



KÖRBER MEDIPAK
pharma packaging systems



2|2012

**Adapting to new market
requirements – flexibly,
with the NeoTOP System**

facts

KÖRBER MEDIPAK - Customer Magazine

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Dear Customers,



Today, responding quickly to changing needs in the pharmaceutical market is the key to growth and success. The rapidly growing number of biotech drugs, niche products for rare diseases or medicines for self-medication, in connection with the growing number of national presentations is leading to falling lot sizes. This requires a rethink for the production and packaging processes. The combination of efficient yet flexible packaging solutions is therefore a key competitive advantage.

Flexible packaging lines with short changeover times for different pack sizes and products is one way forward. The example of one renowned Swiss pharmaceutical company shows how the intelligent line expansion of a Dividella NeoTOP 804 enables even small lot sizes to be economically packaged fully automatically.

Rondo Service is another way of packaging small lot sizes economically yet individually. Folding boxes erected in the plant at Allschwil are delivered to the manufacturer, who can then package his products semi-automatically or manually. This service offers major benefits, for example when new products are launched.

With the newly developed Seidenader GSI (Glass Stress Indicator), even precursors of cracks can now be detected. Polarimetric inspection measures the mechanical stresses in glass containers which significantly increase the probability of breakage and cracking. This means an even greater guarantee of the integrity and sterility of pharmaceutical products.

Minimized downtime thanks to fast trouble-shooting: MediSeal's new MARS remote service system enables reliable, fast and fully documented maintenance of your packaging installation, no matter where it is located.

Read also about how we want to further improve our dialogue with you. Our philosophy of providing customised technologies and solutions depends on our exchanges with you. After the extensive customer survey in the last year and the resulting measures, we shall be introducing a tool within our companies which enables a continuous exchange and which gives your voice even more weight in our day-to-day business relationship.

I hope you enjoy reading this issue!

My very best wishes,

A handwritten signature in blue ink, appearing to read 'A. Breu'. The signature is fluid and cursive.

Gerhard Breu

Survey: analysis of customer satisfaction

The satisfaction of our customers and monitoring our own performance are key concerns for us. This is why in 2011 Körber Medipak for the first time arranged for a representative customer satisfaction analysis to take place among its customers.



On our behalf, about 1000 customers worldwide were interviewed by a team from Georg-Simon-Ohm University of Applied Sciences in Nuremberg, using an online tool. A differentiated survey of the different contacts within the customer organisation was an important feature. The wealth of different results gives us a basis for defining the performance we provide in the future.

What are our customers concerns?

In four key dimensions of quality – the physical environment, reliability, responsiveness and competent performance – a total of 9 criteria were defined (such as on-time delivery, employee competence and processing of enquiries). For each of these criteria, the respondents indicated how important it is to them and how they evaluate the performance of the respective company in relation to this criterion.

Performance criteria and their importance

| Criterion | Importance |
|----------------------------|------------|
| Reputation | 1,7 |
| Employee competence | 1,7 |
| Image | 2,5 |
| Reference..... | 2,3 |
| Quality assurance..... | 1,2 |
| On-time delivery..... | 1,2 |
| Enquiries and queries..... | 1,4 |
| Financial foundation..... | 1,6 |
| Complete solutions..... | 2,5 |



In addition, open questions provided an opportunity for individual feedback.

On the whole, our customers are satisfied with the services provided by our company; the majority of the satisfaction criteria attained an ideal level. The most important performance criteria are "on-time delivery" and "quality assurance". In addition, the survey confirms that in addition to "employee competence" and "response to enquiries and queries" the theme of "reputation" is increasingly important to them. The fact that Körber Medipak is already well placed in this regard is indicated by the positive ratings on these points. However, the survey also showed that particularly with regard to compliance with delivery dates and quality assurance there are opportunities to improve and to differentiate ourselves from our competitors.

A continuous dialogue: individual and immediate

For future improvement we defined several optimisation fields:

Reduction of internal overlaps

Increase of process orientation with sharp responsibility

Optimisation of complaint management

All the findings from the survey were logged and analysed, and processes and measures were optimised. One crucial criterion for continuing improvement of customer-oriented processes is a continuous dialogue with our customers. In future, all the companies within the Körber Medipak Group will be introducing the Net Promoter Score (NPS) – an internationally recognised management tool – as a key corporate indicator. It serves on the one hand as a tool to measure customer loyalty and at the same time it is a means to further improve the customer relationship. It gives our customers an even stronger voice in day-to-day business. In this way we can directly improve the quality of our products and services on the basis of their feedback.



