

FUJIFILM DIOSYNTH BIOTECHNOLOGIES, MORRISVILLE, NC, USA

PAS-X GO-LIVE AT LEADING GMP DRUG CONTRACT MANUFACTURER



Implementation at production site in Morrisville, NC / Werum's PAS-X won selection process / biomanufacturing expertise, local presence and PAS-X scalability as decisive factors

FUJIFILM Diosynth Biotechnologies U.S.A., Inc. has successfully moved PAS-X MES into operation at their US site in Morrisville, NC. The company is one of the world's leading GMP drug contract manufacturing and research organizations for the biopharmaceutical industry and has contracts with some of the top companies in this field.

The scope of the phase 1 go-live comprises essential PAS-X functionalities such as

Weighing & Dispensing and Material Flow combined with pre-configured scales and SAP interfaces. Later, the system will be extended to a full-blown MES.

The contract manufacturer decided for Werum's PAS-X after an extensive selection process. Werum's expertise in biopharmaceutical manufacturing, Werum's local presence and the scalability of PAS-X were the crucial factors leading to this decision.

PAS-X will help the company to improve transparency of manufacturing processes and costs and to meet the FDA compliance requirements.



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WERUM AMERICA

BENJAMIN PIERITZ APPOINTED SENIOR VP OF OPERATIONS FOR WERUM IT SOLUTIONS AMERICA



Benjamin Pieritz

Promoting a manager from within its own ranks, Werum IT Solutions has implemented a high-level management change at Werum IT Solutions America, setting course for opportunities to further expand its US business.

On April 1, 2015, Benjamin Pieritz assumed the position of Senior Vice President Operations for Werum IT Solutions America. In his new role, Mr. Pieritz will oversee business operations in the United States.

Mr. Pieritz has accrued considerable experience at Werum in various upwardly-mobile positions, including Software Engineer, Project Manager and Strategic Program Manager. Most recently, he was responsible for the global MES programs of the pharmaceutical groups Novo Nordisk and TEVA, which are ranked among the largest in their sector. He also was responsible for the product management, development and marketing of Werum's KPI solution, and for working out a joint KPI product strategy with Körber Medipak Systems.

B. BRAUN, IRVINE, CA, USA

PAS-X INFORMATION NUCLEUS AT B. BRAUN IRVINE

US site implements sophisticated multi-level IT architecture with PAS-X



B. Braun's facility in Irvine, CA has installed a new, highly automated production line, with PAS-X as a core component. The line, designed to produce a variety of IV solution bags for hospitals and clinics, will manufacture the empty bags, fill them, sterilize

them, and package them, all under full automation. To achieve such a sophisticated approach, B. Braun has defined a multi-level IT architecture that links ERP to PAS-X to the equipment controllers.

The PAS-X MES is the main link to the overall order and inventory data controlled by the ERP, triggers the correct recipe execution at the equipment level, and consolidates all of the key production data into our final electronic batch record.

The most unique feature of this project was the high level of integration between PAS-X and a large number of equipment types,

resulting in PAS-X supporting 25 different message types.

The expected benefits to B. Braun of this architecture is streamlined batch production execution, final batch review, and product release. Additionally, the captured process data will be used for ongoing process improvement.

This highly integrated approach has already been proven in the LIFE and LIFE Nutrition sites at B. Braun in Melsungen, Germany.

PHARMA MANUFACTURING, BRAZIL

PAS-X GO-LIVE OUT OF THE BOX AT THE WORLD'S FIFTH LARGEST PHARMA MANUFACTURER

Implementation of Werum's PAS-X Weighing & Dispensing at site in São Paulo, Brazil / standardized processes / compliance with Brazilian regulatory requirements

The world's fifth-largest pharmaceutical manufacturer introduced Werum's PAS-X Weighing & Dispensing at its Brazilian site in São Paulo. Here, PAS-X supports the production of anesthetics and cardiovascular drugs, in addition to other products.

The pharmaceutical company required a reliable MES software product that offers standardized processes for the weighing and dispensing operations and helps to meet compliance requirements. PAS-X Weighing & Dispensing is the company-wide standard weighing system and was rolled out in support of the global MES strategy in order to achieve operational excellence in manufacturing.

