EDITORIAL

The challenge for manufacturers is to adapt their complex packaging processes and to integrate new processes for managing and storing serialization data.

At PharmaExpo 2014 – the special PackExpo event – in early November in Chicago, our companies will, for example, be presenting an integrated line solution showing how packaging and serialization processes can be optimally harmonized. From primary packaging to blisters to palletization, including serialization. You can read more about this and about other exhibits in this issue.

In addition, the latest Track & Trace Monitor awaits you, with an overview of the current international requirements for traceability of medicines.

Werum IT solutions is launching a new version of its market-leading MES product “PAS-X” focusing on usability. In an interview, Werum’s specialists explain – using the example of the new PAS-X KPI solution – how important usability is.

I wish you exciting reading and look forward to welcoming you in person at PharmaExpo. See you in Chicago, 02-25 November!

My very best wishes,

Gerhard Breu

In pharmaceutical production two themes are largely the key to success: flexibility and product safety. The pharmaceutical industry needs flexible solutions that can be adapted to different products and production conditions without adversely affecting overall equipment efficiency (OEE). Modular designs of equipment and lines, simple operation and easy cleaning allow fast format changes and consequently shorter downtime.

In addition, product safety is primary for consumers and therefore for the manufacturer too. Even against a backdrop of ever more stringent legal requirements, companies must focus much more closely on safety and hygiene in the production and packaging process. Also, deadlines for the implementation of directives for reliable traceability of medicines move ever closer.

Dear Customers,

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Gerhard Breu
New TopLoading cartoner for parenterals
Dividella is presenting – as a North American premiere – the new NeoTOP x and the possibility not only of adapting the packaging line to different box formats but also of packaging individual products and multipacks (up to 100 items). Possible pack sizes extend to 60 to 260 mm in length, 45 to 200 mm in width, and 17 to 120 mm in height. The variants for feeding in different items have been expanded and offer additional advantages in terms of flexibility. Format changes can be carried out without tools in less than 20 minutes. Dividella provides the proof on its stand. Join us live for a format change and be convinced!

High-speed inspection for parenterals
Seidenader is showcasing its CS-60, a high-speed inspection machine equipped with the latest inspection technologies. The CS has been designed to inspect liquid and freeze-dried parenterals at a speed of up to 36,000 containers/hr. As a complement to camera inspection the CS-60 can be equipped with additional technologies, such as, for example, high-voltage and Head Space Gas Analysis to test container integrity and sterility of the product. For detailed information, turn to page 14.

Manufacturing IT – integrated IT solutions for the packaging process
As the leading international supplier of Manufacturing Execution Systems (MES) for the pharmaceutical and biotech industry, Werum is presenting its complete all-in-one MES solution out of the box. The overall package includes the PAS-X software product, comprehensive services and content packages with pre-configured workflows and business processes based on the industry’s best practice. PAS-X is in use at 17 of the top 30 pharma and biotech companies. You can also read the interview on the latest version of PAS-X, V3.1.7, and its enhanced usability on page 8.
Seidenader’s new Track&Trace software has a consistently modular structure. Depending on the customer’s needs, the solution for the essential tasks (serialisation, aggregation, rework, production data acquisition) is assembled. The high proportion of standard components, variable configuration and modular design significantly reduce development and roll-out times, and therefore line downtime.

Multi-media folding box with HD video screen for pharmaceutical and healthcare packaging

Rondo-Pak has developed a folding box which can be equipped with multi-media features, including a thin, lightweight HD video screen – complete with sound. Built into the hinged lid, it enables multi-media interaction with customers. Such multi-media boxes are the future of packaging – especially in cases where the use of the product has to be explained, e.g. for special medicine schedules or specific medicine products. Benefits include precise and easier-to-understand instructions and interactive experiences.

Containment solution: Safe packaging of solids

Mediseal will be showing its innovative containment solution for the safe packaging of high-potency solids on a true-to-scale model. Using the example of a successfully installed system, prospective customers can experience the advantages of customised system design.