Packaging small lot sizes economically

More and more newly developed drugs are based on the latest findings in biotechnology – and this trend is becoming stronger. These highly effective active ingredients, which are difficult to produce and often very sensitive and expensive, place demanding requirements on secure and flexible packaging.

These medicines are usually packaged in TopLoading folding boxes, which are used whenever fragile filling material requires highly specialised feed mechanisms and a folding box with a specially adapted inner partition (divider) – e.g. for syringes, vials, ampoules, pens, etc.

In addition, packaging processes are becoming increasingly flexible. The production of niche products, e.g. cancer drugs or medicines to treat genetic diseases, the practice of marketing drugs in different country formats, the growing proportion of diagnostics, samples for clinical trials and even personalised medication – all of these factors are leading to a reduction in lot sizes in pharmaceutical production and require a rethink.

TopLoading packs

Enhancing the customer service philosophy through system solutions

Rondo and Dividella jointly provide intelligent packaging solutions, which constitute a system consisting of NeoTOP packaging machines and appropriately designed folding boxes for TopLoading applications; this guarantees flexibility, safety and efficiency. Close cooperation ensures superior machinability, despite individual and special folding box formats.

For pharmaceutical manufacturers whose lot sizes are not large enough for a cost-effective automated TopLoading solution, Rondo offers pre-erection of folding boxes as an additional service, so that semi-automated or manual packaging can be carried out immediately in the pharma manufacturer's plant. The folding boxes are erected on a Dividella NeoTOP 304 in Rondo's factory in Allschwil and the partitions are glued into place. This line, specifically configured by Rondo for this service, plus the option of digital printing, ensures flexible and fast response times.

Also ideal for market testing and fast time-to-market

The range of service offered also brings major benefits when new products are introduced: if market tests are planned before the launch, the products can be supplied, even in the test phase, in NeoTOP folding boxes. And with folding boxes supplied already erected, time-to-market can be reduced: Many pharma customers are already reaping the benefits of outsourcing part of their packaging process. The advantages for customers are evident:

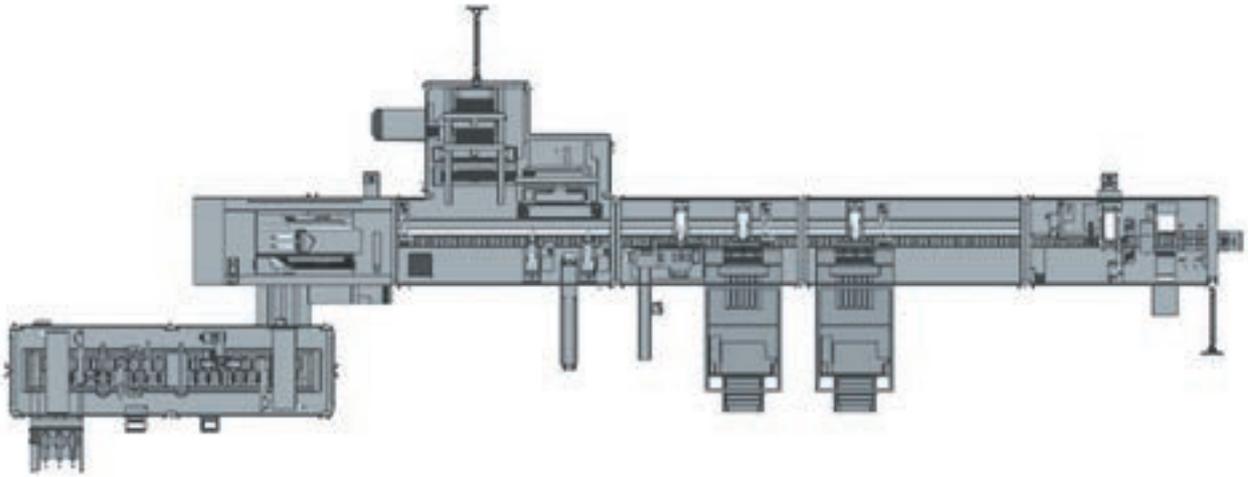
- No capital investment costs
- No maintenance costs
- No investment risk
- Trained and experienced personnel operating the machines
- High reliability and efficiency of the packaging process
- A large degree of flexibility in the choice of folding box formats
- Test facilities in-house

Pre-assembled folding boxes ready for delivery to the manufacturer



However, this service offers an economical and flexible solution not only for small lot sizes but also for pharma manufacturers who have to bridge capacity constraints. As part of an integrated logistics concept, outsourcing can reduce downtime and inventory costs.

