continuous production lines have necessitated the installation of a comprehensive, highly developed Fail Safe system in order to ensure the greatest possible protection of personnel, production and the environment while at the same time allowing the plant to be shut down in a safe and appropriate manner if, for example, a leakage of inflammable fluids should occur.

Tight schedule

Novo Nordisk Engineering (NNE) chose Siemens to supply the sophisticated Fail Safe system on the basis of a supplier survey and a firm belief that Siemens was capable of providing the necessary expertise for the task.

On the basis of NNE’s requirement and function specifications, Siemens supplied the entire Fail Safe system, complete with hardware and software and including everything from system design to the construction of the necessary panels. Siemens also installed the panels and the cables connecting the many units.

The software was configured on the basis of cause-and-effect diagrams provided by NNE. In addition, these diagrams were used to prepare the plans for quality control and testing that could ultimately demonstrate the functions of the Fail Safe system. Siemens was responsible for optimising system design on the basis of the chosen concept, and for providing the necessary hardware and system configuration.

The entire project was completed under a very tight schedule in which IBP was built and equipped in stages, each corresponding to a sixth of the final factory size. This allowed independent tests and trial runs to be performed in individual sections of the factory. It was a difficult process in which many of the tests were performed at night so as to avoid interrupting the production validation being carried out during the day.

Safe production

Large quantities of alcohol are used in the production of insulin. The Fail Safe system therefore includes a large number of sensors capable of detecting explosive gases. If excessive concentrations are recorded, the plant is partially or completely shut down. However, no more of the production line is shut down than necessary, allowing other parts to continue production. At IBP, the entire factory is supplied with raw materials from a central store. This design is more complicated.
than that of decentralized distribution and necessitates a very precise control of the system. The system therefore uses PLCs and Profibus technology, based on an open standard architecture. Both Profibus and the PLCs are approved by the German testing institute TÜV.

The Fail Safe system, which collects some 800 signals from the production lines, has three main functions: shared emergency stop, substance detection, and handling of alarms from the ventilation system.

Meets the most stringent requirements

Ethernet connections have been established at two operator panels in the two IBP control rooms. Fermentation and raw purification are monitored and regulated from one of the control rooms while fine purification is controlled from the other. The Fail Safe system is segmented in the same way as the process control system, thus making it simple to operate.

In addition, the system has a redundant design, meaning that one of the two CPUs in the control room PLCs is constantly on standby, ready to take over should the other fail. The two PLCs also double for each other if faults occur. Furthermore, the network connecting all 19 panels has a redundant design and communicates via Profisafe on a conventional Profibus DP net. Input and output signals are handled via a modular ET 200M-FS system.

The Fail Safe system meets the requirements of SIL 3 (Safety Integration Level) in accordance with IEC/EN 61508, the new EU standard which took effect this year. The Siemens Fail Safe system thus meets the most stringent of safety requirements. Among others, these include requirements on system design and tolerances, elevated monitoring levels and redundant wiring. The Fail Safe system therefore checks connections to all components continuously, and its redundant wiring allows the system to switch automatically to an intact network should faults occur. The system also meets the safety requirements contained in the EU machinery directive, EN 954-1. The system installed at Novo Nordisk is designed to SIL 2.

Flexible cooperation

“The Siemens engineers were extremely flexible, working both day and night when necessary. Often, the Fail Safe system had to be tested under very difficult working conditions where it was necessary to shut down other parts of the plant,” says Claus Danielsen, project manager at Novo Nordisk Engineering. “It was an ambitious plan, but there has been a willingness to cooperate from both sides. Considering that this is the first system to be installed by Siemens in Denmark, the project has run smoothly. Problems have arisen along the way, but both the Danish and German divisions of Siemens have put great effort into solving them.”

Find out more:
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AstraZeneca insisted on the highest levels of security and reliability in the power supply systems at its new factory complex for manufacturing tablets in Plankstadt. Totally Integrated Automation (TIA) and Totally Integrated Power (TIP) ensure that all production units are optimally supplied with power at all times.

AstraZeneca is one of the four leading research-based drug manufacturers in Germany. In Plankstadt, AstraZeneca produces innovative drugs for clinical and outpatient applications, among other things, in a new factory complex for manufacturing tablets.

TIA and TIP meet the highest demands

One of the most important components of any production system is the energy supply. The reliability and security of the energy supply is obviously of crucial importance for production, especially in the pharmaceutical industry, with its stringent quality standards.

