Listening to Leaks:
Acoustic leak inspection on process pumps with Sitrans DA 400

Good as Gold:
Braumat used for malt production at Viking Malt

Focus on Pharma
Solutions and strategies for a changing industry
In the buffer preparation at Chiron in Rosia, Simatic PCS 7 and Simatic Batch handle all process automation tasks including batch control.

RFID technology can contribute not only to higher process visibility but also to higher product safety.

Railway waggon weighing at Kali France is greatly facilitated by Siwarex FTA.

3 EDITORIAL

4 NEWS

Simatic PCS 7 automates space flight simulation system

Siemens Participates in US FDA Pharmaceutical Inspectorate Training

Mettler Toledo and Siemens: Partnership brings first results

Award-winning flow meters at Manila Water

Strategic alliance with SAP

FOCUS

Pharmaceutical Industry

6 Setting Out for New Success

Integrated, multidisciplinary solutions for the pharmaceutical industry

9 Success at Chiron

Simatic PCS 7 and Simatic Batch at Chiron Vaccines in Rosia, Italy

Integrated building and automation solution in Liverpool, UK

Reference project for the filling and freeze-drying of pharmaceuticals in Marburg, Germany

12 New Frequency

RFID in the pharmaceutical industry

15 Envolving toward Perfection

Simatic technology facilitates FDA CFR 21 Part 11 compliance in Courtoy tablet presses

16 Global Expertise

Automation and validation of a Xian Janssen plant

18 Digital Reports

Good manufacturing practice in drug manufacturing plants

19 Perfect Package

Siemens builds ultramodern logistics center for Merckle/ratiopharm

20 Off the Roll

Smotion C in packaging line for band-aids

22 Recipes for Operation

Simatic WinCC flexible for pharma production

23 Qualified Support

Application software development in compliance with FDA 21 CFR 11

Tablet press

Cover picture: Siemens AG
Dear Readers!

In this issue, we’re not only taking a look at the current landscape of the process industry and at the automation and drive systems that keep it running. We’re also using this unique opportunity to look back at 10 very exciting years – because that’s how long it has been since the first issue of Process News was published. And that’s how long we’ve been working to bring you timely information about subjects that interest you, as well as insights into our strategies and plans for the future of process automation.

We’re extremely pleased that, by and large, we’ve been successful in these efforts – at least that’s what reader surveys in 1998 and 2005 have indicated. Particularly, the recent survey, which was conducted a few months ago, reveals a consistently favorable impression of the value Process News provides you, our readers. The majority of those polled consider it an informative, expert, and highly professional publication. We’ll do our best to ensure that Process News will remain exactly that in the years to come.

The main focus of our current issue is on the pharmaceutical industry, an industry that is just emerging from a turbulent period in which both the market and the regulatory environment have changed profoundly. The pharmaceutical industry can employ intelligent solutions along the entire value chain to respond faster and more effectively to these challenges, as shown in examples from Italy, the United Kingdom, Belgium, and Germany.

With our expertise in important areas such as qualification and validation, and in technologies such as RFID, we can support the pharmaceutical industry in implementing these solutions effectively.

We hope that, as with past issues, you’ll find interesting ideas and suggestions in this edition of Process News!

Sincerely,

Cornelia Dürrfeld
Editor in chief, Process News
Simatic PCS 7 automates space flight simulation system

The High Enthalpy Tunnel Göttingen (HEG) of the German Aerospace Center (DLR) is a wind tunnel designed to simulate high-temperature hypersonic airflows, which occur, for instance, during the reentry of space vehicles into the Earth’s atmosphere. The DLR selected Siemens solution provider Bertram Elektrotechnik GmbH to revise and modernize the overall design of the system’s control technology. One key objective was to upgrade the automation solution of the HEG for a broader range of operating conditions in order to accommodate future applications and requirements. A visualization solution was also needed to substantially enhance the ease of use and flexibility of the existing operator controls, and to provide the capability to enter variable test parameters as well as to display reproducible test parameters. In addition, the upgrade needed to enable convenient, on-the-fly diagnostics of control tasks in progress.

The Simatic PCS 7 V6.0 process control system met all of these requirements, and is now controlling and monitoring all of the individual operations of the system. All processes are visualized, and on-the-fly intervention in ongoing processes is possible.

The HEG was originally designed to simulate hot airflows surrounding spacecraft during reentry. This involved the simulation of airspeeds up to 22,000 kilometers per hour. The range of potential applications has now been expanded to include, among others, investigations of innovative air-breathing supersonic propulsion systems able to reach airspeeds of up to 10 times the speed of sound at an altitude of 30 kilometers. The HEG can simulate the resulting flow conditions for several milliseconds. In the measurement section of the tunnel, high-speed measuring methods are used to study scale models. The resulting data are subsequently processed with appropriate algorithms to calculate the aerodynamics and thermal stresses encountered with the tested configuration.

Two Siemens experts participated in training approximately 30 FDA Inspectors, 16 FDA Reviewers, and other FDA personnel. The training, organized by the FDA’s Office of Regulatory Affairs, covered a broad range of topics geared toward FDA’s emerging risk-based and science-based regulations and corresponding inspection methodologies. This training is an important step in the rollout of these initiatives.

Siemens, a recognized industry leader in process analytical technologies (PAT), was asked to participate in this training and to focus on PAT for biologics by sharing project experiences.

Find out more:
www.siemens.com/pcs7
E-mail: roland.wieser@siemens.com
E-mail: satzke@bertram-bevern.de

Find out more:
www.siemens.com/pharma
E-mail: troy.logan@siemens.com
Mettler Toledo and Siemens: Partnership brings first results

As a partner of Siemens, Mettler Toledo markets compatible product combinations for the efficient automation of weighing functions. The new product line for high-precision weighing is the result of a cooperative agreement that the two companies initiated in September 2004.

The digital Modulo WM weighing modules and the Modulo WMH weighing platforms from Mettler Toledo use the Siwarex FTA high-resolution weighing electronics, and are thus integrated with Simatic control technology. Tested product combinations are identified by a certificate from the two companies, guaranteeing problem-free installation and flawless functionality.

The Modulo WM weighing modules and Modulo WMH weighing platforms are based on the principle of electromagnetic force compensation and provide rapid, precise weight measurements. The compact, rugged housing contains the load cell and all of the electronics.

Award-winning flow meters at Manila Water

The Manila Water Company is responsible for production, treatment and distribution of water, as well as for operating the sewage system in the east zone of Manila, Philippines, a zone that has five million inhabitants. A total of twelve Sonokit ultrasonic flow meters were recently installed by Siemens for Manila Water at several points in the pipe system. The flow meters are equipped with integrated data loggers and can send messages via SMS, ensuring continuous data recording. Moreover, the devices are very reliable in operation and require little maintenance.

Siemens installed the devices at twelve measuring points without interrupting the water supply. For the repair and maintenance services of the ultrasonic flow meters, Siemens was recently recognized as “Suki” vendor by the Manila Water Company. This award is given by Manila Water to suppliers and contractors who have provided quality products and services.

Strategic alliance with SAP

Siemens and SAP are working together to coordinate their IT product lines. This strategic alliance was formed in June of this year with the objective of achieving the “real-time company” through the efficient coordination of IT processes, from business management to production. In this collaborative solution, the two companies are supporting the ISA 95 industrial standard, with SAP focusing on business solutions and Siemens on MES and control systems.

The coordinated line of products and services is designed to be industry independent. It will enable companies to respond swiftly and flexibly to fluctuations in the volume of orders while maintaining low materials and product inventories to minimize time to market for new products, and to operate their plants at high levels of productivity. The certification process for the interfaces between Simatic IT and NetWeaver is nearly complete, and Simatic IT products will then be certified as “Powered by NetWeaver.”
Integrated, multidisciplinary solutions for the pharmaceutical industry

Setting Out for New Success

The pharmaceutical industry is experiencing a period of transition and must adapt itself to a totally new market landscape. The industry must deal with pricing pressures due to health service reforms and expiring patents, drastically increasing costs for research and development, and changes in the product portfolio – moving away from blockbusters toward more targeted drugs that must be produced in smaller batches. With a wide-ranging product and service offering, process expertise, and experience from numerous other industries, Siemens offers multidisciplinary solutions with which the pharmaceutical industry can continue to be successful in this new market landscape.

The challenges the pharmaceutical industry faces are immense and varied. The US Food and Drug Administration is aware of this. In recent regulations, it explicitly urges the industry to exploit innovative technologies and to benefit from the progress made in automation and information technology. These changes affect virtually all companies involved in the supply chain of drugs, from the chemical or biotechnical producers of the active ingredients, to the manufacturers of the various dosage forms, and all the way through to the distributors of packaged pharmaceutical products.