More information:
www.rondodruck.ch



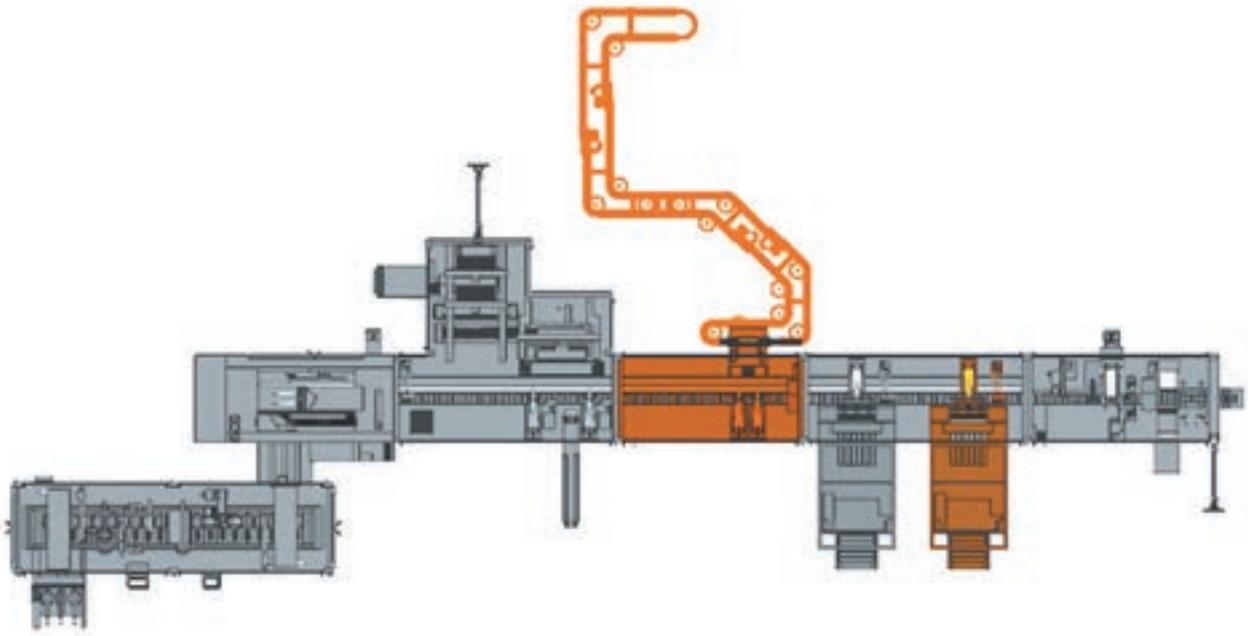
Line expansion brings greater flexibility and efficiency

Dividella expands NeoTOP 804 auto injector line for safety device syringes and packs up to 280 syringes using a puck feeder.

At the beginning of the design phase for a packaging line such as the NeoTOP 804 there is always a to-do list. The specifications for cartoning AIs (auto injectors) and SD (safety device) syringes in a major customer's facility were quite extensive: they grew to include about 100 points in the course of the preparatory talks, estimates Dividella's project manager Josef Buder.

The reason for the careful preparation: on an existing packaging line, a renowned Swiss pharmaceutical company wants to package disposable syringes in a safety device (SD), in addition to AIs. Future requirements also have to be included in the design.

Dividella's task was to expand the existing NeoTOP 804 line with facilities for 1 and 4 packs for SDs. The AIs handled to date were also to continue to run on this line. In addition, from 2013 onwards, new products of the SD (Needle Safety Device) variant will have to be packaged.

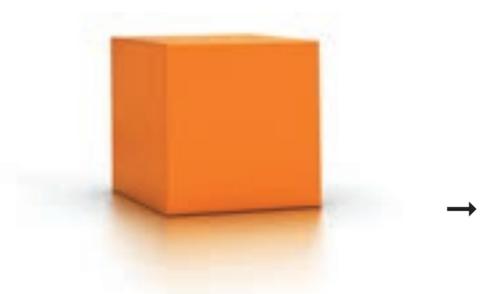


Machine layout before and after expansion of the line

Such conditions demand a line which is specially tailored to the needs of this particular customer. In this context, special attention has to be paid to the transfer systems. In addition to the box blank module and the automated module to feed in the AIs, the Dividella team developed a puck feeder system in combination with an upstream assembly system for the injectors and the safety devices.

