



WERUM
KÖRBER SOLUTIONS

CASE STUDY

WORLD MARKET LEADER IN DIABETES CARE RELIES ON WERUM'S PAS-X

Werum's out-of-the-box MES Solution ensures consistent production and efficiency at eight customer sites around the globe

AT A GLANCE

CHALLENGE

Standardize manufacturing processes across all sites worldwide and keep costs down with efficient production

SOLUTION

Werum's out-of-the-box MES Solution including PAS-X software product, comprehensive services and pre-configured best-practice content packages

BENEFITS

- Standardized software versions across the company
- Efficient management of processes and equipment
- Faster lead times and improved batch consistency
- Improved process security and evaluation

CUSTOMER

A world market leading pharma company based in Scandinavia

INDUSTRY

Pharma & Biotech

SITES

- Brazil
- China
- Denmark
- France
- Japan
- USA

KEY WORDS

**Manufacturing IT · Pharmaceuticals · Biotechnology · MES · ERP
Out-Of-The-Box Software · PAS-X**

**Cross-Plant Standardization · Operational Efficiency · Cost-Effective Production
Quality Assurance · Lead Times · Fast-Track Implementation**

PAS-X PLAYS MAJOR ROLE IN THE COMPANY'S LARGEST EVER IT INITIATIVE

Consistent system standards across all manufacturing sites /
efficient and cost-effective production

To drive revenue growth, pharma companies are increasing their manufacturing footprint across the globe. It's important to ensure that products are absolutely consistent across all the manufacturing sites, and that costs are kept down with efficient and cost-effective production.

Pharma majors are achieving these strategic needs by installing Werum's PAS-X MES, which can optimize and control all the key processes in a manufacturing plant, supporting pharmaceutical and biopharmaceutical production from development to delivery.

PAS-X meets all needs without customization

"We chose PAS-X from Werum because the software meets all of our needs without extensive customization, but it's flexible enough to evolve as the company develops. Werum is well-established in the industry with a proven reputation," says a senior manager of the customer.

"We chose PAS-X from Werum because the software meets all of our needs without customization."

Senior manager of the customer

PAS-X has allowed the customer to replace a range of manual processes, as well as its legacy MES and ERP system, which was no longer meeting the company's needs: "The old system was outdated, and so there was a strategic corporate decision to upgrade and move to a new setup," says the senior manager. "A major goal was to keep the systems standard across all of the sites meaning that it can be administered and upgraded centrally, with centralized support."

Rolling out PAS-X

The customer's program of replacing the legacy MES and ERP software system began in 2008, with a standalone pilot scheme. The aim was to reduce time to market, shorten production lead times, reduce production costs, introduce cross-plant standardization and improvement of the production processes, optimize procedures for quality assurance, and ensure transparency across all sites.

The successful standalone pilot grew into the the company's largest ever IT initiative – a long-term project to install a globally standardized ERP/MES solution on the basis of SAP and Werum's PAS-X across a total of 19 production sites throughout Europe, Asia, North and South America, to provide support throughout the entirety of the supply chain and manufacturing process.

PAS-X: Flexible standard software product

PAS-X covers all of the individual process steps of the company's discrete pharmaceutical production, from manufacturing to packaging. The software product is flexible, and features can be adjusted as required. This allows Werum and the customer to add in site-specific changes, for example to meet local legal requirements, or to provide the software in any language.

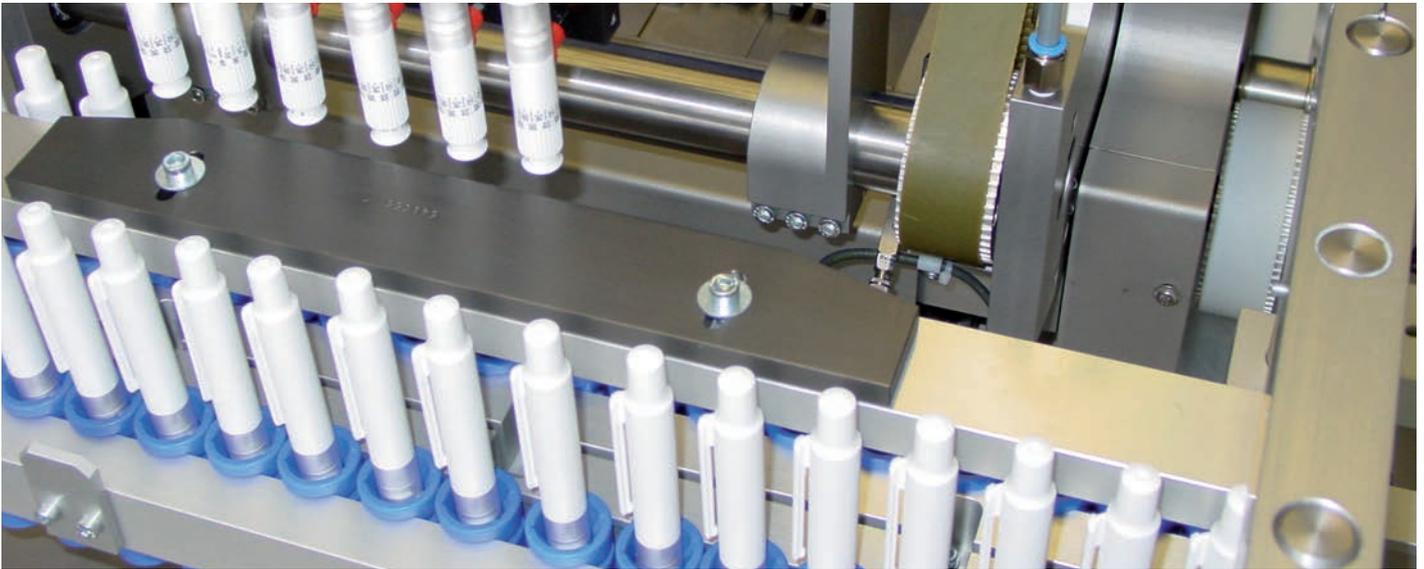
"Through the extended rollout, we have been able to establish an excellent and collaborative partnership with our customer."

