WERUM
KÖRBER SOLUTIONS

PAS-X NEWS

INTERVIEW

WERUM AND KÖRBER – IDEAL PARTNERS FOR INTEGRATED SOLUTIONS FOR THE PHARMA AND BIOTECH INDUSTRY

Rüdiger Schlierenkämper

Gerhard Breu

The international technology group Körber acquired the shares of Werum IT Solutions AG, formerly Werum Software & Systems AG. In an interview, Rüdiger Schlierenkämper (CEO Werum IT Solutions) and Gerhard Breu (CEO Körber Medipak Systems) speak about the motivations and objectives of the acquisition, benefits for the customers and future PAS-X developments.

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PAS|X TUNEDUP MOVINGFORWARD

CONTENTS

PAS-X MES SOLUTION

ALL-IN-ONE MES SOLUTION: PAS-X SOFTWARE, SERVICES AND CONTENT

Werum supplies a complete All-in-One MES Solution out of the box. The package includes the PAS-X software product; a comprehensive set of support and consulting services; and content packages that pre-configure business processes with industry best practices.

In order to jump-start the implementation of PAS-X we offer predefined content templates and libraries specifically designed for pharma and biotech production processes. Consulting services support the customer in all implementation phases and throughout the entire lifecycle of its PAS-X MES Solution.

➔ Find out more about PAS-X software, services and content at **PAGES 4-6**

INTERVIEW

WERUM AND KÖRBER – IDEAL PARTNERS FOR INTEGRATED SOLUTIONS FOR THE PHARMA AND BIOTECH INDUSTRY

Werum customers will benefit from integrated solutions in the future

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Why did Körber acquire the software company Werum?

Breu: Because Medipak Systems and Werum are the optimal fit. Körber Medipak Systems specializes in inspection and packaging solutions for pharmaceutical products. Software solutions are becoming increasingly important to Körber. Our goal is to become the strategic partner to the pharma industry. With the acquisition, Medipak Systems can extend their expertise in the cutting-edge market for software solutions for production control and monitoring for pharmaceutical and biotech companies.

Schlierenkämper: As the world's leading provider of MES systems for pharmaceutical and biotechnological manufacturing, Werum's activities dovetail perfectly with the existing portfolio of Medipak Systems. We see Körber as ideal partner with whom we will be able to open up new perspectives in the pharma MES market of the future.

What are the goals of the acquisition?

Breu: Together, Medipak Systems and Werum will be able to exploit long-term growth opportunities with our strong and shared customer base. Within the Körber Group, Werum will benefit from our international presence as we will be able to share resources, infrastructure and offices around the globe in the future.

What are the benefits for the customers?

Schlierenkämper: In addition to enhancing Werum's successful MES business, the goal of the acquisition will be to jointly develop new and unique products for our customers in the international biotech and pharmaceutical industry.

Are there any changes for Werum customers?

Schlierenkämper: There will be no changes for our customers. They will be personally supported by the same management and teams at Werum. Continuity in management is also ensured because Hans-Peter Subel and I, as Executives, will continue to run the business. Hartmut Krome will support the Körber Group as consultant.

Breu: Werum will remain an independently operating company within the Medipak Systems Group – alongside the existing Pharmaceutical Materials and Pharmaceutical Technology business fields.

Will Werum expand its international presence and activities?

Schlierenkämper: We will use Körber's international presence and our experienced Werum employees in order to attract new customers and to serve our long-term customers even better – wherever they are doing business. We will expand Werum's global activities beyond our well established presence in Europe, North America and parts of Asia. The Pharmerging Markets, which are facing rapid growth in pharma and biotech, will be the focus of our internationalization strategy.

What will be the focus of the future PAS-X product development?

Schlierenkämper: Usability will be a primary emphasis of the future product development. We will make working with PAS-X even more intuitive, improve communication between the operator and the system and optimize the system for use on mobile devices. We want to design innovative PAS-X solutions for the Smart Factory 4.0. It is our vision that PAS-X communicates with intelligent equipment on the shop floor and guides the operator – as the leading system – through the process.

Will Werum solely focus on solutions for packaging processes in the future?

Breu: No. Werum will offer IT solutions for improving the efficiency of all manufacturing-related processes. Under the roof of Körber Medipak Systems, Werum will consequently continue to offer and further develop the existing range comprising process development, manufacturing processes and packaging. And Werum will extend its position as the globally leading MES supplier for pharma and biotech companies. The PAS-X product roadmap will be continued.