The AIs, and in future the SD injectors too, are fed via this tool holder. A star wheel ensures that the quantity exactly matches the products which are used in the box. They are conveyed by a suction plate with a maximum of eight suction channels, which can be connected individually. The suction device transfers the syringes to a grouping unit, which splits them as required for insertion into the folding box.

The work cycle is single-mode for the box of four and triple-mode for the single pack. At reduced machine speed the syringes in the four-pack can also be inserted overlapping. The specially designed puck system now allows machine outputs of up to 280 syringes per minute.



Dividella

This sophisticated solution also allows the NT804 to be used for small lot sizes, because for a change-over only the format parts need to be changed and no tools are required.

The time factor posed a special challenge for the team from Dividella with regard to commissioning. Two deadlines were set. During the first three weeks the old modules were uninstalled and the new ones incorporated. In these weeks the machine was reconditioned to enable a resumption of AI production once the operation was complete. Another two weeks were devoted exclusively to commissioning and adjusting the SD module. This involves perfecting the mechanisms so that a commercial start-up of SD production is viable.

In this project the NT804 once again demonstrates its practical versatility in different applications. The fully automated system for lidded-box packaging works from the flat cardboard blank, for both the boxes and the integrated dividers. Typical products include blisters on the one hand and parenterals such as ampoules, syringes or vials on the other. Medications such as inhalers or pens and sprays can also be packaged without any problems using Dividella's high-performance lines. Outputs from the standard versions can be as high as 800 objects per minute.

Puck feeder
for syringes



We'd like you to meet ...



Stefan Knellwolf
CEO Dividella AG

Stefan Knellwolf (48) took over as Managing Director of Dividella AG in Grabs with effect from September 1, 2012. Most recently he was the Managing Director of the Starrag Aerospace & Power Generation Business Unit at Starrag Heckert AG in Rorschacherberg. Prior he held senior management positions in the fields of production, logistics, development and construction within the group of companies. Stefan Knellwolf is an engineering graduate, specializing in technical business administration, and studied at ETH in Zurich.



Torsten Ziegler
Managing Director
Weimer Pharma GmbH

Torsten Ziegler (46) has been appointed Managing Director at Weimer Pharma GmbH on August 1, 2012, where he will be assuming responsibility for sales and marketing. Torsten Ziegler has worked as Head of Business Development at Körber Medipak GmbH in Hamburg since 2008, and was involved inter alia in the acquisition of Weimer Pharma and the Seidenader Group. Prior to this the graduate chemist held a variety of executive positions within the pharmaceutical and medical technology industry.



**Dr. Ferdinand
von Alvensleben**
CEO Seidenader
Maschinenbau GmbH

As of September 1, 2012 Dr. Ferdinand von Alvensleben (52), is the new Chairman of the Management Board of Seidenader Maschinenbau GmbH. He will be assuming responsibility for the Business Units inspections machines and Track&Trace. He has long-standing professional experience in research and management fields. He latterly held the position of CEO at Swarco Traffic Holding, and at the same time was responsible in the lead company Swarco AG for several international production sites. Dr. Ferdinand von Alvensleben studied mechanical engineering in Hanover and at MIT in Boston.



Mark Davies
COO Körber Medipak
North America

As of July 23rd, 2012 Mark Davies took over responsibility for the operational business at KMNA. In this function he will focus on developing Service Level Agreements with our major customers and integrating the Seidenader business into KMNA. Mark has 30 years experience dealing with complex capital equipment and has specific experience in the pharmaceutical industry. He has been working as Customer Service Manager at IMA Life managing their after-market business for the BOC Edwards division.



Michael Hacker
Key Account Manager
Rondo Europe

As of May 01, 2012 Michael Hacker took over as Key Account Manager for Rondo Europe. In his position he will focus on the German market. Michael Hacker brings 21 years of experience in printing technology in various positions, as pre-production manager, head of sales support and technical sales manager. In the recent 8 years worked in the pharmaceutical packaging sector. Michael Hacker is a trained artwork producer and has a master in print engineering.

MARS Remote Service System – Fast trouble-shooting minimises downtime

MARS stands for MediSeal Assistance Remote Service. The concept is based on a 'meeting point router' (MPR), which is integrated into the machine. Via this MPR, the machine can be connected to the MediSeal Meeting Point Appliance (MPA) server. This enables the service experts to provide assistance and eliminate faults quickly.