The pharmaceutical industry needs suppliers that can deliver effective solutions to respond to this new environment. A survey of 66 pharmaceutical companies revealed that two thirds of companies want to establish supplier relationships that are better capable of addressing their strategic challenges. The study, conducted by Siemens in cooperation with PricewaterhouseCoopers at the beginning of 2005, also revealed that they see the greatest potential for improvement in four central areas of the pharmaceutical industry: manufacturing performance, supply chain optimization, quality step change, and improved asset management. Siemens is well positioned to be an important partner to the pharmaceutical industry in the optimization of these key areas, as Anton S. Huber, member of the board of Siemens Automation & Drives states: “We are perfectly prepared to assist in these areas based on the experience that Siemens has in numerous other industries.

The pharmaceutical industry in the 21st century: New opportunities

In the past, pharmaceutical production processes were dictated by very restrictive legislative specifications. This prevented the pharmaceutical industry from benefiting from technological progress in the fields of automation and process technology to the same degree as other industries. Driven by growing market pressure and developing problems in medicine supplies, the FDA has recognized that the pharmaceutical industry will not be able to develop and produce safe, effective and affordable medicines in the future under the existing specifications. Taking a fresh approach to issues such as quality and safety on the basis of risk-based process control and understanding, the FDA is now allowing the pharmaceutical industry to exploit new solutions in the areas of process automation, validation and monitoring.

Siemens has observed and been involved in this development from the start, and has earned a reputation as a leading technology expert in innovative fields such as process analytical technology (PAT).
The majority of pharmaceutical employees taking part in this study are of the opinion that they will benefit from an integrated multidisciplinary approach. Buying-in of additional know-how is one of the main areas of potential benefit.

Do you think there is added value for a truly multidisciplinary combined approach from solutions providers?

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Have you used this type of approach before?

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What do you understand by “an holistic approach”?

- Buying multidisciplinary knowledge & experience
- Cost efficiency in project handling
- One price offer for combined services & one project leader
- Success secured project implementations
- Speeding-up project implementation
- All encompassing approach
- One global project leader, two separate invoices possible

![Bar chart image](image)

broadth and depth of experience that no other supplier can match. We work together with a large network of partners and solution providers. Together, we can address the many different requirements of the pharmaceutical industry and provide the necessary multidisciplinary expertise. With our Competence Centers, we have also geared our organization to the growing demands of our customers for industry-specific solutions and consulting.”

**Focused competence**

“The Competence Center Pharma has the task of aligning the broad Siemens portfolio specifically to the pharmaceutical industry. First, that means bringing this solution competence closer to the customer, directly into projects. Second, it also means incorporating the industry-specific knowledge gained from this proximity to the customer into our industry suites – in other words, bringing together customer requirements and Siemens’ capabilities”, explains Dr. Wolfgang Scheiding, head of the Competence Center Pharma at Siemens. He, too, stresses the benefits of a broad portfolio and, therefore, the possibility of a multidisciplinary solution: „In the pharmaceutical industry it is not enough to possess only automation knowledge.” Along with its innovative products and systems from the field to the MES level, all based on Totally Integrated Automation and Totally Integrated Power, Siemens also offers solutions for particularly sensitive clean rooms. Siemens can provide integrated solutions for access authorization or clean room monitoring. In addition to process engineering solutions for product lead time reduction using online analytics, improvements in internal company logistics and minimization of expenses in storage and commissioning are important – where Siemens offers solution from its
Key issues in the pharmaceutical industry

With a tailor-made range of GMP-compatible solutions and services, Siemens supports its customers in the pharmaceutical industry by driving improvements in all key areas of production.

**Manufacturing Excellence**
- Process knowledge
- Availability
- Process reproducibility
- Ease of use

To ensure continually optimum productivity in the pharmaceutical industry, processes and work steps must be perfectly adapted, controlled, and monitored by a flexible and in-line system. With a complete portfolio of automation and optimization systems, both for individual machines and complex production plants, Siemens provides the right solutions.

**Overall Quality Excellence**
- Quality by design
- Total quality management
- Right first time quality
- Real-time product release

Using an integrated approach, including tools for process analysis and evaluation, a wide range of solutions for process analysis and automation, as well as Advanced Process Control tools, Siemens supports its customers in the integration of quality assurance measures within the process. This enables a better understanding of the aspects of production that are relevant to quality.

**Supply Chain Excellence**
- Production logistics
- Warehouse integration
- Demand-driven supply net
- Collaborative manufacturing

On the basis of a broad portfolio of products, systems, and services, Siemens offers integrated solutions for the entire supply chain, enabling all processes and areas of the productivity chain to be linked. As a result, production can be adapted to actual market requirements more effectively, more efficiently, and above all, more flexibly. Continuous traceability of all products and processes along the productivity chain can thereby be guaranteed.

**Optimal Asset Valuation**
- Maintenance
- Asset management
- Downtime management
- Maximizing operational efficiency
- Maximizing flexibility

Integrated diagnostic functions and asset management tools, from the equipment level to the manufacturing execution level, simplify production planning, improve maintenance processes, and optimize the exploitation of all resources. In addition, the flexibility of production is increased by solutions for adaptable and recipe-controlled process and production management.

(Continued from page 7)

logistics and assembly portfolio. Needless to say, all solutions Siemens offers meet good manufacturing practice (GMP) requirements.

Another responsibility of the Competence Center is to further innovation for the pharmaceutical industry. As Dr. Wolfgang Scheiding states: “In the areas of process analytical technology (PAT) and radio frequency identification (RFID), for example, we have a clear edge over other providers in the market because we have the multidisciplinary expertise that is indispensable for these projects. Several PAT projects at well-known pharmaceutical companies are already in progress, making Siemens one of the first companies to implement this technology – which is central to much of the FDA’s recent push on innovation – in the pharmaceutical industry. RFID technology is becoming increasingly attractive to the pharmaceutical industry for use in combating counterfeiting of drugs, which causes billions in damages to the pharmaceutical industry, and also put the patient at risk. Once again, we benefit here from our experience in other industries.”

**Find out more:**
- www.siemens.com/pharma
- E-mail: cornelia.duerrfeld@siemens.com
Simatic PCS 7 and Simatic Batch at Chiron Vaccines

Integrated Success

Siemens has proven its project and automation expertise at the Chiron Vaccines sites in Rosia, Italy. With state-of-the-art technology and an experienced project team, Siemens implemented an integrated solution that handles all process automation tasks, including batch control, and interfaces easily with all third-party packages used in the plant.

Chiron Vaccines is one of the world’s leading vaccine manufacturers. In 2002, Chiron decided to construct a new plant at its Rosia site for the production of glycoconjugate vaccines to combat meningitis. Though it faced several strong competitors, Siemens Italy won the order for the complete automation of the new plant because it was able to supply a comprehensive integrated solution for process and batch control using Simatic PCS 7 and Simatic Batch.

The project was extremely complex, and required careful project management in order to satisfy the customer’s needs and to achieve compliance with CFR 21 Part 11 and GAMP 4 regulations, as well as qualification and validation of both process and plant.

Integration of DCS and batch control

The solution provides the complete integration of the distributed control system based on Simatic PCS 7 V6.0. The Simatic Batch system for batch process control also interfaces with all third-party packages used in the plant such as ultrafiltration systems, centrifuges, and pure steam. Moreover, it provides time synchronization for all the plant systems and packages, as well as acquires, centralizes, and elaborates all process-related values and provides a high-level security system for managing user access rights.

triggers batch and recipe execution, including the required sterilization, decontamination, and cleaning procedures — enhancing flexibility in recipe management while ensuring compliance with CFR 21 Part 11 and GAMP 4 through its audit trail and electronic batch record features. With this project, Siemens once again demonstrated the benefits of implementing state-of-the-art automation and control technology in pharmaceutical production.

Chiron Vaccines

Chiron Vaccines, the world’s fifth largest vaccine company, has facilities located throughout Europe, the United States, and Asia. The company is the world’s second largest manufacturer of flu vaccines, and has important meningitis, pediatric, and travel vaccine franchises. Chiron Vaccines is the leading vaccine manufacturer in the UK, Germany, and Italy.

Find out more:
www.siemens.com/pharma
E-mail: francesca.bruzzone@siemens.com
Integrated building and automation solution in the UK

Joint Offer

Chiron is one of the world’s largest developers of vaccines, blood testing and biopharmaceutical products. With a turnover of $1.7 billion and 5,400 people employed around the world, Chiron is a formidable force in global pharmaceutical development. As a company, they see research and innovation as keys to their success.

The company focuses its research and development in three main areas: the development of blood screening tools that help prevent the spread of infectious diseases; vaccines for adults and children; and biopharmaceutical products which focus on infectious diseases and cancer.

Headquartered in Emeryville, California, the company has research centers in the US and Europe, and manufacturing sites spread across the world, including a vaccine production facility in the UK. It is at this UK facility in Liverpool where Siemens has been working closely with Chiron to build a new facility (Site 4) close to the existing site in-line with the highest standards of regulatory compliance.