In addition to requiring high levels of reliability and security, AstraZeneca also stipulated that the energy supply for the Plankstadt factory should help reduce the plant’s life-cycle costs by using maintenance-free resources. Moreover, the supply must have the ability to be connected to a central HMI station and the building control system.

Totally Integrated Automation (TIA) and Totally Integrated Power (TIP) meet these high demands and provide a uniform connection between the automation level and the process control system. This ensures that all systems – from safety relays to energy consumption to operation of the power switches – can be monitored and controlled from one place.

A constant supply

Two supply units distribute the energy through 20-kilovolt and 400-volt low-voltage systems. All plants are designed according to the n-1 principle: a secure power supply is also guaranteed during system failures – for example, if a transformer fails or has to be switched off for retrofitting or modifications.

The factory-internal supply uses a ring network to ensure a steady supply according to the supply security demand of the power consumers. A redundant supply through a parallel or ring circuit is available at all times. In addition, important parts of the plant (such as the computer or the Simatic controller) are connected to an uninterruptible power supply in the case of a total system failure.

Reliable power supply at AstraZeneca

Energy? Sure

Two main supply systems, redundant transformers, and optional ring or parallel circuit structures guarantee a reliable energy supply at AstraZeneca

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Simatic PCS 7 control system for Incinerator in Taiwan

Strategic Project

The new Wu-Jih incinerator plant is a key strategic project for CTCI, Taiwan’s largest EPC contractor. CTCI have significant experience in the design and construction of incineration plants, having completed six major plants since 1993. However, Wu-Jih is the company’s first BOT (Build-Operate-Transfer) environmental project. System reliability was a key issue when CTCI was looking for a process control system – and with Simatic PCS 7, Siemens Taiwan was able to secure the process control system contract for engineering, supply & site services.

The Wu-Jih Incinerator Plant is a new combined industrial and municipal waste incinerator commissioned by the Taichung County Government, Taiwan. The plant is designed to incinerate 600 T/d of municipal waste and 300 T/d of industrial waste whilst producing 25 MW of electricity. System reliability was a key element of CTCI’s selection criteria for the system. PCS 7’s flexible architecture and comprehensive redundancy features at all levels within the system provided the ideal solution.

Redundant, high-availability systems

The plant comprises two incinerator lines, plant utilities and the power generation area. Simatic PCS 7 provides integrated control for all areas. Each process area is equipped with a high availability redundant PCS 7 automation system. Remote I/O communicates via redundant fiber-optic Profibus DP providing a cost effective and robust I/O solution.

Dual fiber-optic Ethernet ring communications are installed at the plant level for communications between controllers and the servers, and a single electrical Ethernet ring for redundant communications with the engineering & operator stations. A multi-client / server architecture is employed with redundant servers and multi-screen engineering and operator stations providing flexible engineering and operator interfaces. Three additional operator stations will be installed in the office area and a demonstration room in future.

Control and monitoring of the power systems has been implemented with a Sicam Sequence of Events (SOE) system that time-stamps the data at a resolution of one millisecond. The Sicam system is seamlessly integrated into PCS 7 so that the data are available directly within the operator stations without the need of separate SOE viewers or printers.

Standardization for future projects

CTCI and Siemens engineers have collaborated closely during project execution to develop a set of standard control modules for incinerator plants with a view to re-use them on future incinerator projects. The PCS 7 platform has proven to be a good fit for the continuous and discrete control requirements inherent in an incineration plant.

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Simatic IT and Simatic PCS 7 integrate processes

Clean-and-Clear Production

Reckitt Benckiser sells its products successfully in more than 180 countries, with well-known brands such as Calgon, Calgonit, Kukident, and Sagrotan. The company understands how to retain its leading position in a fiercely competitive market with innovative products. It is thus no surprise that the production facilities in the company’s Ladenburg plant must always be state of the art. The automation technology for the production system was completely overhauled last year and converted to Simatic PCS 7 – with striking results: productivity was increased considerably, while the vertical integration of information with Simatic IT ensures greater transparency and availability.

The final decision for modernization was made in August 2002. The PCS7 process control system was selected – not only because Reckitt Benckiser had already had positive experiences with the Simatic technology. The strength of PCS7 lies above all in the uniformity of the Totally Integrated Automation (TIA) platform, which is the foundation of all Siemens automation solutions. PCS7, as an integral part of TIA, enables integration of all regulation and control systems into a common system, which makes production particularly transparent and reproducible. Additional convincing arguments were the ergonomic design of the HMI level and the possibility of linking the system to the company management information systems via standardized products and interfaces.