With the new MARS remote service concept, a camera connected to the machine enables the MediSeal technician to carry out remote analysis of the problem which has been encountered. Machine settings can be optimised by remote control and the fault can be fixed within a few minutes. In addition, all the other components of the machine, such as a code reader or a fill checker, can be integrated into this concept. The remote service connection is initiated only by the customer. If remote access is desired, it takes place over an encrypted link.

In practice, the customer operates the "Connect" switch on the MPR and then calls the service technician. The service technician can now connect to the MPA via the internet and activates remote service. Each connection is precisely logged and this guarantees the customer full documentation.

The advantages of MARS

- Easy to use for the machine operator
- Simplified trouble-shooting - fast elimination of faults
- Avoids unnecessary setting-up
- Minimises downtime
- Installation of updates is possible
- Connection can be initiated only by the customer
- All accesses are documented

The entire service portfolio at a glance:

Field service

Spare parts

Tools & formats

Upgrades

Inspection, maintenance & service agreements

Teleservice

Relocations

Production support and OEE improvements

Calibration & validation

Training

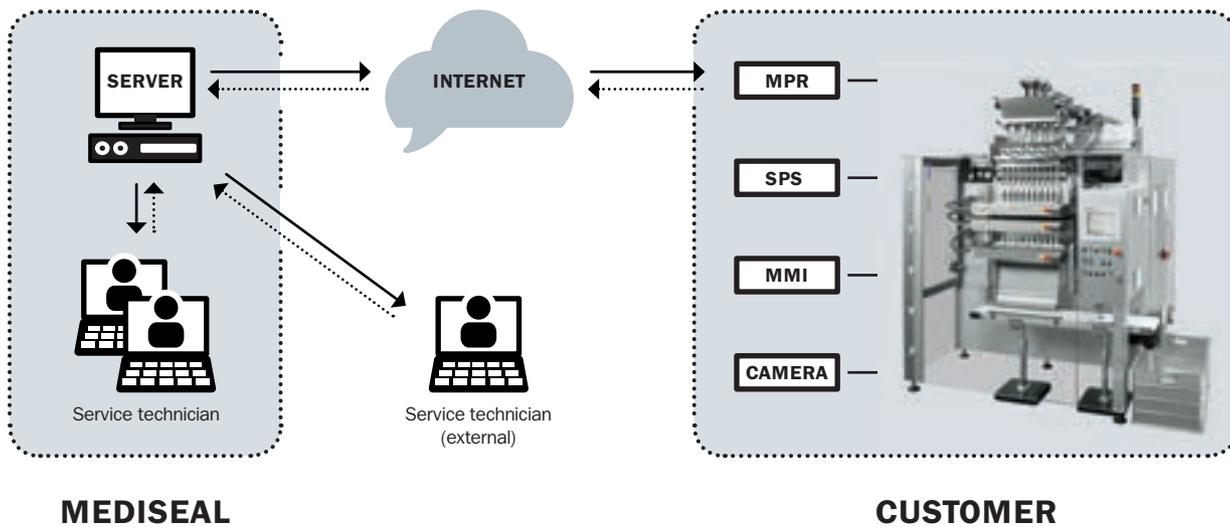
**For more information about
service options, go to:**

www.mediseal.de/de/services.

Fig. left: Trouble-shooting by MediSeal's experts
Fig. right: Initiation of the remote service system by the customer