Chiron’s Liverpool site is already one of the world’s largest facilities for the production of flu vaccine. Ongoing investment in the site is designed to consolidate Chiron’s position as the world’s fifth largest producer of vaccines and second largest manufacturer of flu vaccine. This is complemented by the new Site 4 facility, which is planned to ultimately replace the current primary production plant. The vaccine production process consists of a number of discrete stages. The level of automation provided at each stage depends on the nature of the operation. Throughout the process, package systems – such as incubators, blast chillers, centrifuges, ultra filtration, motor control centers and utilities – interface with the overall Process Control System to ensure that the batch production activities progress through the discrete stages, and that the necessary batch data, including environmental monitoring, is collected and available for in-process control, recording and reporting.

Additional value

The decision to go with Siemens on the new production facility was based on the quality of the engineering team in the execution the project, and provides an excellent example of where a customer could leverage the value of Totally Integrated Automation. It was key that the engineering team could deliver to the time, cost, specification and quality criteria set out at the beginning of the project, but what set Siemens out from the competition was the additional value brought to Chiron’s investment during the project implementation phases and afterward through the service and support team. Siemens approached the solution with a view to provide a total solu-
Siemens was also very successful in another Chiron project on the Marburg site: building a new filling and lyophilization plant for therapeutics and vaccines. Drug manufacturing always has high demands as far as FDA and GMP requirements are concerned.

In this case, however, the requirements were even more stringent, as the project had to deal with an aseptic process: Any microbial contamination of the process and products had to be ruled out from the start.

In addition, the new plant required major changes to the existing building, which had to be carried out during ongoing operation. To ensure the required clean-room conditions, Siemens upgraded not only the process technology, but also the entire climate and clean-room technology of the filling process.

Siemens developed the concept design for the GMP upgrade and took over the basic and detail engineering, including the creation of a 3D model for ventilation systems, piping systems, and cable ducts, as well as the building and installation supervision. The Siemens team also supported Chiron in the commissioning and qualification of the whole plant in accordance with FDA and GMP standards. In mid-December 2003, the old plant was dismantled and the entire building interior removed. The first section of the new plant went into operation at the end of May 2004. Now, Chiron Vaccines not only has greatly improved production installations but can also further increase the capacity of the plant. “The operation is now state of the art,” says Andreas Umlauf, project manager at Chiron Vaccines, summing up the results of the project.

As an indication of the confidence now gained by Siemens, a PCS support contract has been secured, further underpinning the relationship between the two companies.

Indication of confidence

Although this is the first Siemens installation at the Liverpool facility, Site 4 Engineering Manager Harald Rueckl, who was previously based at Marburg, had completed several PCS7 installations. This, combined with the approach of the Siemens UK team, gave him confidence that the project would be completed on time and to the quality, cost and incorporating engineering standards and specifications established by Chiron.

Find out more:
www.siemens.com/pharma
E-mail: ian.bowman@siemens.com
What is RFID?

Rather than laser light, as in the case of barcode technology, Radio Frequency Identification (RFID) utilizes radio waves for product profiling. Essentially, an RFID tag consists of a silicon chip and an antenna. Contrary to barcode labels, additional data can be stored and altered during the handling of the object. Also, one reader can read multiple tags at the same time, without the tagged item being in the line-of-sight of the reader – thus speeding up the identification process significantly compared to barcode technology. There are two different tag versions: active and passive tags. Active tags are equipped with a battery-powered power supply, enabling larger memory sizes and greater reading distances. Passive tags are powered only by the reading signal, which delivers just enough energy for the tag to reply.

In “closed loop” applications, RFID tags can be reused many times, offering a very attractive cost-per-cycle ratio. “Open loop” applications, where tags are part of a disposable packaging and information is available over the life-time of the package, are becoming more and more interesting as well, as they offer the opportunity to track and trace items over the entire supply chain.

Since tags can be as small as a rice grain, application options are numerous. Today’s RFID applications range from car keys to livestock, airplane parts, consumer electronics, shipping containers, medical devices – even to patients who are being examined.

RFID tags will help increase logistics and production visibility – both in “closed loop” applications within factory gates and in “open loop” applications that could extend to the patient’s bedside.

RFID in the pharmaceutical industry

New Frequency

Radio Frequency Identification, or RFID, is nothing new. The technology which employs “smart tags” to track, trace and identify virtually every type of item – even human beings – has been around since World War II. Within the past decade, RFID has found renewed interest. The vision of a world in which complete product profiles can be called up with the push of a button has tremendous appeal to a number of industries. For the pharmaceutical industry in particular, it seems that RFID has finally come of age.
RFID enables the tracking of goods from their point of origin to create a new quality of supply chain transparency. With RFID, each individual product possesses an electronic “pedigree” containing all relevant information on the product, including: the raw materials that were used, production data, shipping dates, storage conditions and times, handling events and, finally, the sale or application of the product. This information in turn can be used to improve everything from product availability at the point of sale to stock management, lead times, investment planning and, ultimately, customer satisfaction.

RFID can also contribute greatly toward enhancing productivity and product security. For high-value items, RFID information can be used as a tool for product-authentication in the fight against gray markets, theft and counterfeiting. In order for item level tagging to have a global impact, however, three major issues must first be resolved: the price of the individual tag, a standardization of the various technologies which now exist, and improvement of the physical performance of RFID in different environments. In all three cases, a solution is expected soon. Another important issue involves privacy concerns. Consumers generally do not want their products to be traced after purchase. For patients requiring special medication, on the other hand, a monitoring capability for their physicians and pharmacists can be a source of welcome added security.

Addressing key concerns
In an attempt to deal with the increasing problem of counterfeit drugs and its implications for patient safety, the US Food & Drug Administration issued an extensive report recommending the use of RFID as a key technology to enhance consumer medication safety.

These recommendations, as well as recent US state-specific regulations on drug pedigrees mean that many pharmaceutical manufacturers could now rank among the “early adaptors” of item level RFID tagging.

As soon as the proof of the authenticity of a drug (related to its original, i.e. certified, manufacturing data and preferable at point-of-sale) and measures such as electronic pedigree (a record documenting that the drug was manufactured and distributed under secure conditions) become mandatory, in the US or on a global scale, drug manufacturers will have to comply to these rules to stay in business. However,
For distributors, pharmacies and hospitals, RFID can greatly improve the support of operational processes by eliminating human failures and increasing product throughput. In hospitals, an RFID-supported wireless infrastructure could reduce paperwork, providing hospital staff with more time for patient care.

A long history in RFID

Siemens has extensive RFID experience in various disciplines spanning decades: from production-skid tagging in the automotive industry to RFID-enabled warehouse processes and material flow, access-control solutions and patient data recording.

Aware of the multidisciplinary character of large scale RFID applications, Siemens has united the expertise of various specializations to achieve the end-to-end integration needed to make RFID attractive for all parties, and is currently working on solutions that specifically address the needs of the pharmaceutical industry. One example can be found in Austria, where Siemens provided a pilot tracking and tracing system for bloodbags in close cooperation with the local bloodbank and hospital. Currently, together with the Swiss packaging company Limmatdruck, one of the leading packaging machinery suppliers for the pharmaceutical industry, Siemens is developing new ways to attach RFID tags to the carton or packaging of individual products, enabling in-process writing of data onto the tag.

For more information, please visit our website: www.siemens.com/pharma
E-mail: christoph.doenges@siemens.com

Find out more:
www.siemens.com/pharma
E-mail: christoph.doenges@siemens.com

(Continued from page 13)
Simatic technology facilitates FDA CFR 21 Part 11 compliance in Courtoy tablet presses

Evolving toward Perfection

At Courtoy, the future lies with constant evolution on the path toward improved FDA compliance. “In pharmaceutics, people, above all, want quality and reliability. This is why one of our major clients in the pharmaceutical sector insisted on us working with Siemens,” says Wouter Happaerts, chief software designer at Courtoy. In the design of a new tablet press, engineers at Courtoy greatly benefited from Totally Integrated Automation.

Courtoy N.V. near Brussels, Belgium, is the leading manufacturer of rotary tablet presses. The company is part of Niro Pharma Systems, and has been designing and building versatile rotary tablet presses for over 80 years.

Today’s tablet production operations are faced with two seemingly contradictory demands: being able to safely handle more potent drugs, and reducing overall production costs. At the same time, batch sizes are decreasing and production planning must allow for maximum flexibility. No single solution existed to meet all of these needs simultaneously.

This is why Courtoy developed the exchangeable functional module (EFM) which, as applied to the latest generation of Courtoy rotary tablet presses, is quite straightforward. On rotary presses, all parts in contact with the product, and all product format parts, are concentrated around the central turret or die table. This turret – complete with punches, dies, powder feeder, scraper, ejection finger, dust extraction nozzles, and the tablet chute – is integrated into one self-contained box, allowing for a complete machine changeover by a single operator in 30 minutes.