NOVO NORDISK, BRAZIL

GO-LIVE OF NEWEST PAS-X VERSION IN THE CONTEXT OF NOVO NORDISK'S LARGEST EVER IT INITIATIVE

Combined ERP/MES rollout in the framework of PS@SAP / Excellent Go-Live support

Novo Nordisk, the world market leader in diabetes care, implemented PAS-X V3.1.5 successfully at their Brazilian site in Montes Claros. With 18 production lines in five process areas, including lines for formulation, filling, inspection, assembling and packaging insulin pens, and two lines for tablet packaging, Montes Claros is one of the company's largest sites.

PAS-X was rolled out with SAP in the context of the global PS@SAP program, Novo Nordisk's largest ever IT initiative to install a globally standardized ERP/MES solution across all production sites. Montes Claros has been the fifth site on the PAS-X rollout plan. Since PAS-X V3.1.5 covers all major functionalities out of the box, only minor customizations were made. "Werum's support as we went live was excellent, for example putting people on site short-term and providing support whenever needed," says Roberto Soares Toledo, Novo Nordisk's project manager in Brazil. "Since PAS-X 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."

The next stage of the PS@SAP rollout is already underway, with a PAS-X installation at Novo Nordisk's site in Tianjin, China.

COMPLIANCE

FDA COMPLIANCE EXPECTATIONS FOR EBR-MBR VALIDATION

Statement by Monica J. Cahilly, President, Green Mountain Quality Assurance

U.S. and EU regulatory observations highlight the importance of adequate controls to document data integrity – that is, controls must ensure that data used to make decisions that may affect patient safety is accurate, complete, consistent, and reliable. These expectations include that data integrity control strategies are risk-based, i.e., commensurate with the potential impact of the regulated process on patient safety and product quality, and that these include measures to prevent and detect data integrity issues.

Implementation of an MES-controlled manufacturing process, using EBR, promises to reduce data integrity risks – as well as improve the business efficiencies and effectiveness – associated with the critical processes of lot release and batch record review when compared to a manually controlled manufacturing process documented on paper batch records. Realizing this promise requires that the MES-EBR system be properly implemented and validated to ensure mastery of these complex workflows by the technology.

For example, thorough and documented control strategies would be expected to preventatively mitigate any risks posed by the MBR design, functionality, and performance. These steps may include documented verification of the accuracy and completeness of the MBR master data entries and any calculation algorithms against predefined and validated process specifications.

Simple, efficient, and effective automated manufacturing and batch record review processes are realized when the technology,

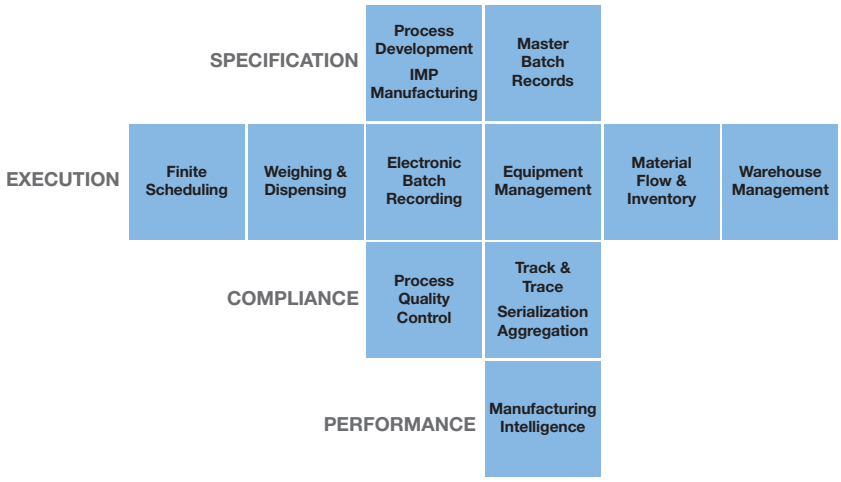
Monica J. Cahilly

and those implementing it, absorb the complexity of these workflows through sophisticated design and control. In the words of Steven Jobs: "It takes a lot of hard work to make something simple, to truly understand the underlying challenges and come up with elegant solutions." The shared talents, dedication, and hard work of Werum and the PAS-X User Community hold the key to these elegant solutions for PAS-X.