Remote service with MARS

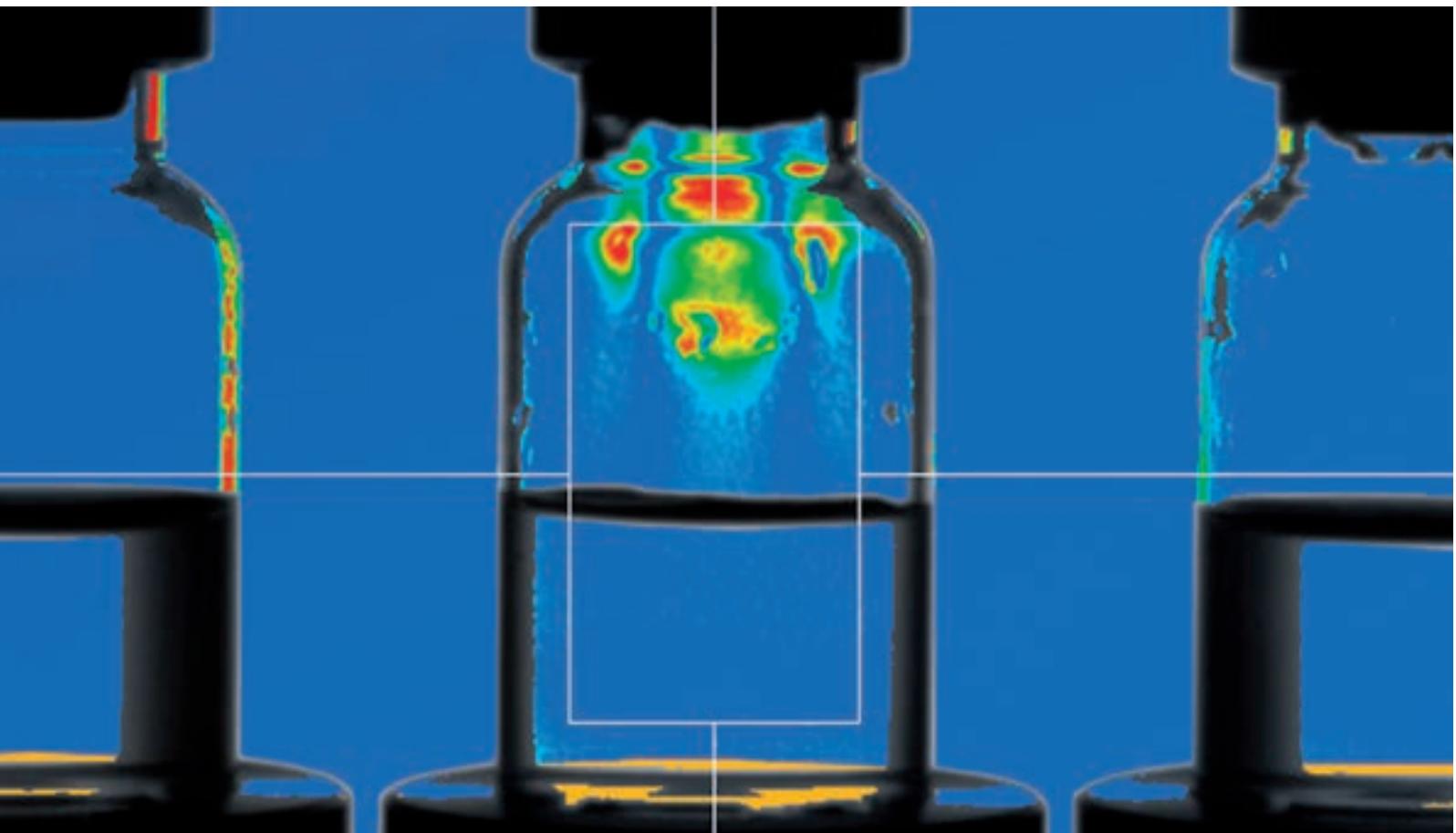


It's good to know:

Five MARS systems are currently already in use worldwide and 13 more have been ordered.

Integrity Inspection of Pharma-Containers

Detection of cracks and leaks in pharmaceutical containers to ensure the integrity and sterility of the contents is one of the top issues which Seidenader have met by provision of various inspection methods.



Seidenader GSI: Mechanical stress in glass (middle) is recorded and evaluated inline

Technical details:

In a relaxed state, glasses are optically isotropic, i.e. the refractive index is equal in all spatial dimensions. The propagation speed of light depends, among other things on the density of matter. Mechanical stress causes deformations in the material structure, i.e. different particle densities in the various spatial dimensions. This ultimately results in different speeds of light in the medium – the refractive index is dependent on the direction, the medium is birefringent. This birefringence can be analyzed with a polarimeter, which determines the angle of rotation of the polarization direction of linearly polarized light as it passes through a sample.

So far, correct measurements of the rotation angles with manual polarimeters were time-consuming and experienced laboratory personnel were required. Improvements could be achieved with the development of automated imaging polarimeters, which allow for inspection of not just one point, but of the whole object, and also exclude operator-induced measurement errors by automation. Due to the consistent further development of the automated imaging polarimeter it is now possible to measure and evaluate mechanical stress in glass containers in real time.

Cameras detect visible defects like cracks at sidewall, neck, shoulder and heel of containers. Leak detection with high voltage reliably identifies smallest pinholes and cracks in glass containers. The Head Space Analyzer (HSA) compares absolute pressure, oxygen concentration and H₂O partial pressure in the headspace of a container to reference values. These are the inspection methods that are currently used for container integrity inspection. However, only defects which already exist at the time of the inspection can be detected by such methods. In cooperation with ilis gmbh Seidenader has developed an inspection method by which already specific pre-stages of crack formation may be identified. The polarimetric inspection of Seidenader GSI (Glass Stress Indicator) verifies mechanical stress in primary packaging materials made of glass.