Benjamin Pieritz, Senior Head of Strategic Program Management, Werum IT Solutions



"Through the extended rollout, we have been able to establish an excellent and collaborative partnership with our customer, which makes the whole process simpler and more effective," says Benjamin Pieritz, Senior Head of Strategic Program Management, Werum IT Solutions.

And the customer's senior manager adds: "Over the past years we have become a team rather than just client and supplier."



PAS-X GO-LIVES IN THE CONTEXT OF THE IT INITIATIVE

→ October 2009

Denmark

- assembly and packaging of insulin pens

→ February 2011

France

- filling of insulin vials

→ May 2011

Denmark

- formulation, filling and inspection of insulin vials

→ October 2011

USA

- assembly and packaging of insulin pens

→ October 2013

Brazil

- formulation, filling, inspection, assembling and packaging of insulin pens

→ October 2014

China

- formulation, filling, inspection and packaging of insulin pens, assembly and packaging of durable devices

→ 2015/2016

Japan

(currently planned)

Roll-out at the manufacturing site in Brazil – one of the customer's largest plants

This site, around a thousand kilometers from Rio de Janeiro, has 18 lines overall in five process areas, including lines for formulation, filling, inspection, assembling and packaging insulin pens, and two lines for tablet packaging. These involve around 400 users, many of whom use mobile terminals. Adding in around 10,000 holding areas in the warehouse, this creates a large and diverse user base, which was a challenge, but one that PAS-X is designed to meet.

“We began this project by taking a step backwards and looking at how we could apply everything we have learned from the previous projects,” says Pieritz.

Meeting the challenges

Pharmaceutical production, packaging, and material flow each have specific challenges, but the PAS-X system is able to meet these with minimum customization, relying on its functional completeness.

“One challenge we faced was the method of supplying material to the lines,” says Pieritz. “PAS-X was able to solve this using its standard functionality for automatic replenishment and a special development to better support the picking process in the warehouse. The warehouse operators use PDAs to operate PAS-X and the system will exactly tell them automatically which pallets they have to deliver to which line.

Another of the challenges is the size of the site and the number of people involved. However, this was solved by close teamwork between Werum and the customer.

Providing the support

Because of the time zone difference between Brazil and Europe, when the software was ready to run, project teams travelled to Brazil so that they could be available in site, supported by teams on standby back in Europe.



“Werum’s support as we went live was excellent.”

Local project manager of the customer

“Werum’s support as we went live was excellent, for example putting people on site short-term and providing support whenever needed. Since the system is so flexible, user-friendly, and intuitive, it’s possible to begin with the basics and then build on these, learning to use PAS-X step by step,” says the local project manager of the customer.

“There are always teething problems in any installation of this size, but these were minor and completely manageable. We worked with the customer to smooth the process, and this meant that we could keep production loss to a few days only”, says Pieritz.

BENEFITS OF USING PAS-X

The pharma company chose Werum’s PAS-X because it comes with an out-of-the-box setup, providing as standard all the essential functionalities needed by pharmaceutical, healthcare, and life sciences industries. This includes built-in compliance with FDA, EMA and other regulatory authority guidelines.

“PAS-X increases our chance of ‘right first time’, so reducing costs and downtime. It also provides us with complete traceability from beginning to end of the process,” says a senior manager of the customer.

The benefits:

- Faster lead times through streamlining electronic approval and release workflows, and reducing paperwork.
- Shorter time to release a manufactured batch through the review by exception approach.