Extremely tight schedule

In the implementation, Reckitt Benckiser coordinated the necessary equipment retrofitting while Siemens was responsible for delivering the hardware and switchgear cabinets, completing all the electrical installations, creating the software, and integrating all components. Testing, commissioning, and trial operation were performed jointly in the end.

Networking and integration

Production is divided into three large units: the logistics section, where the solid and liquid raw materials are delivered (either in BigBags by truck or by tanker) and stored; the mixing plant, the actual heart of production, where the powders are mixed with liquid components and stored in containers for manufacture; and finally the production lines on which the tablets are pressed or the powder is packaged.

The company’s existing automation technology no longer met the standards of modern production plants, however. Reckitt Benckiser wanted to increase productivity and simplify process optimization, in particular by networking and integrating all information more closely. Another aim was to minimize the number of interfaces and different components and to build up the automation system on a uniform platform. In addition, the interaction between the individual process steps had to be improved.

Standardized components

The final decision for modernization was made in August 2002. The PCS7 process control system was selected – not only because Reckitt Benckiser had already had positive experiences with the Simatic technology. The strength of PCS7 lies above all in the uniformity of the Totally Integrated Automation (TIA) platform, which is the foundation of all Siemens automation solutions. PCS7, as an integral part of TIA, enables integration of all regulation and control systems into a common
verters of the weighing units were integrated with the process control system via Profibus DP.

All material containers were equipped with writable and readable data chips of the Moby F non-contact ID system, which was also seamlessly integrated with PCS7. This enables Reckitt Benckiser to trace the flow of materials through production. The previous recipe system, based on a SCADA application, was also replaced by Simatic PCS7. The basic recipes for the production were downloaded via a central Simatic IT server connected to the existing ERP system. (Simatic IT is the modular MES from Siemens; in addition to the communication functions between the company and automation levels, it also offers a number of coordinated functions that optimize the plant operation during all phases of production.) The more flexible processing of the recipes in the AS 417 automation systems increases the number of batches produced per day and considerably increases the overall production capacity of the plant.

Because production in Ladenburg runs around the clock, Siemens was given a time limit of four weekends with a maximum of 24 hours for the changeover. Thanks to the high degree of standardization of the PCS7 components, as well as the commitment and hard work of the project team, this extremely tight schedule was met.

Increased capacity and transparency

The conversion began with the replacement of the old weighing technology by Swarex M. The 63 new weighing controllers increased the dosing accuracy while speeding up the dosing processes. In addition, a considerable reduction in dosing variance was achieved. The frequency parameters. Operators can now monitor weighing processes continuously and intervene when necessary. A sophisticated alarm system provides advance warning of initial deviations from the nominal state in the process and points to possible causes in the event of a fault.

Further steps planned

Based on the success of the previous application, even closer coordination and monitoring of the production processes is planned. Reckitt Benckiser has already taken the first steps in this direction: the installation of a bar-code reader in the Big Bag raw material input and monitoring with Moby F at 12 dosing stations that supply material to 120 containers. The Moby F data storage and reading systems are integrated with PCS7 via Profibus DP and can easily operate in harsh ambient conditions.

The next step is already being planned: the entire production process – from incoming goods to discharge to the packaging units – is to be continuously monitored, evaluated, and archived.

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Schering is a research-based pharmaceutical company that makes major contributions to medical progress and improving quality of life through innovative medications. This area also includes diagnostic imaging solutions, which enable diseases to be diagnosed earlier and treated more specifically. These solutions supply the physician with important information about the condition of bones, vessels, and other organs. The best-known diagnostic imaging systems include magnetic resonance tomography (MRT) and ultrasound, in addition to the classic X-ray, as well as computed tomography (CT), a further development of X-ray technology. To improve the contrast between the different kinds of tissue, special radiopaque media are frequently used in X-ray, CT, and MRT examinations.

Schering continues successful collaboration with Siemens

One Building, One System

The partnership between Schering AG and Siemens goes back many years. The two companies previously collaborated on several successful projects at the Schering site in Bergkamen. The positive experience with these projects and Schering’s resulting confidence in Siemens’ pharmaceutical expertise were two of the reasons why Schering again chose Siemens for the automation of a new production in Berlin for sterile injection and infusion products.