Seidenader GSI

- 100 % inspection of all containers
- Minimize post inspection cracks
- Ensure sterility throughout entire shelf life of product
- Fully integrated on inspection machine

Stressed vials may constrict production processes

Mechanical stress can reduce the fracture strength and processability of glass and plastic containers. Even small residual stress can increase the likelihood of breakage or cracking significantly.

The consistent enhancements of the automated imaging polarimeter enable us now to measure and evaluate mechanical stress in glass containers in real time. With the integration of such a system into a fully automatic inspection machine, objective and reproducible measurements at production speeds of up to 600 products/min. can be recorded so that production induced stress is detected early. Containers with residual stress can be automatically removed from the production and discharged into the defect channel. Therefore formation of stress-related cracks in the downstream production process or after product delivery is excluded to the largest possible extent.

More information:

www.seidenader.de



OPEN HOUSE **at Körber Medipak North America**

March 2013 is the date to look forward to. Körber Medipak is inviting its customers from the healthcare industry to Florida. Under the banner "White Technologies and Serialization", Körber Medipak will be presenting the latest technologies in these areas. There will also be reports of practical case studies, as well as information about current legislative developments with regard to anti-counterfeiting and the traceability of medicines.

Some of the highlights:

White-Line by MediSeal

Specially designed for batch sizes in the range from 1 to 2000 blisters, the innovative White-Line concept revolutionises the entire supply chain – all country variants can be grouped together in one batch.

Instead of a host of country-specific packaging materials and pack inserts, the White-Line concept is based on "white" (blank or

unprinted) materials. Both lidding films and boxes and inserts are not printed with the country-specific information until they are in the packaging line. This means that many small lots, which in a traditional production line involve very long changeover times, can be combined into one large lot. The switch to a different language is controlled automatically by a line management system and is completed in 10-12 minutes.

Seidenader T&T Solutions: serialization and aggregation

Acquisition and consolidation of serialized data, plus application and verification of information on the parent packaging unit. Coding stations integrated into the packaging line, code readers and camera systems provide the data for a full guarantee of origin of the product (the "grandparent/parent/child" relationship). For data exchange, the system can be interfaced with higher-level ERP/MES systems.

Rondo-Pak: Tamper Evidence and production of digitally printed folding boxes

Rondo's folding box with Tamper Evidence features an innovative form of tamper-evident protection. First-time opening (which will be mandatory from 2016 under an EU directive) is clearly and irreversibly evident once the tab on the sealed lid is torn. This solution is characterised in particular by its amazing simplicity and its machinability. With this solution, the original machine speed can be maintained at 100%.

Digital printing technology enables flexible and economic production of small lots as well as serialization.

Dividella will be introducing its new TopLoading cartoner with an enlarged format range.

OUR PROGRAM

Tuesday 12 March 2013

Our Open House event starts with an entertainment program – all guests are cordially invited to attend.

Wednesday 13 March 2013

You can look forward to presentations and user reports from experts from the pharmaceutical industry, plus presentations of individual machines.

You will find more information and regular program updates on the internet at

<http://medipakevents.com>

You can also register online for the event on this site.