- Verified data entry, improving data quality, accuracy, and security.
 - Improved process security through early detection of changes in parameters, cutting the wasted time and costs associated with faulty batches.
 - Process evaluation allowing continuous improvement based on production and quality data.
 - Improved accuracy and consistency compared with previous manual processes.
 - Standardized software versions across the company, making installation, support and upgrades simpler and more cost-effective, harmonizing working practices, and improving transparency across the company.
-



PAS-X IN PHARMA AND BIOTECH PRODUCTION

With PAS-X, Werum provides a complete package that includes software, comprehensive services and pre-configured content:

PAS-X Software

PAS-X is a mature standard software product which offers high performance and enables fast implementation. The business functions provided by PAS-X cover all areas related to specification, manufacturing control, quality assurance, and process optimization out of the box. PAS-X supports all key manufacturing processes from process development to commercial production and packaging for all pharmaceutical process types. The functional architecture of PAS-X closely follows the ANSI/ISA 95 standard.

“The PAS-X software product is constantly updated, implementing planned improvements and integrating technology trends,” says Robert Welter, Head of PAS-X Product Management, Werum IT Solutions. “This allows our customers to benefit from continuous innovations and improvements, which are supplied as upgrades without compromising the stability of a running system.”

PAS-X Services

With comprehensive services Werum supports its customers during all PAS-X implementation phases: from Ready to Fit and Build to Run Phase. Thus, Werum can take over many tasks which previously had to be accomplished by the customer and can unburden the customer during the MES implementation phase. The service portfolio is based on the expectations of the PAS-X User Community and on best practices of the pharmaceutical and biotechnology industry.

Werum helps its customers with its long-standing pharmaceutical MES knowledge and specialized personnel to avoid resource gaps when implementing MES projects. The goal is to ensure knowledge transfer from the very beginning so that the customers can implement PAS-X quickly and, after Go-Live, operate and manage the system on their own.

PAS-X Content

In addition to supporting consulting services, the pre-configured PAS-X Content Packages allow a jump-start to deploying PAS-X. They are GMP-compliant, based on the best practice of the industry and directed by the PAS-X User Forum “PAS-X For Us” (PFU). In the PFU's Special Interest Groups companies work together to help develop best-in-class MES technology, functionality and services.

To set up PAS-X, Werum's industry-specific templates save the customer a lot of time and efforts. These templates are comparable to Word or Excel templates for typical documents. With them the customer no longer needs to start from scratch when configuring PAS-X, but can instead use prebuilt modules. The templates are designed for specific pharmaceutical industries such as the chemical and biopharmaceutical API production. Together with a Werum consultant the templates will be configured to suit the customer's business processes.

PAS | X

SERVICES
SOFTWARE
CONTENT



SUMMARY

MES systems will become increasingly important as pharmaceutical companies expand globally and look for global standardized and integrated IT solutions.

This was exactly the situation at the customer, a large pharmaceutical company based in Scandinavia. The world market leader in diabetes care had to replace manual business processes as well as its outdated MES/ERP system to stay competitive. Werum's PAS-X MES was chosen because it covers all needed functionalities as standard and is flexible to evolve with the company.

Since the first rollout in Denmark, PAS-X became the standard MES at the customer and plays a major role in the company's largest ever IT initiative to install a globally standardized ERP/MES solution.

Werum's successful PAS-X installations at the customer's sites have confirmed the product's ability to optimize and standardize manufacturing processes across sites ensuring cost-efficient production and absolute batch consistency. In future, the pharma major and Werum will embark on further PAS-X rollouts and continue their combined strategy for success.

ABOUT WERUM IT SOLUTIONS

Werum IT Solutions is the internationally leading supplier of manufacturing execution systems (MES) and manufacturing IT solutions for the pharmaceutical and biopharmaceutical industries. Its out-of-the-box software product PAS-X is used by 17 of the world's top 30 pharmaceutical and biotech companies in more than 700 installations. Founded in 1969, the IT company employs more than 400 people at its headquarters in Lüneburg, Germany, and at nine other locations in Germany, France, Switzerland, the United States, Japan, and Singapore.

Werum is part of Medipak Systems, the Pharma Systems business area of the international Körber technology group. Körber unites more than 11,000 professionals in about 50 industry-leading companies, achieving annual earnings of

more than two billion euros. As a Medipak Systems company, Werum provides integrated IT solutions for all phases of pharmaceutical and biopharmaceutical production – including process development, commercial production, and packaging as well as track & trace serialization.

www.werum.com

ABOUT THE CUSTOMER

The customer is a global healthcare company with leading positions within diabetes care, haemophilia care, growth hormone therapy and hormone replacement therapy. It employs approximately 37,000 employees in 75 countries, and markets its products in more than 180 countries.