Integrated, open automation solution

Jürgen Boeckx, research and development manager at Courtoy, stresses the importance of automation in regulatory compliance: “Control elements such as Simatic WinCC, which we use in our presses, or the integrated Simatic S7-400 controller and fieldbus technology, have the potential to continue development toward ever better regulation compliance.” Moreover, because the Simatic WinCC-based SCADA solution offers the potential for superior integration on the end-user side, Siemens equipment is the standard setup for Courtoy’s Modul press.

Significant benefits

For the designers at Courtoy, the Totally Integrated Automation approach has brought some dramatic improvements in machine development. The greatly simplified fieldbus cabling solved some critical design problems, and at the software level, the Courtoy engineers fully benefited from WinCC’s ability to integrate standard packages as well as higher-level systems – for example, for networking at the MES level without extra programming.

Striving for ever better compliance

Courtoy plans to expand the integrated diagnostic functionality with WinCC to be able to meet increasingly rigorous requirements from the regulating bodies. “Even though perfect compliance is tough to achieve due to the stringent regulations, we now have the potential to actually get there,” Wouter Happaerts and Jürgen Boeckx conclude.

Find out more:
www.siemens.com/pharma
E-mail: Geert.De_Coninck@siemens.com

The Modul tablet press uses a new, modular concept that also ensures better levels of compliance
Automation and validation of a Xian Janssen plant

Global Expertise

There is no room for ambiguity in the pharmaceutical industry: strict international guidelines regulate the production processes. Automation systems must go through an exhaustive validation process before they can begin operation. In modernizing the automation system of a Xian Janssen production plant in China, Siemens has once more been able to prove its expertise in the pharmaceutical industry. Redundant systems provide maximum reliability, and Siemens’ extensive know-how considerably simplified validation of the systems.
Xian Janssen Pharmaceutical Ltd. is a joint venture between the Belgian pharmaceutics company Janssen, which belongs to Johnson & Johnson, and a Chinese partner. The company is considered the number one in the Chinese pharmaceutical industry and produces a wide range of very successful products. The Xian Janssen production facility, situated in the historic city of Xian, manufactures patented drugs that are used, for example, in mycology, gastroenterology, anesthetics, psychiatry, and neurology. The production facility complies with the international standards of the pharmaceutical industry and is certified in accordance with CFR 21 Part 11.

Xian Janssen recently determined that the process control system implemented when the factory began production in the mid-1980s was no longer meeting current requirements. The company decided to replace the system with a state-of-the-art solution, and chose the Simatic PCS 7 process control system. A decisive factor in the selection of PCS7 was the ability of Shanghai-based Siemens Industrial Automation Ltd. (SIAS) not only to provide the necessary engineering competence locally, but also to support Xian Janssen in the validation of the system.

Reliability through redundancy
The process control system in Xian had to satisfy both national and international standards of the pharmaceutical industry, including the specifications of the American Food and Drug Administration (FDA), the requirements of the World Health Organization (WHO), and Good Manufacturing Practice (GMP) regulations.

The control system was divided into two sections based on the production structure at Xian Janssen: the production of pharmaceutical products in liquid form, and the manufacture of ointments. The liquid product section accounts for a much greater share of the production. Thanks to the open architecture of PCS 7, it was easy to link the new process control system to the existing infrastructure with the associated field devices, which considerably reduced the investment costs for modernization.

To ensure unrestricted availability of the automation solution, all essential functions were designed redundantly. This guarantees complete documentation of all production parameters. An extensive document management system was also implemented to guarantee access to all records at any time.

The process control system consists of two automation systems to which three operator stations and one engineering station for each of the two production sections are linked. Both sections can, therefore, be controlled completely independently. Moreover, the control and status display for ointment production is possible from both subsystems.

A special feature of PCS7 is the event-controlled synchronization of the redundantly designed systems. In the event of a fault in one system, the control system automatically switches over to the other without impairing the current cycles of the production process. There is no need to interrupt operation for maintenance work, or to change hardware components either.

Validation support
In addition to the hardware design, software configuration, and installation of the control system, the project scope also included the final validation of the system. The Siemens team helped Xian Janssen run a structured validation process based on the V-model. The team provided special engineering services to document every project step in detail, and to prove the appropriate functionality within the scope of validation – quite a task, considering that validation of such a project consists of 20,000 pages of documentation, as well as numerous test runs to prove the reliable functioning of the plant, which must run according to exactly specified criteria.

Siemens has extensive global experience in controlling production processes in the pharmaceutical industry. Thus, the SIAS project team was able to draw on a large reservoir of knowledge, facilitating the team’s flawless first validation of a Chinese production facility.

Safety in ongoing operation
The modernization of the production facility at Xian Janssen was SIAS’s biggest project in the pharmaceutical industry to date.

Siemens was able to impressively demonstrate its global expertise in pharmaceutics-specific issues (such as validation), and that the necessary related services are also available locally.

Since implementation, the new system has also proven its effectiveness in ongoing operation. The redundant design of the systems provides an extremely high level of safety, although PCS7 has not yet had to resort to this functionality.

There have been no faults at all since the new process control system was commissioned – further proof of the technological reliability of the implemented systems and the competence of the Siemens project team.

Find out more:
www.siemens.com/pharma
E-mail: lin.hong@siemens.com
Some years ago, centralized weighing operations were introduced to pharmaceutical and biotech manufacturing companies to ensure that materials introduced into the process were of the correct type, quantity, and quality. Now, new electronic dispensing systems provide further significant efficiency and quality gains over manual operations.

In a typical manufacturing execution system (MES) environment, coordination between the ERP level and the shop floor level is essential to execute the planned operations. The MES must be able to manage these complex operations reliably and efficiently. In order to fulfill the bill of materials associated with the weighing and dispensing orders, concepts such as campaign or order weighing and container allocation are applied.

The Simatic IT MES offers drug manufacturers an integrated solution that includes weighing and dispensing. Weighing and dispensing orders are downloaded from the ERP system through an XML-based interface (Simatic IT Data Integration Service), and can then be handled directly by authorized operators.

Orders can be sequenced and dispatched, or split into phases, and the necessary information will always be available for full tracking and tracing – from raw materials to the pallet in the warehouse. This applies in particular to wall-to-wall MES solutions that need to guarantee consistent quality for incoming goods that are received, tested, and released for production. The Simatic IT solution for weighing and dispensing also features direct links with various scales and barcode readers, allowing these operations to be fully automated.

**Efficient downtime management**

The Simatic IT OEE- DTM (Overall Equipment Efficiency and Downtime Management) product option provides consistent monitoring and control of a plant’s efficiency in an intuitive, easy-to-use environment, and is closely integrated with the Simatic IT Production Suite.

The standard functionalities provided by Simatic IT and Simatic Batch are tightly integrated, leveraging the full potential of Totally Integrated Automation, including Simatic PCS 7 and Simatic Batch. Batch dispatching, material management, electronic batch recording, and batch reporting are some of the standard and native functionalities provided by this close integration between the various Siemens products within the portfolio.

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**Good Manufacturing Practice in Drug Manufacturing Plants**

**Digital Reports**

One main objective of the pharmaceutical industry is to make processes standard and repeatable throughout all manufacturing facilities. Electronic batch reporting and documentation, as provided by Simatic IT, offer significant benefits over traditional paper-based solutions.

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**Find out more:**

www.siemens.com/pharma  
www.siemens.com/simatic-it  
E-mail: andrea.molinari@siemens.com
Siemens builds ultramodern logistics center for Merkle/ratiopharm

Perfect Package

Siemens Logistics and Assembly Systems has built a logistics center for the Merkle/ratiopharm pharmaceutical group at the company’s Ulm/Donautal location in Germany. This highly automated logistics center is setting new benchmarks in the field of pharmaceutical distribution centers, with an output of about 1,000 pallets and 170,000 picks per day.

For this project, Siemens upgraded the equipment in the existing goods distribution center and linked the material flow to the new logistics center. The distribution center was retrofitted with the latest Simatic S7 generation of material handling controls, and the drive and control equipment of the S/R machines was also modernized. The Siemens material flow software also links both the new and existing warehouses to the SAP LES (logistics execution system) software in a uniform manner.

State-of-the-art warehouse

Items coming directly from the adjoining production facilities and items delivered from external suppliers arrive on euro pallets in the high-bay warehouse, which has 28,000 storage spaces. There, they are automatically stored double-depth by six S/R machines. The employees on manually operated picking cars take original boxes directly from the stored pallets, attach a bar-code label to each box, and then push it onto the continuous conveyor integrated into the picking car. Conveyor belts permanently fitted in the rack aisles take the marked boxes directly from the continuous conveyor on the picking car and transport them to the head of the rack structure, where they are collected and forwarded toward the order-picking hall.