PORTFOLIO

PAS-X SOFTWARE PRODUCT

PAS|X



Robert Welter
Head of Department Product Management, Werum IT Solutions AG

PAS-X SOFTWARE

The new V3.1.6 stands for simplicity and efficiency

In cooperation with the PAS-X User Community, Werum further improved the most stable and mature MES for pharmaceutical production. „We improved the usability, making working with PAS-X even easier and more efficient“, says Robert Welter. „PAS-X is a functionally complete and scalable MES out of the box, which widely automates actions that previously had to be performed manually.“

Accelerated MBR creation

The extended control of storage conditions and the automation of basic functions improve both production security and efficiency in creating MBRs or executing EBRs. MBR creation is simplified by „External Parameters“ based on generic Master Batch Records (GMBRs).

„Our customers face the challenge of managing a large number of packaging MBRs while also being required to quickly react to changes, e.g. in packaging design. The new PAS-X feature offers the possibility of making changes in the ERP and directly creating an executable EBR. The creation of individual MBRs becomes obsolete. In this way, we enable our customers to considerably reduce the number of packaging MBRs.“

Efficient EBR execution and release

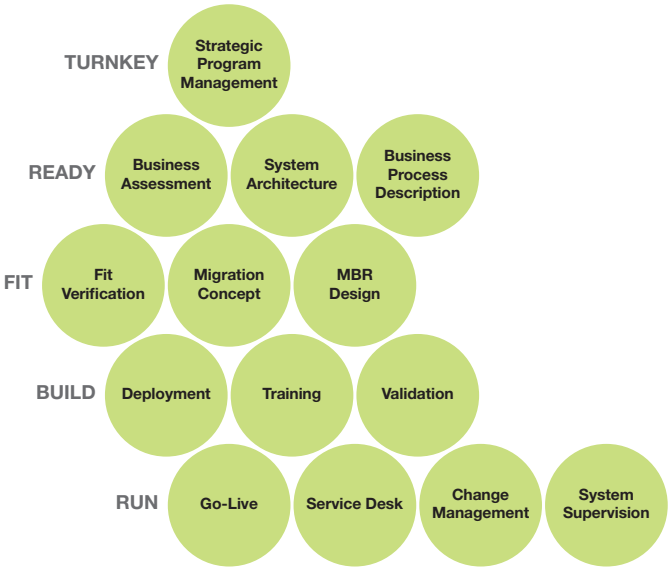
The new alarm & event handling ensures an even better shop floor integration and guarantees a smooth information flow between PAS-X and SCADA, DCS and Historian. Via interface, PAS-X retrieves the exceptions from Level 2 and allows the seamless assessment of all exceptions. This improvement enables QM personnel to go for a full „Review by Exception“ (including Level 2 alarm & events) and allows the accelerated release of Batch Record Reports (BRR).

The release process can be further accelerated by „Auto-Closure of BRR“. It automatically closes the BRR if there are no exceptions. As a result, QM personnel do no longer have to check batches without any exceptions and critical parameters.

Customers benefit from PAS-X innovations

„All our customers benefit from continuous PAS-X improvements. New functions are provided through upgrades without compromising the stability of a running system“, says Robert Welter. „For the introduction of PAS-X, we also offer services and content. Along with the latest PAS-X V3.1.6, our customers can thus achieve a high return on investment.“

PAS-X SERVICES



Rolf Blumenthal
Senior Director
Consulting & Training,
Werum IT Solutions AG

PAS-X SERVICES

Werum adapted its service portfolio to meet further customer requirements and added comprehensive services. The service portfolio is based on the expectations of the PAS-X User Community and on best practices of the pharmaceutical and biotechnology industry.

With these services Werum supports its customers during all PAS-X implementation phases: from Ready to Fit and Build to Run Phase. 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.

Fast-track implementation

Before the project – in the **Ready Phase** – Werum offers consulting services to ensure process understanding and the organizational readiness of its customers. This includes architectural blueprinting, benefit analysis, business case development, and implementation and rollout planning.

The actual implementation is then carried out in two phases: In the **Fit Verification Phase**, the PAS-X software product is parameterized on-site according the business processes and production recipes of the customer. This phase also includes consulting and training, and by the end of this stage, the standard system is parameterized to support the customer's business processes.

In the subsequent **Build Phase**, the product is configured or enhanced, for example, with interfaces, and it is implemented and qualified at the customer's plant. In parallel to this configuration, the system can be prepared for operational use through parameterization of the master data and creation of the final MBRs. At that point, the system can go live.

Once the system is operational, Werum supports its customers in the **Run Phase** with its global Service Desk Team and with maintenance agreements that ensure the protection of the investment with upgrade guarantees.