All the exhibits at a glance:

Meet the experts

Dividella
- NeoTOP x – TopLoading cartoner for parenterals

Mediseal
- CP400-P1600 – complete line for solids
- Containment model (CP200) – solution for high-potency solids

pester pac automation
- PEWO-form SLP 2 Compact

Rondo-Pak
- Multi-media folding boxes
- cGMP compliant packaging solutions

Seidenader
- CS-60 – High-speed inspection machine for parenterals
- SingleUnit-Basic
- CaseUnit-Integrated

Werum
- Pharma Manufacturing IT – MES solution PAS-X

Reliable and efficient all along the line

Mediseal, Seidenader and pester pac automation are showcasing a complete line for packaging solids – including serialization

Pharmaceutical markets worldwide are increasingly demanding regional and customised packaging variants for specific target groups. At the same time, the various legal regulations for product and process safety must be met without compromising line efficiency (OEE). In Chicago, Mediseal, Seidenader and pester pac automation will be showing a complete line for solids, from primary packaging to palletization, with an integrated serialization and aggregation solution which effortlessly meets the requirements of efficiency and safety.

The basic element is a Mediseal CP400-P1600 blister line in the medium performance range (up to 400 blisters/min) – a reliable, flexible system incorporating a blister and cartoning module, quick format changes and a simple operating concept. The individual boxes are coded and checked in-line on a Seidenader SingleUnit-Basic. The modular design concept allows the compact SingleUnit to be adapted quickly and easily to a wide range of customer requirements; the new software meets all statutory Track&Trace requirements worldwide.

End-of-line, the individual packs are packaged in cases and palletized on a PEWO-form SLP 2 Compact. This, the world’s smallest casepacker/palletizer combination, is equipped with a built-in Seidenader CaseUnit-Integrated, for recording and consolidating the serialization codes, and applying and checking information relating to the parent packaging unit (case and pallet).
Werum’s MES Software “PAS-X”:

a whole new level of user experience

Werum, since the beginning of 2014 part of Körber Medipak Systems and the leading provider of IT solutions for pharma manufacturing, will release a new version of their pharma Manufacturing Execution System (MES) “PAS-X”. In an interview, Robert Welter and Svenja Fischer explain the role of usability for the further development of PAS-X and the usability improvements of the upcoming V3.1.7 version.

What do you actually mean by software usability?

Fischer: Usability means that a computer program supports the task of the user and applies the principles of software ergonomics. The objective is to avoid errors in operation and to optimally support users in their actual tasks by designing a graphical user interface – the so-called GUI – that can be understood intuitively. When designing the GUI, both the tasks of the end user, empirical findings and guidelines as well as the technical feasibility are considered.

How important is usability in the context of the further development of PAS-X?

Welter: Pharmaceutical companies have to make their production more and more efficient and agile. To meet these requirements, an MES system is needed that is not only convincing in terms of functionality but also in terms of usability and allows easy and efficient system operation without a long training period. Besides developing new and innovative functions, it is most important in PAS-X development to ensure a high level of usability.

How is the topic usability established at Werum?

Fischer: We hired specialists with the appropriate expertise in the field of usability and design of user interfaces. In this way, we can combine the expertise in usability with the technical know-how of the software engineers that are well-experienced with PAS-X. We are well-acquainted both with empirical standards and norms and with most recent findings in psychology of perception. We also consult a design agency to further optimize human-machine interaction. By also leveraging our internal employee feedback system, all Werum staff members can contribute their own ideas on PAS-X usability based on their project experience.

How are PAS-X users involved in the improvement process?

Fischer: We interview end users at our customers and watch them as they operate PAS-X in daily business. In addition to this, we invite users from all levels to our workshops: this includes the operator from the shop floor as well as the shop floor supervisor; the MBR design and the master data administrator. In close collaboration with the member companies of the PFU – the “PAS-X For Us” User Forum – and other interested customers, we develop novel concepts for future versions of PAS-X.