**Make a note of the date:
Open House Körber Medipak
North America
Wednesday 13 March 2013**

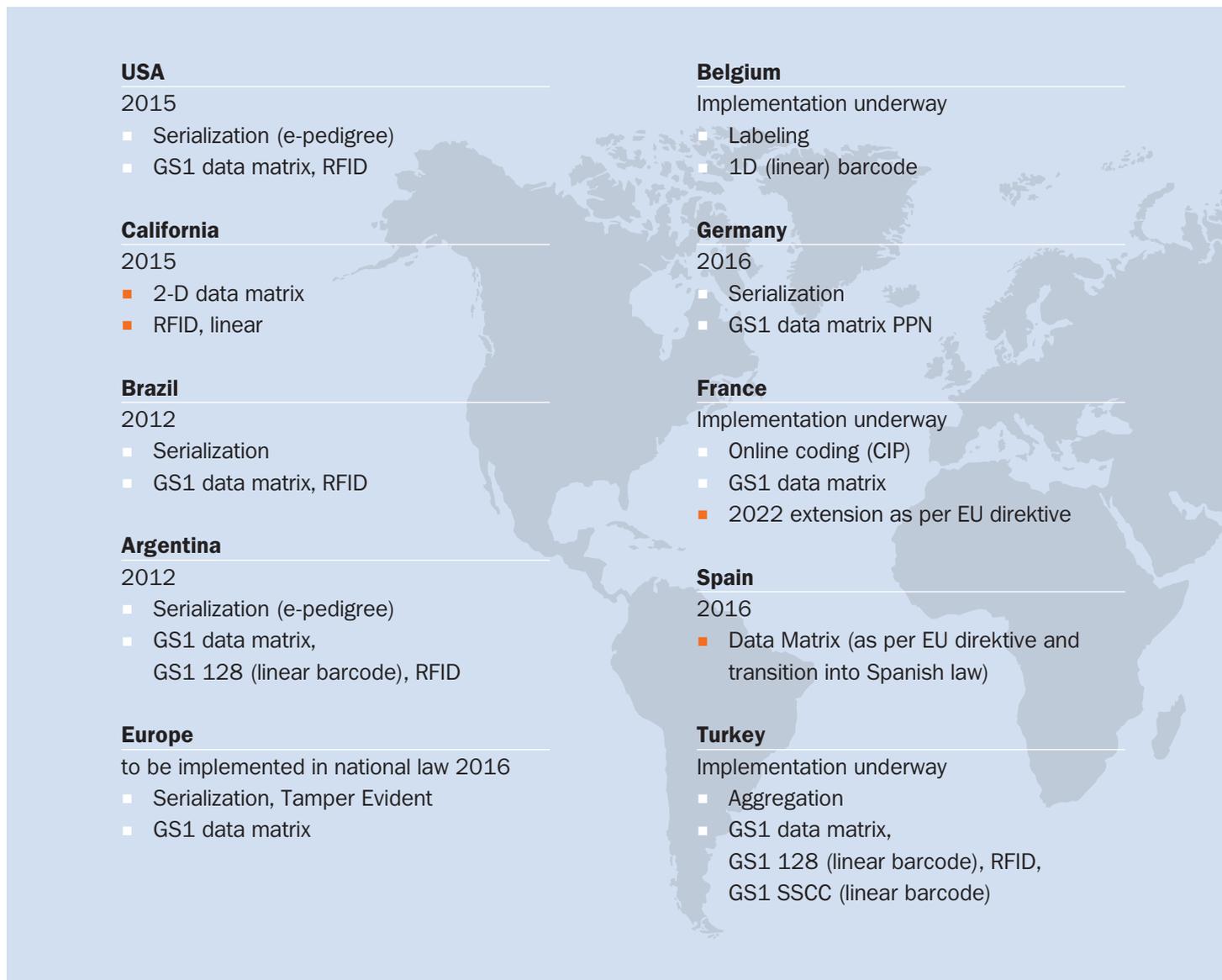
**Further information and registration:
<http://medipakevents.com>
info@kmedipak.com**



Körber Medipak
North America

Seidenader “Track&Trace Monitor” – international demands at a glance

Since different countries have different requirements and regulations for labeling medications, we will use this platform to present information about the most important current developments on an ongoing basis.



Show Previews 2012_13

All information
and regular updates:
www.seidenader.de



Greece | Italy

Implementation underway

- Labeling (Bollini)
- 1D (linear) bar code

Russia

2015

- Serialization (serials provided by Government)
- 1D (linear) barcode (not GS1 compliant)

India

2012

- Aggregation
- GS1 data matrix, GS1 128 (linear barcode), RFID, GS1 SCCC (linear barcode)

China

2015 (some have started in 2010)

- Serialization (serials provided by Government)
- 1D (linear) barcode

Korea

2015

- Serialization
- GS1 data matrix

We are not liable for the accuracy of any of the information provided

■ Update

ScanPack

October 23 – 26, 2012 | Gothenborg (Sweden)

PACK EXPO

October 28 – 31, 2012 | Chicago (USA)

Salon de'l Emballage

November 19 – 22, 2012 | Paris (France)

P-MEC India

November 21 – 23, 2012 | Mumbai (India)

Pharmtech

November 26 – 29, 2012 | Moscow (Russia)

Pharmapack

February 13 – 14, 2013 | Paris (France)

Open house KMNA

March 13, 2013 | Clearwater (USA)

Interphex

April 23 – 25, 2013 | New York (USA)



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pharma packaging systems

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