Ensuring MES knowledge transfer

"We support our customers with our long-standing pharmaceutical MES knowledge and specialized personnel to avoid resource gaps when implementing MES projects", says Rolf Blumenthal. "It's our goal to ensure knowledge transfer from the very beginning so that our customers can implement PAS-X quickly and, after Go-Live, operate and manage the system on their own."

PAS-X CONTENT

Torsten Isenberg
Director Head of Department Consulting & Training, Werum IT Solutions AG

PAS-X CONTENT

"Werum now offers PAS-X Content Packages for its customers out of the box to enable best practice based configuration of the PAS-X software product", says Torsten Isenberg.

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 content. The GMP-compliant templates are based on the industry-specific best practices and are continuously verified by the PAS-X User Community. Together with a Werum consultant the templates will be configured to suit the customer's business processes – saving the customer a lot of time and efforts.

"PAS-X Rights & Roles" Content Package

The "PAS-X Rights & Roles" Content Package supports the configuration of PAS-X user rights based on global GMP-compliant profiles and specific roles such as Operator, Supervisor and QA/QM personnel. It considerably simplifies the configuration and maintenance of PAS-X's highly flexible user rights capability. System administrators and project team members can save up to 95 % of the time usually required for the initial configuration and testing of rights.

"PAS-X Reports & Labels" Content Packages

The "PAS-X Reports & Labels" Content Packages offer preconfigured reports and labels along with the associated comprehensive consulting services. These packages are based on best practices of the pharmaceutical and biotechnology industry. They comprise GMP-compliant templates for reports and labels which are specifically tailored to pharmaceutical industries such as chemical and biopharmaceutical API production or production of solids and liquids. Using the mature and reliable PAS-X Content Packages contributes to accelerating the PAS-X implementation.

"PAS-X Process Libraries" Content Packages

The "PAS-X Process Libraries" Content Packages accelerate the creation of MBRs and help to assure high quality MBR design based on the industry best practices. There are process libraries available for all major pharmaceutical industries, such as API production, solid dosage, fill & finish or packaging. The "PAS-X Process Libraries" Content Packages contain MBR Design Elements – templates to create MBRs for specific pharma and biotech processes such as granulation, IPC testing or reconciliation.

PAS-X SMART SOLUTIONS

LEADING MID-SIZED PHARMA AND BIOTECH COMPANIES BENEFIT FROM PAS-X OUT OF THE BOX

Complete MES functionality and implementation times of less than 12 months / Best-practice-based content packages including pre-configured business processes

Medium-sized pharma and biotech companies face enormous challenges: They are required to improve efficiency and quality, to reduce costs and cycle times and to meet regulatory requirements. This situation is aggravated by the increasing pressure to consolidate, fixed budgets and the cut-throat competition in these industries.

Werum delivers a complete out-of-the-box MES package including the standard software product, pre-configured content and comprehensive services – all specifically tailored to the pharmaceutical industry. Customization can almost entirely be omitted resulting in implementation times of less than 12 months.

The system is easily scalable enabling customers to start with selected functions as an introduction to MES, and to later extend the system to cover other functions or process areas.

”As the market leader, we provide a unique offering: our out-of-the-box PAS-X MES with complete and scalable functionality that is operational in less than 12 months.“

Jan-Henrik Dieckert, *Head of Sales, Americas, Werum IT Solutions America, Inc.*

Out-of-the-box MES for fast implementation

Werum’s PAS-X MES provides optimal support in meeting these challenges. PAS-X is not only suitable for the largest global pharma organizations, it also fulfills the needs of medium-sized pharma and biotech companies:

Complete and scalable functionality

PAS-X is a stable and mature industry-specific software product providing all MES functionalities required by medium-sized pharma and biotech companies. Functions include Weighing & Dispensing, MBR, EBR and Equipment Management, to name just a few.

Content and service packages to facilitate implementation

PAS-X Content Packages which include pre-configured workflows and business processes based on the pharma and biotech industries’ best practices ensure a comparably fast implementation. In this way, customers do not have to start from scratch when configuring PAS-X.

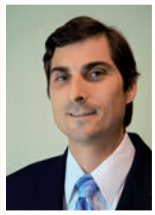
Instead, they can use predefined templates and libraries specifically designed for the production processes of the pharma and biotech industries. Werum also provides consulting service packages to support customers in using these templates and to facilitate a smooth implementation and Go-Live. Wherever the customer’s location is, Werum experts are available.