Original boxes designated to be shipped as complete boxes are sent directly to dispatch, while those intended for a mixed order with other drugs go to the transit warehouse.

Automation makes manual work easier

The transit warehouse is dedicated to customized picking, and the efficiency of the work is supported by a pick-to-light (PTL) system in the nine picking aisles.

One special feature of the plant is a precise check weigh linked to the PTL system. The orders are weighed on a movable weighing unit after each filling process. The higher-level computer system can assign a precise weight to each retrieval process. Automating the monitoring of the picking quality prevents errors.

At the end of the picking zone, the employee acknowledges the entire order and pushes the tray bearing the order box back onto the conveyor track. This takes the box to the next order-picking station.

The completely picked mixed boxes are then collected into a single material flow with the original boxes, and temporarily stored in eight central walking beam devices, where they stand ready for packaging according to the individual order at the large and small package stations.

More flexible and accurate

The new distribution center went into operation at the end of 2004. Merkle/ratiopharm is very satisfied with the center’s performance, as increased flexibility and improved accuracy help ensure customer satisfaction. Both individual mail items and large packing drums can be quickly assembled and dispatched as needed in the distribution center.

Find out more:
www.siemens.com/pharma
E-mail: roland.fritzsche@siemens.com

Weighing of orders significantly reduces the number of errors

Fotos: Siemens AG
Simotion C in packaging line for band-aids

A Straight Line

Until the end of 2003, a large share of the band-aid production at BSN medical in Hamburg was packed by hand. The old packing line needed to be automated. For this project, BSN medical found a committed and competent partner in Vector Vepackungstechnik GmbH, with Siemens as the electrical installations provider. Nearly 20 machine modules were equipped with the Simotion motion control system, and could, therefore, be commissioned step by step, independently of each other – allowing even the very tight schedule for this project to be met.

BSN medical GmbH & Co. KG, a cooperative of divisions of Beiersdorf AG and the British company Smith & Nephew, addresses the clinical “medical care” market segment worldwide, in which products for wound dressing play an important part. The bandage materials are produced by proven machines taken over from the parent company, Beiersdorf. The automation of product packing was long overdue because the problematic link to the production machines had always delayed modernization. A BSN team finally addressed this problem at the beginning of 2003.

Due to the expansion of the sales market after the merger with Smith & Nephew, and to the need to set an example for other company divisions, the project was under great pressure to succeed – and quickly. Thanks to the committed cooperation of all of those involved, the entire packing line was installed after only seven and a half months’ development and construction time, in the second week of December 2003; full production in three shifts commenced at the beginning of 2004.

Twin-portal robot copes with high product volume

The packing line consists of two folder box assemblers, a box closer, a side packer for dispatch boxes, and a twin-portal robot – the real heart of the line. The band-aids are produced in long webs and stored as rolls. A cutting machine spools off smaller rolls with band-aid lengths of 5, 10, or 20 meters. These rolls are then cut according to the desired width. In total, the plant feeds about 10 box types with about 70 products from widely different kinds of band-aids in 20 delivery formats.

The wide variety of products that the plant has to cope with is sometimes tricky.
“A robot solution cannot cope with small formats. Therefore, we suggested a portal grabber system that picks up all band-aid rolls simultaneously,” says Klaus Zott, regional sales manager of Vector, explaining the necessity of an individual top-loader solution. “Moreover, the cutting machine is heavily exposed to the band-aid adhesive. For this reason, quite a lot of free space must be left in front of the machine for manual cleaning and servicing of the cutting device, which means the traversing distance for the portal is very long. We have therefore designed a twin-portal machine, in which two groups of grabbers at different traversing heights pick up the band-aid rolls alternately and place them in the boxes.”

**Complete equipment and motion control expertise**

The two box assemblers (with four axes each), the box closer (seven axes), and the side packer (eight axes) are fully controlled by Simotion C230. A Simatic S7-300 with the FM 357 track and positioning controller is used in the twin-portal robot. The HMI of both the individual machines and the overall plant is provided by Simatic Multi Panels with touch screens. All components of the plant communicate via Profibus DP, and the individual machines are linked by DP-DP couplers. Communication via the safety-oriented Profisafe protocol reduces the wiring effort considerably, as safety devices such as safety door contacts or emergency stop switches can be connected directly to the distributed periphery.

The handling of the product variety is made much easier by this motion control-based automation. The individual motion parameters of the motion control axes are saved for every box type and can be called up by the according recipes. The operating personnel has to make only a few manual setting changes for the format change, so the plant can respond very flexibly to the current delivery situation.

Based on this highly consistent communication, the automation system offers the possibility of telediagnosis and teleservice – a service that both Vector and BSN medical greatly appreciate. “Support must come fast, when it is needed,” says electrical engineer Claus Goldberger, stressing the high availability requirements at BSN medical.

**Successful project**

The Hamburg-based medical products manufacturer is very satisfied. Project manager Bernhard Bandel and his team have installed an exemplary packing plant that operates reliably. With the decision to involve Siemens as both a complete supplier and a provider of engineering services for the project, Vector concentrated its capacities in a consistent and strategically effective manner. The convincing use of Simotion motion control has since led the parent company, Beiersdorf, to adopt Simotion as a solution for motion control tasks as well.

Find out more:
www.siemens.com/packaging
E-mail: hans-benno.bruss@siemens.com
Simatic WinCC flexible for pharma production

Recipes for Operation

The production of pharmaceuticals is subject to more stringent restrictions and requirements than in almost any other industry. Simatic WinCC flexible 2005 provides comprehensive process documentation functions to support compliance with GMP requirements such as CFR 21 Part 11, while also ensuring a maximum level of safety and transparency even at the panel level.

Documentation and safety are key concerns in pharmaceuticals production. Any intervention in the manufacturing process that could affect product quality must be documented. A detailed audit trail must record any changes, including when and why and by whom they were made. Preventing changes by unauthorized persons is equally important.

These requirements can now be fully met with Simatic WinCC flexible 2005 – and not just in conjunction with PC systems, but even with Simatic Class 270 and 370 panels.

Access security, audit trail, and electronic signature

The user management function of Simatic WinCC assigns specific rights to users in a hierarchical order. Users are forced to change their passwords at certain intervals to increase access security. A selectable password history, automatic user logoff after prolonged inactivity, and account blocking after several wrong password entries are additional protective functions in WinCC flexible.

The Audit option in WinCC flexible 2005 can be used to define quality-relevant variables and data. Changes to these variables are monitored and recorded in the audit trail along with a time stamp, the logged-in user, and the name of the variable, plus the old and new values. The system also provides commentary options (which may be voluntary or obligatory) concerning why the value was changed. In particularly critical interventions, the system requires an electronic signature: the user must validate the change by entering his or her password.

Pharma-compatible engineering

WinCC flexible 2005 not only monitors the variables of the production process, but also any changes in the system. This is a critical task, because without appropriate documentation, the system loses its validation. The Change Control option automatically records any configuration changes in the change log: who made what change in which object, complete with a time stamp. The automatic version control supports functions such as comparison and rollback.

More efficient configuration

An intuitive library concept that also contains pre-engineered objects supports fast and effective configuration. Picture blocks can be changed from a central location. A large number of intelligent assistants provide useful functionalities such as simple project generation or graphical object trajectories. As a result, WinCC flexible ensures that the configuration of machines and plants is not only compliant with the guidelines of the pharmaceutical industry, but also quick and convenient.

Highlights

Flexible use
- For use at machine level and process level
- Suitable for applications with panels as well as PCs
- Configurable with engineering software and for use in the most diverse automation solutions
- Usable worldwide (multilingual)

Maximized configuration efficiency
- Easy-to-use interface
- Intelligent tools
- Reusable picture blocks
- Multilingual configurations
- Convenient migration of configuration data from the ProTool family

Innovative HMI concepts
- Systemwide access to variables and images
- Distributed user terminals
- Local control-room solutions
- Link to the office world

A part of Totally Integrated Automation
- In Simatic Step 7, Simatic iMap, and Simotion Scout

Find out more:
www.siemens.com/wincc-flexible
E-mail: stefan.krauss@siemens.com
Application software development in compliance with FDA 21 CFR 11

Qualified Support

The application support for the automation of packaging machines provided by Siemens for its customers in the machine building industry is backed by more than 20 years of experience. Seasoned specialists support the development of a packaging machine from its conception and configuration to its implementation, on-site commissioning, and optimization.

The Application Centers for Motion Control Solutions are distributed around the globe, with 13 locations in seven countries. They provide industry knowledge and technology expertise for the development and optimization of motion control solutions in machine building. More than 100 application engineers work closely with customers to develop the best possible application for each machine based on standard components – from a detailed analysis of the present configuration and requirements to the resolution of technical issues, a feasibility analysis, and the implementation proposal. This approach gives machine builders much greater planning certainty.