Until recently, the production and packaging of Schering’s sterile products took place at two different sites. To optimize transport routes and save valuable production time, Schering has now combined all processes – from preparation of the solutions to packaging and delivery – in a new plant at a single site in Berlin. The new plant was to be built from scratch, including the process technology and all necessary electrical and process control installations, in a building that was being modernized and expanded at the same time. The focal points were recipe-controlled production and validation-related execution.

The plant was completed on a very tight schedule by a consortium consisting of a plant engineering company and Siemens as the supplier for electrical technology, field technology, and the process control system. The complex processes used in the manufacture of the sterile products require a highly sophisticated process solution that must be very closely linked to the corresponding control technology.

Based on the process and automation concepts of the Schering Technology/En-
From preparation of the solutions to packing: all processes are combined under one roof at Schering
Siemens implements innovative disposal concept for Infraserv Hoechst

Double Score

Due to the constantly increasingly complex composition of wastewater, specially adapted processes are penetrating areas that were previously the private domain of complex, multistage processes. Both ecological and economic considerations in this context make it necessary to integrate new waste-treatment systems into existing plant structures. The safe disposal of waste, the protection of the environment, and adherence to recycling principles can be combined in perfect harmony, as the project for Infraserv Hoechst impressively demonstrates.

Almost two years ago, the world’s largest production plant for the manufacture of inhalable human insulin went into operation at Industrial Park Hoechst near Frankfurt, Germany, in summer 2001. Another similarly large insulin plant has recently begun production in the Industrial Park as well. Relatively little wastewater is produced by these plants; however, due to the high nitrogen content and strict municipal requirements, this wastewater could not be disposed of in the biological wastewater treatment plant operated on site. As soon as this became evident, the industrial park operators, Infraserv Hoechst, began planning a new treatment plant for wastewater containing urea.

Concept with double benefits

After comparative studies of various processes and numerous location discussions, Infraserv Hoechst decided to build an innovative two-stage evaporation plant in the industrial estate’s sewage sludge combustion facility.

Infraserv had worked successfully with Siemens in the past and was therefore certain that Siemens had the expertise to provide the necessary technology for the new treatment plant. It was also important to
link the control technology with the already installed Teleperm M systems.

The thermodynamic design and the materials for the evaporators were specified by Siemens and built by a plant engineering company with many years of experience in building special evaporator systems. By using the steam produced by the second evaporation phase to heat the first evaporation stage, the previously necessary amount of steam can be reduced by almost 50 percent. Preheating the wastewater containing urea with the steam condensates saves additional energy. The steam produced in the heating boilers of the sewage sludge combustion plant heats the second evaporation stage.

This sophisticated concept of combining the various plants finally tipped the balance in favor of the decision to concentrate the wastewater by evaporation. Another advantage of this plant combination is the use of the resulting concentrate in the combustion plant to reduce NO\textsubscript{x} concentrations in the flue gas. This method is well known in combustion technology and is used in many power stations, combustion plants, and in the cement industry to minimize flue gas NO\textsubscript{x} emissions. As a result, Infraserv Hoechst can both clean the wastewater containing urea and reduce NO\textsubscript{x} emissions – and therefore benefits twice from the new disposal concept.

**Close cooperation for trouble-free implementation**

Reliability was the key factor in the choice of the control system. Because Simatic PCS7 could produce good references in many other projects, Infraserv also chose Siemens for the process automation – not least because Siemens had already developed and successfully implemented a mature migration strategy for the Simatic PCS7 process control system on many occasions. In addition, the Infraserv personnel had had positive experiences with Teleperm M.

Siemens was responsible for the compilation of the license documents and the engineering, construction, assembly, commissioning, and training of operating personnel. It was important to minimize the disruption of ongoing operations during the installation and commissioning of the new plant. The Siemens team, headed by project manager Karlheinz Steyer, therefore worked very closely with the staff of the sewage sludge combustion plant and operation assistant Rainer Weber at Infraserv Hoechst during all phases of the project. That way, the new facility could be integrated into the existing plant structure and a rapid, trouble-free implementation of the project during the ongoing operation of the combustion facility was guaranteed. The new plant was connected to the company’s steam system during a scheduled operating shutdown of the sewage sludge combustion plant.