We also involve our customers when we implement the ideas. They can participate in the agile software development process and give their feedback even during the development period. Thus, we receive an early feedback by the users and enhance the quality of PAS-X in a sustainable way.

What are the specific improvements in PAS-X usability?

Fischer: With the upcoming PAS-X V3.1.7 version, the dialog for electronic batch recording was given a new design to optimally support users on the shop floor in performing their tasks. Despite the complete functional scope of PAS-X, we are able to display the information in a way that allows the operator to work intuitively and efficiently. We want operators to focus on the essential aspects of their working process while still being able to find additional information at any time and in a direct way.

Based on the customer feedback, we also optimized the “touch operability” of the execution dialog. The buttons are now placed in a better position with an improved design and the font size can be changed. This is particularly relevant for mobile devices and Asian languages, such as Chinese and Japanese.

And yet another advancement: Due to the feedback by end users from the shop floor, we optimized particular automatic processes to improve the user experience on the shop floor.
Are there further examples for the improved usability?

Welter: Yes, PAS-X has device-optimized dialogs. For this purpose, we had a look at the devices the operators use and then we provided improved usability. Depending on the device, users are displayed a dialog that has the optimal size and can be operated easily.

Our new PAS-X KPI solution also comes with device-specific dialogs. They are optimized for large screens, as for example used at packaging lines, as well as for tablets for the supervisor. The GUI has a well-structured and color-coded design that draws the operator’s attention to the essential aspects. Monitors on the shop floor display all important Key Performance Indicators in real time so that operators and supervisors can view the status of their line at any time.

Thank you for the interview.

The company at a glance:

Werum IT Solutions GmbH

Werum, based in Lüneburg, near Hamburg, is the internationally leading supplier of Manufacturing Execution Systems (MES) and Manufacturing IT solutions for the pharmaceutical and biopharmaceutical industries. Their PAS-X software product is run by 17 of the world’s top 30 pharma and biotech companies in more than 700 installations.

PAS-X covers all key areas in pharmaceutical and biopharmaceutical manufacturing such as process development, commercial production and packaging including Track & Trace. The software supports all major pharmaceutical manufacturing technologies, e.g. for vaccines, biopharmaceuticals, solids, liquids and for other manufacturing operations.

More than just packaging – the everyday life of the Development department at Rondo AG

In the end it is “just” packaging – but the work that goes into it is often varied and very involved. Many parameters have to be taken into consideration to achieve reliable production which is compliant with legislation. The packaging requirements for pharmaceutical packaging are stringent, especially in relation to patient compliance* or prevention of counterfeiting. Aesthetic and functionally convincing packaging solutions are required, as well as efficient and fault-free production.
From concept to solution
The Development department works constantly on the design of integrated packaging concepts. Jürgen Nowak has been Head of Innovation at Rondo AG since early May. “To ensure machine productivity, aspects such as construction, design and materials have to be matched,” he says. “And efficient technical implementation must also be ensured. Often, customers’ products are coordinated with pack design in close cooperation. Here the key thing is to consider the logistics and packaging of the product on the manufacturer’s premises”, continues Jürgen Nowak.

This is why Rondo AG also cooperates closely with its partners in Medipak Systems to ensure an optimal match of machine and packaging. Projects for clinical trials impose specific requirements on the Development department.

Before a drug can go into circulation, it has to be tested in many studies. Here, it is especially important that there is no confusion of different series of trials or recognition of a product. This was the case in a recent Rondo AG project.

Form follows function
The requirement of IL-CSM Clinical Supplies Management GmbH was the development of a folding box for a double-blind study** which includes several ampoules. It is essential for these to remain in the correct order and to be removed in the correct order. Under no circumstances can there be any confusion. “In this case, form clearly follows function” says Jürgen Nowak.

After sampling by the customer, the initial prototype did not yet possess all the desired functionality – there was insufficient protection from confusion. It was the packaging developers’ task to increase this protection.