If the customer wishes, the Application Center will configure the application and supply all of the equipment, including the control console, based on a wide range of industrially proven solutions and standard applications. Siemens also provides appropriate training programs to ensure that the customer will be able to maintain, modify, and expand the solution in-house. This single-source concept reduces the number of interfaces, and creates synergies in the conception, testing, and optimization of the machine solution so that both the complexity and the cost of machine development can be substantially reduced.

Commissioning and validation support

The support provided by the automation and drive systems specialists from the Application Centers always includes the commissioning and optimization of the machine, from parameterization and pilot operation to personnel orientation and training. This comprehensive support is complemented by a hotline and remote service. All of these activities help ensure that the machine will function flawlessly in actual operation.

The application specialists excel at designing software specifically for pharmaceutical packaging applications that are based on the Simotion automation system, and that are specified, developed, tested, and documented in accordance with the V-model. Such an application has recently been developed in ST-Code in accordance with IEC 61131, with integrated motion control functions as a “validation-proof shift register” for modular machine designs, and in cooperation with a leading maker of blister machines.

Optimized support from A to Z

In the past few years, many machine builders have already benefited from the cumulative experience of the expert teams in the Application Centers for Motion Control Solutions. Optimized product selection and integration, the reliance on standardized and open solutions, an in-house high-tech machine test center, plus customer-specific project management are only some of the advantages that result from close collaboration between machine builders and Siemens.

Find out more:
www.siemens.com/motioncontrol
E-mail: alexander.foerster@siemens.com
Vaccine production at Virbac with Simatic PCS 7

Guaranteed Results

Dogs, cats, cattle, horses – most of these animals will come into contact with Virbac products at some point in their lives, as the French company is one of the leading manufacturers of animal vaccines. In the production of these vaccines, the same strict regulations apply as in the production of human medicines. Most recently, the Simatic PCS 7 process control system is ensuring that Virbac’s products always comply with the pertinent regulations with regard to safety and effectiveness.

The active pharmaceutical ingredients of the vaccines are obtained from cell or bacteria cultures. These ingredients are then transferred under sterile conditions to one of the formulation vessels of the Bio 4 preparation unit. After formulation and quality control, the vaccine is portioned in 3-milliliter doses in vials and then packed. Depending on the requirements, it is then stored freeze-dried or in liquid form in cold rooms at 4 degrees Celsius. The entire process takes place in a special building and requires 48 hours from start to finish.

The manufacturing process is subject to the same requirements as are applied to the production of human medicines. The processes must therefore run in accor-
dance with GMP specifications and the requirements of the AMM (Autorisation de Mise sur le Marché, the guidelines regulating approval of medicines in France).

**Controlled process in a sterile environment**

The Bio 4 preparation unit consists of four similar tanks with different holding capacities, operating independently of each other. In each of these tanks, pH, pressure, temperature, and the weight of the raw materials are monitored throughout the mixing process and stored in a batch log. Load cells on every tank also continuously monitor the weight of the tank and suspension. Because the entire process must run under absolutely sterile conditions, the plant includes clean-in-place (CIP) and sterilize-in-place (SIP) systems.

**Proven system under new control**

"Our preparation unit is now more than 10 years old, and the corresponding automation system was no longer state of the art," explains Philippe Gugi, production manager at Virbac.

For the technical implementation of a modern automation solution, Virbac approached Siemens in nearby Nice. The company chose Siemens not only because of the technical advantages of Simatic PCS 7, but also because of Siemens' geographical proximity. It was very important to those responsible for this project at Virbac to have a competent partner with a local presence.

Virbac's technical and quality assurance departments worked together closely with the Siemens project team on the modernization of the systems. Simatic PCS 7 was chosen as the automation system. The data from the processes are acquired via Profinet DP and transferred to the control system. Profinet DP guarantees not only a fast data flow to all sensors and actuators of the four production tanks and to the CIP and SIP systems, but also the activation of the agitators and the weighing equipment.

"In this way, we were able to achieve the response times we need in the processes," explains Thierry Simon, project technician at Virbac.

Several specific functions were also added to the process control system. For example, the status of the plant components is color coded so that the current operating state is always visible at a glance. The system automatically takes into account the fact that certain process states have an expiration date. If, for example, a cleaned plant is not sterilized within five days, it loses its "cleaned" status and must be cleaned again before sterilization. If a process unit has been sterilized, this status expires after three days.

"With Simatic PCS 7 we can ensure continuous traceability of the products and the processes," says Thierry Simon. The production data are saved simultaneously in both control stations.

Philippe Gugi adds: "At the end of every lot, documentation is created for the batch and saved for the duration of the legally prescribed storage time. In addition, the operator can add an electronic signature to the batch documentation."

**Excellent results**

Simatic PCS 7 has been in operation in the preparation unit at Virbac since mid-September 2004, and to the customer's complete satisfaction. The traceability and repetitiveness of the lots have been significantly improved. Those responsible at Virbac were also satisfied with the course of the project. "We fully achieved our goals, and budgets and deadlines were met," Philippe Gugi confirms.

The next projects are already being planned. For example, another formulation plant is soon to be expanded.

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**Find out more:**

www.siemens.com/pharma

E-mail: franck.mercier@siemens.com
Chromatography process at Schering is automated with Simatic PCS 7

Flexibility and Process Reliability

Flexibility, reliability, and the ability to provide complete documentation are just some of the requirements that process control systems must meet in today’s pharmaceutical industry. In two separation systems for active pharmaceutical ingredients (APIs) in its Bergkamen plant, Schering decided to replace the existing control systems with newer technology that would make it convenient and cost-efficient for the company to define and change recipes in-house. In this project, Schering decided to continue a long and successful partnership by relying once again on the expertise of Siemens.

Established by Ernst Schering in Berlin in 1851, Schering AG has always ranked among the great innovators in pharmaceuticals. Schering began research on sex hormones in 1921, and in 1961 the company presented the first preparation for hormonal contraception. Today Schering is one of the leading producers of preparations for gynecology, andrology, and diagnostics. APIs for these pharmaceuticals are manufactured at the Bergkamen plant. The actual preparations for the international market are then produced in various pharmaceutical plants in Europe, Asia, and South America. At its API production facility in Bergkamen in Northern Germany, Schering operates several plants for microbiological and chemical processes. Resources employed to guarantee the absolute purity of the final API products include two separation systems based on the HPLC (high-pressure liquid chromatography) process. The API is filtered through a column filled with silica gel at high pressure to dissolve and remove any remaining impurities until only the pure API remains.

The result of years of cooperation

In the past, Schering purchased its HPLC columns complete with their proprietary control system from the same manufacturer. The downside of this approach was that any change in the process control was extremely complex and costly, which, of course, raised the life-cycle costs of these systems. Late in 2002, Schering decided to change its approach and opted for a solution that would be based on open industry standards and support easy changes of parameters and recipes. The selection of the right automation system was not just a technical decision. It also required a high level of confidence in the partner that would install and commission the system, because the pharmaceutical industry processes products that are often extremely costly. One kilogram of an API may easily cost tens of thousands of euros.
The cooperation between Schering and Siemens has continued for many years and has proven its value in numerous projects. In the 1980s, Schering used type R-30 Siemens controllers, which were subsequently replaced with Teleperm M models. The decision to convert the HPLC systems to Simatic PCS 7 with Simatic Batch was therefore not only a decision to upgrade to the latest technology generation, but also a vote of confidence in Siemens as a partner.

Maximum performance in minimum time

Siemens was responsible for the entire hardware and software installation and the engineering of the control system. In addition, Siemens trained the Schering employees and provided support in the validation of the system.

As always when a functioning plant is involved, this project had to be completed in a very short time frame. The contract was issued in mid-December 2002, and project work began promptly in January 2003. The factory acceptance test was completed by the end of January, and the system was commissioned in mid-March 2003. The production system was then validated before the two HPLC columns were started up in early May 2003. A special challenge, particularly in this short time frame, was the fact that Version 6.0 of PCS 7 was being introduced while the project was under way, and the customer wanted to adopt this latest release of the control system right from the start. But the Siemens team managed to clear even this additional hurdle and integrated the new version with no major problems. The Schering plant is now operating with an automatic process control system based on the latest technology.

Getting a grip on a complex process

The HPLC columns are operated in batch mode, which requires a sampling rate in the millisecond range. Direct communication via Profibus between the process control system and the interconnected drives, sensors, and actuators enables the control system to access process information rapidly, and to promptly respond to the current process situation.

The individual recipes are composed of as many as 400 different recipe parameters that are accessed from a library. To achieve the range of functionalities required by Schering, many special applications were derived from the basic functions that existed in SCL. These new applications were developed in WinCC and Visual Basic to provide such functionalities as the creation of parameter images, check images, and chromatograms.