The new evaporation plant was completely automated with Simatic PCS7. Moreover, Siemens also supplied the pump motors. The new control system was linked to the existing Teleperm M systems via a gateway – during ongoing operation.

**Successful synthesis of economy and ecology**

“We have satisfied both the requirements of the pharmaceutical companies and the aims of Infraserv Hoechst: the wastewater generated is treated and disposed of safely, while at the same time the plant operates absolutely reliably and cost-effectively,” Karlheinz Steyer noted, commenting on the results of the project. “And, of course, the evaporation plant also complies with current regulations.” Infraserv Hoechst also has a favorable impression of the Siemens team performance, as a customer feedback evaluation at the end of the project revealed.

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High above Industrial Park Hoechst: the new evaporator just before installation
Simatic PCS 7 controls new steroids plant

**A Whole Bunch of Benefits**

The Italian pharmaceutical company Farmabios is constantly striving to improve its products through ongoing research and new syntheses strategies while at the same time reducing production costs in order to be able to supply even more customers on all world markets. In 2001, Farmabios decided to double its steroids production capacity by building a new totally automated batch production plant. Siemens was able to secure the automation contract, and with its high performance, reliability, and user-friendliness Simatic PCS 7 ensures production quality while greatly reducing downtimes.

Farmabios S.p.A is situated in Gropello Cairoli, Italy and specializes in the production of active pharmaceutical ingredients, in particular steroids and antibiotic cephalosporines. Since the products are also exported to the USA, all production processes including automation systems have to be compliant with FDA regulations.

Moreover, Farmabios required that the system of the new steroids plant had to be very robust to ensure high plant availability while at the same time being flexible enough to allow manual changes to recipe parameters as well as multi-purpose use. Also, the new system should allow for later expansions and provide open interfaces to integrate third-party and legacy systems.

**Comprehensive solution based on Simatic PCS 7**

Simatic PCS 7 and Simatic Batch could meet all these requirements: the entire process control system features a complete redundant architecture at the level of supervision, control and network for high system availability. It can manage up to 1800 distributed I/O, including distributed modules located in the hazardous zones. Through Siemens Batch Flexible software, the main processing phases can be run in automatic as well as semi-automatic mode. The PCS 7 system controls all actions from raw material loading through synthesis up to air conditioning.

The local Siemens team, who was responsible for project development and implementation, chose a client-server architecture based on Windows NT to ensure maximum production security. Four of the five multi-clients are directly installed in the hazardous zone of the plant. PCS 7 also integrates a Simatic Siwarex weighing system and communicates via Profibus with other automation systems in the plant.

Thanks to the excellent Siemens project management, everything from specification data structuring up to the validation protocols was prepared compliant to cGMP recommendations and according to FDA regulations. Together with standard tools integrated in PCS 7, this greatly reduced validation expenses.

**Multiple benefits in day-to-day production**

Batch by batch, PCS 7 demonstrates its advantages in everyday production: shorter downtimes between batches increase plant productivity, while a better process control enhances production quality.

**Find out more:**

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Always ready to listen: Forum for Process and analysis device users

The continuous dialogue with customers and partners in all industries is an important part of Siemens’ company strategy – this is especially true in process automation and instrumentation. To further promote the dialogue with users, Siemens has founded its own forum devoted to process and analysis device users in the chemical industry. The aim of this forum is to provide background information and discussion points on important topics in process instrumentation and analysis as well.

forumchemical.pia@siemens.com

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The article “Cooperation in the Cement Industry” in Process News issue 4/2003 has lead to some misinterpretation regarding the Process Control System ECS of the Danish company FLSmidth Automation. Therefore we would like to clarify that FLSmidth Automation will of course keep their own ECS in their portfolio as an independent solution and technology provider of cement automation. Cemat based on PCS 7 will from now on be a preferred external process control system of the global leader of cement making equipment.
Field technology fully integrated –
costs drastically reduced!

Reduce hardware costs, simplify installation, speed up commissioning and enjoy optimum
maintenance with precise diagnostics and fast fault recovery. The solution: SIMATIC® PCS 7,
the process control system that fully integrates field technology, enabling direct access from
field-level engineering and operator stations. With all the advantages of Totally Integrated
Automation. And international field bus standard PROFIBUS-DP/PA (IEC 61158), redundant and
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deVICES – the largest line of intelligent field devices available. Cost-saving thanks to central
engineering, including the SIMATIC process device manager.

SIMATIC PCS 7. Setting a New Standard of Integration!

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