A completely new idea was developed: a dispenser in which the ampoules are packaged in individual boxes, these being interconnected in such a way that the order in which the folding boxes are extracted is guaranteed. In addition, a special function ensures tamper evidence. The advantage for the customer: economising on a label for the individual folding boxes.

This outline illustrates just one example of many exciting projects being handled by the Development department. It is important to understand customers’ requirements and to translate them into a form which ensures the best possible benefits for the end product – regardless of the complexity or unusual nature of the requirement for the folding box.

* Patient compliance – Good patient compliance means consistently following medical advice
** A double-blind study is a randomised controlled trial in which neither the investigator (in clinical trials: the doctor) nor the participants in the study (the patients) have any knowledge of the group to which they belong: control group, experimental group. (Source: Internet DocCheckFlexikon, http://flexikon.doccheck.com/de/Doppelblindstudie)
US debut for the high-speed inspection machine CS-60

Strong appearance of the new CS-60 at PHARMA EXPO International 2014 in Chicago: Seidenader is presenting the high-speed machine for the first time in the USA in November. Even before this official unveiling, a US pharma contract manufacturer opted for the latest model from the CS series.

Automatic inspection of 600 containers per minute with a low space requirement and fast availability: the new Seidenader CS-60 offers all the benefits for a quick return on investment. Now the new German-manufactured high-speed development is making its debut in the USA at PHARMA EXPO (from 2 to 5 November 2014 in Chicago).

The machines of the CS series can be equipped with up to seven camera stations for the inspection of liquid or lyophilized parenterals, while offering a high degree of flexibility by virtue of its modular design. The detection of the smallest leaks is thus possible due to the integration of the HVLD SLIM module. This module can be retrofitted at a later time by plug-and-play. In addition, further interesting modular options are available for individual and customer-specific requirements.

Efficiency and economy

Ampules, cartridges and vials of up to 100 ml are inspected for particles in the product and defects in the containers. Efficiency in everyday operations is additionally ensured by intelligent design details: a changeover can be realized quickly and simply in 20 minutes. What’s more, thanks to its compact design the machine requires very little space in the customer’s production area.

Last but not least, Seidenader achieves short delivery times due to optimized supply chain processes. A competent service team is also available to support US customers in project planning, implementation, commissioning and validation. Seidenader can thus provide for a smooth start of operations and ongoing support.
Seidenader Track&Trace Monitor – Advanced serialization and aggregation

Counterfeited drugs are a global issue not only causing losses for the pharmaceutical industry but bearing a tremendous risk for patients health and safety and their trust in pharmaceutical products.

Eye on global legislations

In the combat against counterfeit and fake drugs are already today legislations and standards in place - and more to follow.

So introduced for example the USA with the Drug Supply Chain Security Act (DSCSA) just end of November 2013 new requirements to have all pharmaceuticals serialized by the end of 2017, while in Europe everyone expect the release of the Delegated Act for the Falsified Medicine Directive in Q4 of this year. Also are regulations in place changing rapidly, as for example India has been demonstrating with the change of their definition of primary packaging recently.

It’s more than ever important to have an eye on existing and upcoming legislations and their timelines. Seidenader Track&Trace Solutions provide expert know how and have been successfully supporting CMO, small-, mid-sized and global pharmaceutical companies in local and global multi-site rollouts, to fulfill legal requirements and to be prepared for the future.

USA
- Serialization (11.2017)
- Aggregation (11.2023)
- GS1 Datamatrix

Brazil
- Serialization (12.2016)
- Aggregation (12.2016)
- GS1 Datamatrix

Argentina
- Serialization (06.2012)
- Aggregation (Not req.)
- GS1 Datamatrix

Europe
- Serialization (12.2017)
- Aggregation (Not req.)
- GS1 Datamatrix

Turkey
- Serialization (01.2010)
- Aggregation (11.2012)
- GS1 Datamatrix

Saudi Arabia
- Serialization (03.2016)
- Aggregation (Not req.)
- GS1 Datamatrix

USA
- Serialization (01.2013)
- Aggregation (Serial on outer pack)
- GS1 Datamatrix, Code 128