PAS-X was implemented nearly out of the box. Some customizations were made in

order to meet the specific Brazilian regulatory requirements – for instance, the serial number system to track handling units. PAS-X Weighing & Dispensing is integrated with SAP via an ERP interface.

“The implementation of PAS-X was very successful – we thank the Werum team for their remote consulting and support,” says the project manager of the customer. “Now, we are evaluating the further rollout of PAS-X to other manufacturing areas.”

The pharmaceutical manufacturer has already installed PAS-X at plants in the USA, China, India, and Sweden.



MANUFACTURING OF THE FUTURE

DEVELOPING THE PERFECT PLANT: A HIGH TECH APPROACH TO MEETING THE NEEDS OF LOW COST BIOPROCESSING PLANTS



Amgen to define a standardized and integrated IT architecture for seamless information exchange



Robert Gamber,
Principal Architect –
Platform Lead,
Amgen

The biopharmaceutical manufacturing industry is experiencing an inflection point. Competition, price controls, globalization, biosimilars, and technology shifts have resulted in a new approach to building and operating manufacturing facilities.

ny, is on the leading edge of this change, building new more flexible facilities and retrofitting existing plants to be more efficient. In order to achieve these goals, Amgen is identifying a standard IT architecture and integration approach between MES and other systems to streamline the flow of manufacturing data in support of electronic batch records and continued process improvement. The result is a highly automated shop floor with integrated systems that are both faster to startup and require fewer ongoing resources to maintain.



Amgen, the world's largest biotech compa-

TURNKEY BIOTECH FACILITIES

NEW PARADIGM: MULTI-PRODUCT SINGLE-USE FACILITIES FOR BIOPHARMACEUTICAL COMPANIES



Configurable site architecture and complete MES-based operations management from a single source



Barbara Paldus, CEO,
Finesse Solutions

As the challenges in biologics and vaccine manufacturing increase, companies are turning to multi-product single-use facilities. These facilities can provide higher yield production with fewer employees at a greatly reduced capital expenditure.

The Finesse SmartFactory is based on measurement and actuation building blocks at ANSI/ISA 95 Levels 0 and 1 which ensure flexible process automation solutions that are compatible with various control and batch platforms at Level 2. In order to provide a complete operations management solution, an MES – like Werum's PAS-X – is required at Level 3. The MES optimizes plant-wide resource utilization, integrates manufacturing batch information, and facilitates training and validation record management.

batch records. Implementation is flexible so that the user can focus on the level of automation required for each unit operation and the consistency of single-use film materials between upstream and downstream, without compromising the project budget or timeline.

Finesse offers a platform that can serve customer needs for both newly developed products in a pilot plant providing clinical materials and large-scale commercial production. Such a SmartFactory represents a new paradigm having a configurable architecture for single-use facilities.

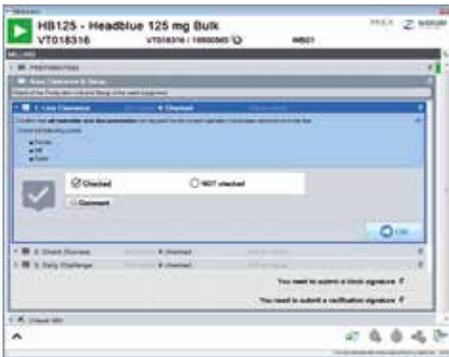
SmartFactory has been designed with an open architecture. This enables the process flow to be designed with user-preferred equipment in a modular and scalable manner, while fully maintaining quality and regulatory compliance in the electronic



PAS-X V3.1.7

WERUM REDEFINES MES USABILITY: NEW PAS-X VERSION AVAILABLE

New user guidance concept and improved device-specific design provides easy, efficient operation



New PAS-X EBR dialog: straightforward user guidance through the execution process

Werum IT Solutions has released the latest version of its worldwide market-leading Manufacturing Execution System (MES) for the pharmaceutical and biopharmaceutical industries. The new PAS-X V3.1.7 software offers new levels of usability, and serves to further improve overall operational efficiencies.