PAS-X MES FOR GROWING MID-SIZED PHARMA AND BIOTECH COMPANIES

”When selecting an MES solution, pharma and biotech companies must have a clear understanding of their organization’s business, technology and regulatory requirements, challenges and opportunities. They must also look forward and take into account the company’s roadmap for the next 5 to 7 years.

This is especially critical for growing mid-sized pharma and biotech companies. These companies must be relentless about evaluating solutions to ensure they meet current requirements and assess solution roadmaps against future plans.

Leveraging pre-configured workflows and business processes based on industry best practices, such as PAS-X Content Packages, can expedite implementation times. This approach allows growing mid-sized pharma and biotech companies to benefit from predefined templates specifically designed for their production processes thereby minimizing the need for customizations and reducing configuration cycles.“



Daniel R. Matlis,
President, Axendia

DR. REDDY'S LABORATORIES, INDIA

GREENFIELD ROLLOUT OF WERUM'S PAS-X MES IN ONLY FIVE MONTHS

Successful implementation and Go-Live at greenfield manufacturing plant in Visakhapatnam, India / Full compliance and FDA approval ensured

The pharmaceutical major Dr. Reddy's Laboratories Ltd. successfully rolled out Werum's PAS-X Manufacturing IT Business Platform at their Indian greenfield site in Visakhapatnam. Dr. Reddy's deployed PAS-X for the first time as full-blown MES covering all operations from material receipt to production.

Dr. Reddy's required an MES Go-Live within a minimum of time. The system had to reliably document the batch production processes to meet all regulatory requirements. In order to ensure the approval of the greenfield plant by all regulators – especially the US health authority FDA – the pharmaceutical company was especially interested in a fully tried and tested MES.

"Based on the good experiences with PAS-X V3 at our Hyderabad plant, we took this system as template and rolled it out at our site in Visakhapatnam", says Mr. Sanjay Mantri, Director at Dr. Reddy's Laboratories Ltd. "This way, the PAS-X MES was set up within five months only and we were able to quickly start producing the first trial batches. PAS-X helps us to ensure full compliance and the highest quality right from the beginning."

The MES project was implemented by the Werum Asia Support Centre in close cooperation with Dr. Reddy's Centre of Excellence. The pharmaceutical manufacturer plans to install Werum's PAS-X at three further facilities in India.

ASTRAZENECA, CHINA

FURTHER PAS-X GO-LIVE IN THE CONTEXT OF ASTRAZENECA'S OPERATIONAL EXCELLENCE STRATEGY

Standardized weighing processes and compliance at the new Chinese facility in Taizhou, Jiangsu province / PAS-X user interface localized in Chinese

PAS-X Weighing & Dispensing went successfully live at AstraZeneca's new facility in Taizhou in China's Jiangsu province. Here the world's fifth-largest pharmaceutical manufacturer produces oral solid medicines for the growing Chinese market.

For the green-field site, AstraZeneca required a software product that offers standardized processes and compliance to the weighing and dispensing operations. The current project is part of the global strategy that AstraZeneca follows to achieve operational excellence in manufacturing. The rollout is based on the PAS-X standard software product. PAS-X Weighing & Dispensing, whose user interface is localized in Chinese, integrates existing weighing systems seamlessly into the manufacturing process. In addition it offers a „Gross Weight Check" function, a special safety weighing feature, where by standard the gross weight of all input materials is checked twice. PAS-X is integrated into AstraZeneca's decentralized SAP ERP system.

Werum's PAS-X Weighing & Dispensing is already in operation at other sites of Astra Zeneca in China, India, Sweden and the USA. The decisive factors for using this product were the extensive range of functions offered by PAS-X MES, the standardized SAP integration features, and Werum's global service network.

MANUFACTURING INTELLIGENCE

KPI FEATURE PACKAGE: DECISION-MAKING TOOL FOR OPERATIONAL EXCELLENCE

Pharmaceutical and biopharmaceutical companies are required to record data from their production and packaging processes in detail and compress this data in real time to represent significant Key Performance Indicators (KPI). Werum's KPI Feature Package provides powerful functions for ensuring operational excellence and lean manufacturing using PAS-X data for performance management.

The KPI Feature Package automatically acquires and evaluates all operating data on shop floor monitors in real time – thus turning data into key figures to aid decisions. Operators and supervisors can view the current status of the packaging lines at any time. If data is not provided by the equipment, the KPI Feature Package also allows operators to manually enter the causes of interruptions, such as setup times, pausing times or maintenance. This enables a gapless documentation of events in the system ensuring continuous improvements in terms of costs, quality and compliance.