China
- Serialization (12.2015/all)
- Aggregation (12.2015/all)
- Code 128

South Korea
- Serialization (01.2015)
- Aggregation (01.2017)
- GS1 Datamatrix, RFID, Code 128

India
- Serialization (01.2013)
- Aggregation (Serial on outer pack)
- GS1 Datamatrix, Code 128

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**North America**

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All information without guarantee

Counterfeited drugs are a global issue not only causing losses for the pharmaceutical industry but bearing a tremendous risk for patients health and safety and their trust in pharmaceutical products.
The Dividella project team convinced the customer of the benefits of the TopLoading solution for packaging vials in boxes in record time. Contact was made shortly before Interpack 2014 – and the FAT is scheduled for mid-December.

Dividella’s TopLoading concept proves convincing in South Korea. First NeoTOP x for CAVAC.

The Dividella project team convinced the customer of the benefits of the TopLoading solution for packaging vials in boxes in record time. Contact was made shortly before Interpack 2014 – and the FAT is scheduled for mid-December.
Expert advice and quick production of samples led to success. In an interview, the Dividella project team, consisting of Wolfgang Nimmerfroh, Area Sales Manager and Andreas Summer, Project Manager Engineering for the design and consultation phase, report on how the customer was finally convinced of the benefits of the TopLoading solution.

Interview

facts: How was contact made with the customer?

Wolfgang Nimmerfroh (wn): The customer enquiry was very much targeted at us specifically, i.e. we obviously have a good reputation in the market. Also, the information and details that we supplied to the customer at their request were so convincing that an additional representative of the customer travelled from South Korea to Interek in Düsseldorf. This new TopLoading NeoTOP x customer could be seen working there. About 2 weeks later we had the order.

Andreas Summer (as): Then everything happened very quickly. We created the initial 3-D packaging concepts based on product photos and vial dimensions and sent them to the customer.

facts: How was the cooperation with the customer during the design phase?

as: Very professional and open, and decisions were taken very promptly. Fast feedback was received following our initial efforts, so we jointly continued to adapt the packaging to the customer’s needs. From a cardboard box which was optimised for volume to a pack which provides the best protection for the product but still has a significantly reduced volume. For the customer, this is an optimal combination.

facts: In your view, what were the most important arguments for the customer choosing Dividella?

wn: I think the good advice and the speed with which we were able to present different designs to the customer and implement his requirements were decisive. Our colleagues from Engineering have done a lot of work. In the final analysis the customer is not just buying a machine but choosing a packaging concept.

as: Yes, modern engineering tools with 3-D templates and interactive drawings, in which the customer himself can make adjustments, greatly supported coordination.

facts: And what now for the project?

wn: The project manager was on site with the customer at the end of July to discuss the technical details and the timely provision of materials for operating trials. We have adopted a schedule which provides for the FAT as early as mid-December 2014. If cooperation continues to be so harmonious, I see no problems here at all. We are very pleased with this project – our first NeoTOP for South Korea.

Good luck and thank you for the interview.
80 years of competence
and innovation

Themed “People meet Technology” Mediseal celebrated its anniversary on September 13th. Hundreds of visitors followed the invitation and joined the open house. Besides speeches, e.g. from Dieter Westerkamp from VDI (organization of German engineers) and guided factory tours the topics education and career were at the spotlight. Mediseal is an important employer in the region as major Eric Landwehr pointed out in his laudation.

Future pharma manufacturing:
Integrated manufacturing IT solutions
will play key role

Manufacturing Execution Systems (MES), like Werum’s PAS-X, will play a crucial role for efficient production and packaging processes in the pharmaceutical industry. This was the key message of the PAS-X User Group Meeting 2014, that took place end of September in Lüneburg hosted by Werum IT Solutions. 120 experts from the worldwide leading pharma and biotech companies attended this event to learn more about the latest trends in pharma manufacturing and Werum’s new products.