Easy-to-use MES for pharma companies

“Pharmaceutical companies are pressed to make production lines increasingly efficient and agile,” says Robert Welter, Senior Head of PAS-X Product Management, Werum IT Solutions GmbH. “To meet these requirements, an MES is needed that is ideally suited, not only in terms of functionality but also in terms of usability in order to allow easy system operation. In addition to designing new and innovative functions, it is essential to ensure an unsurpassed level of usability.”

New user guidance concept

With PAS-X V3.1.7, the dialog for electronic batch recording was given a new design to optimally support production plant personnel in performing their tasks. Despite the complete functional scope of PAS-X, the information is displayed in a way that allows operators to work intuitively and efficiently, allowing them to focus on the most

demanding aspects of their work while still being able to find additional information at any time. Based on feedback culled directly from shop floor end users, Werum also optimized certain automatic processes to further improve the overall user experience.

Device-optimized and improved design

PAS-X comes with device-specific dialogs. Depending on the device, users are displayed a dialog that has the optimal size and can be operated easily. For instance, the KPI dialogs are optimized for large screens – frequently used, for example, on packaging lines – as well as for tablet screens often used by supervisors. All operating elements are placed in optimal on-screen positions and font sizes can be changed. This is particularly relevant for mobile devices and Asian languages, such as Chinese and Japanese.



New PAS-X KPI Operator dashboard: important performance data at a glance



This is what our customers say

“We tested the redesigned EBR execution in practice,” says Stefan Moris, Business expert POM – INM, Janssen Pharmaceutica N.V. “Everybody was impressed with the quality of the new graphical user interface.”



Stefan Moris

INTERVIEW

PAS-X OFF-STAGE: TECHNOLOGIES AND METHODS

PAS-X is the internationally leading MES – both in terms of functionality and usability. In an interview, Arndt Erdtmann (Senior Director PAS-X Development, Werum IT Solutions) and Jens Blödorn (Senior Head of PAS-X Development, Werum IT Solutions) provide an insight into the development technologies and processes this success is based on.



Arndt Erdtmann

In which areas is PAS-X MES deployed?

Erdtmann: PAS-X covers all key areas in pharmaceutical and biopharmaceutical manufacturing from process development to commercial production and packaging. It supports all major pharmaceutical manufacturing technologies, e.g. for vaccines, biopharmaceuticals and solids.

What software technologies does Werum use for the development of PAS-X?

Erdtmann: We rely on efficient state-of-the-art technologies which have become standard in software development. They support concepts such as mobility, web technology and cloud computing. Our team leverages Hibernate, Spring or Vaadin – technologies that are successfully used for software projects all around the world.



Jens Blödorn

What are the benefits for our customers?

Blödorn: These software technologies provide stability and performance. For example, compared to Enterprise JavaBeans, Hibernate achieves significantly higher performance. The technologies are also compatible with all available database systems and can be extended easily. By using them, our customers are provided with maximum flexibility.

Does Werum always rely on the latest technology know-how?

Erdtmann: Werum stands for continuity and stability – even with software technologies. We do not follow each and every trend, but when it comes to mature technologies we are in the vanguard of applying them. In other words: We intend to be conservative as we want to ensure that the software technologies will still be available and can still be updated in three years from now – which is totally in line with the interest of our customers.

We deal with new technical possibilities by closely working together with technical universities, that, for example, organize hackathons. In the context of hackathons, developers, designers and other experts meet to develop new ideas within a short time frame.

How do customers benefit from Werum's software development methods?

Blödorn: As we use agile methods like Scrum, our development process is flexible, lean, and fast. We work in small, effective teams – following an iterative and incremental approach. The result at the end of each development cycle – which usually lasts three weeks – always is an executable software version.

Our customers are involved in this process and are able to give feedback during the development. We are able to implement this feedback within a short time and can adapt our activities appropriately.

How is the software tested?

Blödorn: Currently, we are performing about 3,000 fully automated user interface tests per day. In addition, there are about 9,000 unit tests performed every 15 minutes. In this way, our developers can verify almost immediately – and not after weeks or even months – whether the software still functions as intended.

We are pioneers in test-driven software development. The number of tests is continuously increased. This means that we really put into practice what is often described and demanded by experts. We implement these approaches on a large commercial scale.