With this new solution and thanks to the modular and open design of the entire system, the customer can now use the graphical user interface to create new recipes swiftly and easily with in-house resources. Changes and adjustments can now be made at any time, without major complexities or expense. For both companies, the project represents the continuation of a successful partnership that has lasted for many years. For Schering, it also marks the important transition to a production environment that finally provides the desired flexibility.

Find out more:
www.siemens.com/pharma
E-mail: frank.schwuchow@siemens.com
Pointek level monitoring in whiskey production

Tradition Meets Technology

With its unique inverse-frequency approach to capacitance technology, Pointek level monitoring instruments can reliably detect foam levels. This helps ensure the high quality of the whiskeys produced at the renowned Dufftown distillery.

At the Dufftown Distillery in the Highlands of Scotland, William Grant & Sons Distillers Limited has produced fine Scotch whiskey since 1866, including Glenfiddich, the best-selling single malt whiskey in the world. Quality ingredients and careful process monitoring are vital to the art and science of whiskey making. First, malted barley and water are mixed in a mash-tun, a round metal vessel with mechanical stirrers, to produce wort (sugar solution). Wort is cooled and pumped into pear-shaped fermenting vessels called wash stills, where operators add yeast, and the mixture produces wash (weak spirit). The wash is distilled to strengthen and purify the spirit.

The spirit is then matured in oak casks for a minimum of eight years to become Scotch. In the wash stills, prior to vaporization, foam is produced that can result in boiling high levels of froth mixing in with the “low wines” from the first stages of distillation. To control the foam, the burners must be turned off, then restarted, as the foam dissipates. The Dufftown plant wanted to automate the wash still operation to control foam. Because foam is neither liquid nor air, it has traditionally been impossible to detect with older level measurement equipment such as floats or vibrating forks.

Better resolution and accuracy

In 2003, the distillery installed a Siemens Pointek CLS 200 instrument on the neck of each wash still. When foam reaches the tip of the instrument probe, the CLS 200 detects it and automatically turns off the burners. It restarts the burners when the froth level diminishes and the sensor is clear. Pointek instruments use a unique inverse-frequency approach to capacitance technology that ensures accurate, reliable, and repeatable level detection. Traditional capacitance devices measure voltage drop or current flow and are affected by changes in material properties. However, Pointek sensors monitor the effect of capacitance based on frequency change. Because even small level changes create large changes in frequency, the result is better resolution and accuracy.

The CLS 200 has a high frequency oscillator with the sensor encapsulated in the probe tip. The sensitive tip is a very accurate and repeatable switchpoint, and the probe is unaffected by material build-up, humidity or moisture. The device is easy to install and calibrate.

Technology helps ensure quality

Reliable level detection helps the plant deal effectively with the foam produced in the wash stills, preventing spills and protecting the process. One of the other major benefits is consistency of distillate, because the burners operate only when needed. This also reduces staff and maintenance requirements, freeing the operators for other duties, and allowing production to continue on weekends. “This technology helps us ensure quality product and enhance efficiency,” said Willie Thomson from the Dufftown Distillery. “It’s an ideal meeting of our time-honored traditions with modern technology.”
Siwarex FTA for weighing railway wagons

Calibrated for quality

The products of Kali France are loaded onto railway wagons in Wittenheim, near Mulhouse, and dispatched for sale. A crucial criterion for the modernization of the company’s weighing system, therefore, was that the new solution had to be calibratable. That was no problem for the Siwarex FTA weighing processor, which is also convincing in day-to-day production. The smooth integration into the automation solution considerably simplifies the weighing processes.

The Kali France factory, near Mulhouse, supplies customers (primarily in France) with potassium and magnesium products. The salts are loaded ready for sale on railway wagons.

In modernizing the company’s automation system, Kali France was also on the lookout for a new, more modern solution for weighing the wagons, because the system currently being used was no longer state of the art. A decisive criterion was that the new system had to be calibratable, because the wagons go directly into sale.

Integrated solution
The new solution consists of a combination of robust Siwarex CC stainless steel load cells, which are resistant to the aggressive salts, and a Siwarex FTA weighing processor, which is integrated directly into the new Simatic S7-300 controller. The personnel can monitor and operate all of the processes locally with an OP270 operator panel. The weighing control can be integrated into the factory-wide automation solution via Industrial Ethernet so that the scales’ parameters can also be changed remotely.

The measures for certifying the calibratable weight measurement by the French calibration authority DRIRE have been taken over by the Alsace Pesage company, which has years of experience in this field. The basis for certification of the Siwarex FTA weighing processor was the European certificate for application as nonautomatic weighing instrument. This simplified the certification procedure considerably.

Positive experience all around
Marc Pupka, technical manager at Kali France, especially appreciates the integration of the weighing processor into the automation system: “It allows us to combine the diagnostic functions of the weighing module with the high functionality and flexibility of an automation system. The distributed monitoring of the system also reduces the response times in the case of operating problems. Failures can now be eliminated without an employee having to be directly at the scales.” Since Siwarex can also be used for other jobs such as proportioning control or quality control, maintenance at Kali France is easier as well.

All in all, those responsible at Kali France are very impressed by the many advantages of the Siwarex FTA processor. Siwarex is now being used as a standard weighing system in the automation solutions at Kali France.

Find out more:
www.siemens.com/siwarex
E-mail: pierre-michael.heck@siemens.com
Acoustic leak inspection on process pumps with Sitrans DA 400

Listening to Leaks

Many process pump owners would like to see a great improvement in the availability of these often process-critical components. With the Sitrans DA 400 diagnostic device, Siemens has developed a solution with which the slightest leaks can be detected reliably on pumps.

Regular plant inspections used to be necessary to detect faults or wear on pumps. Leaks at pump valves could be detected by experienced staff from the operating noise. Other methods, such as systems that employ comparative observations, allowed only relatively general statements to be made about the condition of pumps or pump valves. Neither method was sufficiently reliable or consistent, and frequent unexpected failures were the result.

Acoustic pump diagnosis
Sitrans DA 400 now allows continuous status monitoring of oscillating displacement pumps. The diagnostic system detects the slightest leakage on the pump valves through the structure-borne noise of the pump system, and thus enables damage to be detected in its early stages of development. The principle of acoustic diagnostics is based on the fact that a structure-borne noise in the ultrasonic range occurs at leak points due to cavitation. This noise can be detected online by external structure-borne noise sensors. The piezoelectric sensor of the Sitrans DA 400 measures the noise emission of the cavitation, which is propagated as structure-borne noise (in the ultrasonic range greater than 20 kilohertz) in the pump housing with a piezoelement.

Sitrans DA 400 consists of an evaluation unit and the structure-borne noise sensors, which are simply mounted on the outside of the pump system.

Flow measurement technology at Friesland Foods Cheese

Friesland Foods Cheese produces various types of cheese that are sold under different brand names. In Bedum, the Netherlands, the company recently built a new cheese production facility with two production lines.

In many areas of production, Friesland Foods Cheese uses Siemens flow measurement technology in the new plant – in total, 45 magnetic-inductive Sitrans FM flowmeters and 11 Sitrans FC Coriolis mass flowmeters.

Friesland Foods Cheese was impressed by the high quality of the flowmeters and the positive experience the company has had with these systems over the last 10 years. The flexible equipment concept and the simple commissioning and maintenance of the devices were further important advantages.

Good experiences and an excellent price/performance ratio where decisive factors in favor of Siemens
of the pump, and can therefore be retrofit-
ted to existing pumps. The diagnostic sys-
ystem can easily be integrated into existing
equipment or control systems via Profibus
DP or PA.

Exact and reliable measuring results
The system can even determine the func-
tionality of each individual pump valve
selectively – from a leakage of just 2 per-
cent. The diagnostic device also allows the
continuous, simultaneous, and independ-
ent monitoring of up to four valves on one
pump. Four other universal inputs are
available for the external sensors, for mon-
itoring other important wearable parts or
process variables.

Efficient, durable,
and safe according
to SIL2: Sipart PS2
Using Sipart PS2 with an external, non-contacting
position sensor is beneficial especially in very critical
application conditions. The magnetic non-
contacting position sensor (NCS) is made up of a
sensor control and a permanent magnet gives exact
readings of rotary or linear angles. With linear
drives, the magnet is attached to the spindle for
measuring the position. On rotary drives, the
magnet is attached to the cam shaft for measuring
the corresponding angle. Since no forces are transmitted through levers, rollers, or
joints, the position control is absolutely free of wear.

Sipart PS2 electropneumatic positioner is also uses piezo technology to control the
flow of compressed air while consuming only minimal power. The pneumatic main
control triggers opening and closing the pressurized air supply, so the air itself
performs the task. The piezo control is only used to trigger the main control and
consumes very little power for this task. Another benefit of piezo technology: the
positioner consumes only two percent of the compressed air required by conventional
positioners – resulting in substantial savings over time.

The Sipart PS2 electropneumatic positioner is now also suitable for safety-relevant
applications with requirements up to SIL (Safety Integrity Level) 2.