Pre-configured KPIs such as Overall Equipment Effectiveness (OEE), Capability and Availability support transparent processes both for operators and the management. These KPIs can be made available in standard reports immediately. The pre-configured and certified PAS-X standard interfaces guarantee a seamless data exchange with the shop floor equipment.

WHY KPI FEATURE PACKAGE

- Manufacturing intelligence tool
- Real-time data acquisition and evaluation
- Delivery of key figures to aid decisions
- Continuous improvements ensured
- Integrated and transparent data access across levels and systems

KEY BENEFITS

Management

- Reduction of costs – factors driving costs such as bottlenecks and reasons for equipment downtimes can be identified easily.

Operator

- Saving of time – data for performance management is available immediately enabling the operator to focus on the production workflows.

Administration

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

NEW SIG MANUFACTURING INTELLIGENCE

The PAS-X User Community PFU founded a new Special Interest Group (SIG) on the topic of Manufacturing Intelligence (MI). Headed by Ilan Eden, Solutions Architect – Global Operations at TEVA, this SIG will support and drive the development of powerful MI tools in PAS-X.

PACKAGING SOLUTION

ALL-IN-ONE: THE PAS-X PACKAGING SOLUTION

Performance, compliance and serialization are the key challenges of today's pharma and biotech packaging operations. Shop floor operators face three major tasks:

- Operate the line and ensure right-first-time operation
- Optimize performance of the packaging process including changeover
- Manage the serialization and aggregation process

PAS-X: One standard system for EBR, OEE and Track & Trace

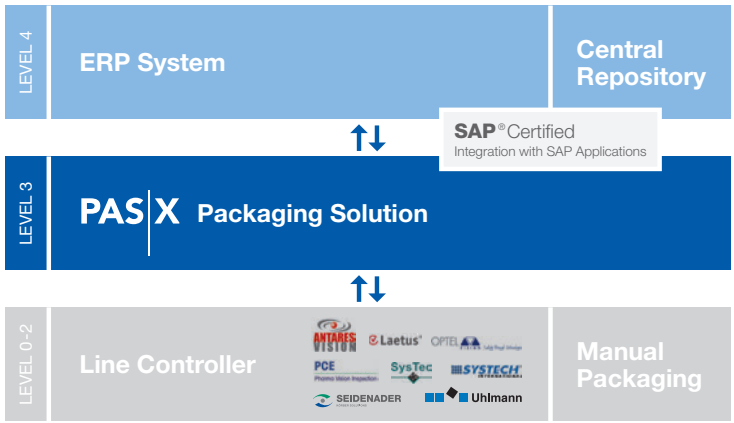
Werum supports pharma and biotech companies with its All-in-One PAS-X Packaging Solution – a combination of software, content and services relevant for packaging operations out of the box. The software functions comprise EBR, Overall Equipment Effectiveness (OEE) and Track & Trace in one system with one user interface. This way, both operators and administrators need to handle only one easy-to-use system. As the central Level 3 application, the PAS-X Packaging Solution integrates the ERP and the Central Repository with the shop floor packaging equipment and line controllers.

Faster creation and maintenance of packaging MBRs

Packaging processes always follow the same workflow and differ only in terms of product specific characteristics. All common parameters are summarized in generic Master Batch Records (GMBRs). Thus, the number of recipes can be reduced from hundreds of MBRs to only a few GMBRs. A faster creation and easier maintenance of packaging MBRs is additionally ensured by predefined, packaging-specific Process Libraries Content Packages. Together with a Werum consultant the templates will be configured to suit the customer's specific business processes.

Efficiency gains and standardization through integration with PAS-X

To integrate the PAS-X Packaging Solution with an existing PAS-X MES is the easiest and most beneficial way for enhanced efficiency. However, it is also possible to first implement the PAS-X Packaging Solution and later expand the system into a full-blown PAS-X MES. The benefits: All functionalities are provided by the same standard system, only one user interface for the shop floor operators, and a seamless data exchange.



The PAS-X Packaging Solution integrates ERP and Central Repository with the shop floor packaging equipment and different line controllers.

IMPRINT: Werum IT Solutions America, Inc. · 5 Sylvan Way · Parsippany, NJ 07054 · USA
Tel. +1 973 644 4000 · Fax +1 973 644 4600 · info@werum.com · www.werum-america.com