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INTERVIEW

PAS-X OFF-STAGE: TECHNOLOGIES AND METHODS

→ Continued from PAGE 5

Where do you see future trends?

Erdtmann: The need to use mobile devices in pharmaceutical and biotech manufacturing will increase. PAS-X already supports these use cases, for example with dialogs optimized for specific devices. There is also great potential in contact-free interaction with computers, for example through gesture control and wearables. Operators who have their hands free can act more efficiently on the shop floor. However: Processes should not simply be transferred from the static world to the mobile world. We rather think about how mobility paves the way for entirely new procedures and we develop our software accordingly.

Blödorn: Other future trends are cloud computing and microservices. Both concepts are targeted at the modularization of software which allows to deploy functions independent from each other and

thus to execute these functions in a faster and more efficient way. Our technologies and architecture concepts enable us to implement these approaches.



LOCAL PRESENCE

NEW: LOCAL PAS-X TEAM IN LATIN AMERICA

Office in São Paulo, Brazil / Werum customers benefit from local pharma MES experts

Werum IT Solutions is expanding its local presence in Latin America. In the future, pharma and biotech companies in the Latin American region will benefit from well-trained local pharma MES experts as Werum IT Solutions – together with the Körber Medipak Systems companies Dividella, Mediseal, Rondo and Seidenader – will open an office in São Paulo, Brazil in May 2015.

“With the new Brazilian MES consultants who are located in the same region as our customers’ production sites, we will be able to offer PAS-X MES services in Latin America even faster and more efficiently in the future,” says Lars Hornung, Director Global Sales, Werum IT Solutions GmbH. “It is also an important step to further expand our position as the globally leading MES supplier for the pharmaceutical and biopharmaceutical industries.”

Torsten Isenberg, Director Head of Consulting & Training, Werum IT Solutions GmbH, adds: “With Daniel Bosso Gonçalves and Tiago Cefas de Queiroz we were able to recruit two local experts with more than 15 years of pharma MES experience plus profound PAS-X know-how. After additional intense PAS-X training during the last six months, our Latin American customers really can look forward to an excellent local Werum support by highly qualified experts for their MES projects.”

In addition to Werum’s manufacturing IT solutions based on its market leading PAS-X MES product, local pharma manufacturers will also benefit from the presence of the other Medipak Systems companies which offer a complete range of machines, packaging development, and material for pharmaceutical products including after-sales service and technical support.

Your local MES experts:



Borja Guerra,
General Manager



Tiago Cefas de Queiroz,
Senior Consultant



Daniel Bosso Gonçalves,
Senior Consultant



INTERVIEW

PAS-X TRAINING SERVICES: DEVELOPING SKILLED USERS WHILE KEEPING YOUR TEAM FOCUSED

In this interview, Jörn Sawinski (Manager Training & Consultant, Werum IT Solutions) explains how Werum’s training concepts, out-of-the-box training modules and video tutorials support manufacturing sites in an optimal way



Jörn Sawinski

How does Werum support customers during PAS-X implementation?

Sawinski: To ensure the success of a PAS-X project a comprehensive, elaborated training concept is of significant importance. In a workshop, we analyze the specific training requirements in cooperation with our customers. It is important to define who requires which training

and when the course is to be held in the very beginning. This approach enables a smooth, successful implementation and a skilled workforce prepared for go-live.

How is the training concept put into practice?

Sawinski: There are two options: We can either train selected key users who are then responsible for the training of all other users within their company, or we can provide PAS-X training courses for all users. The latter approach is much more beneficial for our customers because we relieve their key users in terms of workload. Additionally, we guarantee the technical competence and high quality of the training courses.

How are the PAS-X training courses structured?

Sawinski: The PAS-X training courses are composed of standardized modules out of the box. These modules can be selected and organized flexibly to cover all PAS-X functionalities for our customer’s specific processes, such as chemical or biopharmaceutical API manufacturing. Based on real-life production processes

in a virtual factory, our customers learn how to operate PAS-X and how they can optimize their processes and design them to be more efficient with our software. There are three training tracks covering PAS-X operation, PAS-X administration, and customer-specific topics.