The SIL qualification for the 4-20 milliampere versions, including HART
communication for simple drives, was conducted by Siemens in cooperation with
exida.com.

A particularly important factor for the owners of pumps is the reliability and infor-
mation content of the monitoring. The pump and system also produce noise that
can interfere with the signal evaluation of the structure-borne noise sensors. There-
fore, the evaluation of the signal takes into
account that no cavitation occurs either
with an open valve or a closed, intact valve,
and the measured noise level thus corre-
sponds to the working noise of the pump.
The appropriate application software for
the diagnostic system suppresses this noise
level and other interference noise so that a
useful signal, free from side effects, is
obtained for evaluation.

Continuous monitoring
Displacement pumps can now be moni-
tored continuously for the first time with
acoustic diagnostics. This enables condi-
tion-based preventive maintenance, which
allows the operational reliability and avail-
ability of the pump – and thus ultimately
the productivity of the entire system – to be
considerably increased.

Find out more:
www.siemens.com/processinstrumentation
E-mail: winfried.demmerle@siemens.com
The principle behind the malting process is very simple. The first stage is the steeping, in which barley and water are stored in large containers to initiate controlled germination. After approximately two days, germination begins, the key enzymes are released, and the barley gains just the right friable consistency needed for the subsequent brewing process. After five to seven days, germination is ended by the kilning process, a specific dry blowing action that, within one or two days, gives the barley just the right taste and color required for the type of beer that is intended for.

A tradition of successful collaboration

The production of malt is now almost completely automated to ensure consistent quality. Nevertheless, the individual processes require in-depth expertise on the part of the plant and equipment makers as well as the automation suppliers.

Viking Malt is one of the largest malt producers in Europe, with malt houses in Lahti, Finland; Söderham and Halmstad, Sweden; and Panevezys, Lithuania. The company’s total capacity is more than 340,000 tons a year. The technical equipment deployed by Viking Malt comes from Schmidt Seeger AG in Germany, a renowned specialist in malt house equipment and silos for grain and seeds.

The automation technology comes from Siemens. Through its Braumat process control system, the company provides the electronic intelligence that allows breweries and malt houses to control their highly sensitive processes and to run them fully automatically, while still retaining the famous taste.

Since Schmidt Seeger and Siemens had installed the first malt tower for Viking Malt in Sweden and provided the site with technical support for many years, it was only logical for the company to again rely on the excellent working relationship established by these two proven partners for the construction of a second malt tower in Halmstad, Sweden, and for setting up a new plant in Lithuania.

Given the national significance of the new production complex in Panevezys for Lithuania’s economy, its handover was celebrated on August 26, 2004, in the presence of Lithuania’s prime minister, Algirdas Brazauskas, and the Lithuanian minister for agriculture, Jeronimas Kraujelis. In building this plant, Viking Malt is responding to the rising demand in the Baltic states and neighboring countries, and is making a major contribution to enhancing farming in the region, which is considered the best growing area in the country.

Two construction methods, one principle

To meet specific local requirements, different approaches were used in constructing the two malt houses. The company’s new malt house in Lithuania was planned using a flat design and was initially set up for an annual production rate of 60,000 tons. It consists of a flatbed steeping system, three germination tanks, and one kiln, along with 16 barley and eight malt silos, as well as the peripheral areas for receipt, drying, and cleaning of the raw materials.

From a technical standpoint, the entire system is characterized by numerous drive units for transport, circulation, and han-
dling. The malt house alone has 200 drive units, and 600 are located in the silo area. These units need 1,400 control signals, which are exchanged with the process control system via Profibus DP. The 54 reversing drives in the germination tanks are connected to the system via ET 200S direct starters.

In Sweden, the company elected to use what is commonly known as a malt tower in which the individual subprocesses are positioned one on top of the other. It consists of 10 tapered cylindrical steeping units, six germination tanks, and three kilns. It has increased the plant’s annual production from 85,000 tons to a total of 170,000 tons. Its mechanical structure requires around 550 drives and follows basically the same system concept as the plant in Lithuania.

Made exactly according to recipe

Malt houses use sophisticated recipes from which different malt grades and their distinct characteristics are produced. Siemens has developed a fully automatic recipe control system for the two new Viking Malt facilities, resulting in two state-of-the-art and financially viable malt houses characterized by predominantly fully automatic process cycles operated with minimum staffing costs.

Siemens’ Braumat process control system offers just the right system environment for such processes. It not only makes specific programming and modernization of recipes possible by means of a graphical user interface, but it supports flexible production planning with variable parameters and controls the individual batch processes in a fully automatic manner. All the plant’s sensors, actuators, and drives are linked directly to the control system so that all relevant information is available at all times. Moreover, the ongoing malting process is totally transparent, from the removal of barley from the silo to the point at which the completed product is placed into storage.

Batch- and time-related archiving ensures complete documentation of the entire production system. Process-related data and sequences can also be accessed, which means that several production processes can be centrally controlled at the same time. The scalability of the production control system installed by Siemens was also an important feature for Viking Malt. Upon commissioning of the malt house in Lithuania, Bengt Ohlsson, managing director of Viking Malt, said: “By building this ultra-modern malt house, we have taken another step toward our objective of establishing ourselves as a reliable malt producer for our international customers.” During the official opening event, the company issued a statement that it would be doubling the capacity of the new plant in the foreseeable future.

Find out more:
www.siemens.com/malt
Rüdiger Selig
E-mail: ruediger.selig@siemens.com
Ekkehard Rupp
E-mail: ekkehard.rupp@siemens.com
Simatic PCS7 automates glazing system production

Stepping into the Future

The Profilit™ glazing system from Pilkington is rapidly moving beyond its original purely industrial function to becoming a design-oriented element in modern architecture. This development has spurred a fundamental modernization of the company’s process control system.

Architects have long known Pilkington Profilit™ as a product to be used for glass facades. Now, however, demand for the glass is increasing as its role expands to include more decorative functions. The Profilit™ system consists of self-supporting glass channels that are manufactured at Pilkington’s building glass plant in Schmelz, Germany, using a specially developed mechanical rolling process.

As part of a recent cold repair, Pilkington subjected the entire production site to a comprehensive refit before refiring the new melting furnace in April 2004 and continuing with the production of glass elements.

Entering the 21st century

According to production manager Christoph Claesges, the technical upgrade of the plant has enabled profiled glass production to take a step into the 21st century, adapting Pilkington Profilit™ to future market requirements. A new control system for the melting furnace, shaping unit, and utilities such as the compressor station and hydrostation were a key part of the upgrade. Pilkington decided to work with Siemens on the implementation of the project and chose the Simatic PCS7 process control system.

The fully redundant system permits the uniform control and monitoring of the entire production process from one control room. It is accommodated in four standard cabinets and is expanded by process instruments such as Sipart controllers, Siwarex weighing system, Sitrans P pressure transmitters, Sitrans FR flow meters, and Simovert Masterdrives.

Siemens was responsible for the implementation of the entire project, including the development of the circuit diagrams, the cabling, the software configuration and parameterization, as well as the commissioning of the entire system. Simovert Masterdrives VC control the transport of the raw glass within the shaping machine and in the annealing lehr. Their functions are also integrated into the PCS7 interfaces.

Experienced project management

Pilkington was very satisfied with the experienced project management provided by the Siemens team, and was able to start operations on time with no problems. From a technological viewpoint, the company has now set a course for the successful manufacture of its unique product, which began life as purely industrial, but which is now well on its way to becoming a creative design element in modern architecture.

Find out more:
www.siemens.com/glass
www.profilit.com
E-mail: glass.team@siemens.com
Siemens is continuing to attend and support numerous interesting events on current topics in the pharmaceutical industry. Some of the major events this fall are:

ISA Expo 2005, October 25 to 27, Chicago
Contact: ivo.backx@siemens.com

China-Pharm, October 25 to 28, 2005, Shanghai
Contact: lin.hong@siemens.com

Pharmaceutical Manufacturing 2005, October 31 to November 2, 2005, Miami
Contact: erik.prins@siemens.com

Make2Pack Workgroup, November 15, 2005, Milano
Contact: ivo.backx@siemens.com

ISPE Annual Meeting, November 7 to 10, 2005, Scottsdale, Arizona
Contact: troy.logan@siemens.com

Do you want to know more about the systems and solutions for the process industry from Siemens Automation and Drives? Simply visit our information portal on the Internet:

www.siemens.com/processautomation
Let PAT clear the way toward making product quality a built-in aspect of your production process. With our combined knowledge of control, analytics, IT and process technology, we support you in identifying your production potential, and develop an implementation strategy that gives you the right tools to fully control your product quality and to release your product in real time. On top of that we have the technologies and expertise to help implement your PAT solution – and to turn your processes into a fast, improved and highly controllable production operation. contact: pharma-info@siemens.com