Where do the courses take place?

Sawinski: We conduct the PAS-X training courses locally at your plant and on your date of preference. Apart from this, we regularly offer training courses at our modern premises in the USA, Germany, or at one of our other international locations. You can download the PAS-X training program with all upcoming courses and dates at www.werum-academy.com.

Are there any other novelties in the Werum Academy?

Sawinski: We are currently creating video tutorials for the PAS-X basic training course and for new features of PAS-X. The videos demonstrate how particular processes work and how the features are to be used. We will provide these tutorials in addition to our training courses. The participants can purchase the video tutorials to recall and permanently memorize the learned contents. This way, they have the opportunity to continuously repeat what they have learned and to significantly improve the quality of the learning process.

PAS-X training tracks

PAS-X OPERATING TRACK	PAS-X ADMINISTRATION TRACK	PAS-X ADAPTED TRACK
<ul style="list-style-type: none"> □ PAS-X introduction □ Business Functions □ 3 levels: Basic, Professional, Enhanced 	<ul style="list-style-type: none"> □ System administration □ Printing and reporting □ PCS administration 	<ul style="list-style-type: none"> □ Individual program for companies
<ul style="list-style-type: none"> → Operators → Supervisors → Key users → Quality controllers → Project managers 	<ul style="list-style-type: none"> → Key users → System administrators 	<ul style="list-style-type: none"> → Operators → Supervisors → Key users → Quality controllers → Project managers → System administrators

MANUFACTURING INTELLIGENCE

WERUM'S KPI SOLUTION: THE OPTIMAL FIT FOR MEDISEAL AND DIVIDELLA MACHINES

PAS-X KPI – The shop floor performance booster for pharma and biotech manufacturing

For efficient pharmaceutical manufacturing it is essential both for operators and supervisors on the shop floor and for production site managers to constantly monitor the operating data. Thus, all stakeholders can use the key performance indicators (KPI) from the production and packaging lines to optimize their processes or equipment. Werum's PAS-X KPI Solution provides powerful functions for ensuring operational excellence and lean manufacturing by combining PAS-X data and equipment data for performance management.

Live monitoring of production

On the shop floor, the PAS-X KPI Solution automatically acquires process data related to Overall Equipment Effectiveness (OEE) in real time. The results are visualized on different monitors and can be understood easily to aid decisions. Operators and supervisors can view the current status of their packaging lines and their production targets at any time. If data is not provided by the equipment, the PAS-X KPI Solution also allows operators and supervisors to manually enter the causes of interruptions, such as set-up times, pausing times, or maintenance.

Software-aided decision making

Production site managers benefit from standard reports allowing the analysis of aggregated data with drill-down functions for root cause analysis. For example, the OEEs for the same product manufactured on different equipment can be compared easily. The gapless recording of process data in the system facilitates continuous improvements in terms of efficiency, productivity, and profitability.

Device-optimized and improved design

The PAS-X KPI Solution comes with device-specific dialogs. They are optimized for large screens, as for example used at packaging lines, and also for tablets used by supervisors.

PAS-X KPI solution for packaging machines from Mediseal and Dividella

In the future, Werum's KPI tool will be available as a stand-alone solution for lean implementation with packaging machines of Mediseal and Dividella. KPIs such as Availability, Effectiveness, and Quality are displayed together with the resulting OEE in real time right where they are generated.



Operators will be able to directly monitor the performance of their line on mobile HMI monitors or on the screen at the equipment.

Pharma and biotech customers benefit from a powerful and user-friendly KPI tool directly at their packaging line, supporting them in maximizing the manufacturing performance. "Our KPI solution offers the advantage of a fine-tuned interaction of software and equipment. Thus, it can be introduced in a more secure and faster way than third-party components", says Karl Hoffmann, Senior Director Marketing & Business Development, Werum IT Solutions GmbH.



WHY PAS-X KPI SOLUTION

Management

- Increased profitability – software-aided decision making to facilitate improvement processes

Supervisor

- Achieving production targets – knowing that performance falls behind before problems arise

Operator

- Increased transparency – live monitoring of individual production performance and status

Administration

- Ease of configuration – all functions and data are available within a single system

