labeling businews 001

HERMA INDUSTRY SERVICE

More and more markets demand extensive measures, to ensure the traceability of pharmaceutical products. A key function involved in this is the marking and labelling of containers. That is why HERMA's comprehensive industrial know-how is more in demand than ever.

pharma

Solving the tasks at Grifols

One of the world's leading experts for blood plasma derivatives, employs HERMA's 132M HC wrap-around labelling machine.

One of the world's largest suppliers of plasma-derived products, Grifols has recently built a new logistics centre at an Irish location. The company, which is headquartered in Barcelona, Spain, chose HERMA and their Spanish sales partner SINEL SYSTEMS to implement a labelling solution at the new site. The task required finesse: it involves the precise labelling of cylindrical infusion bottles and the printing of variable information on these labels. The labels feature a small attached plastic loop that can be folded back later to serve as a hook in the hospital. In close cooperation, HERMA and SINEL SYSTEMS designed a labelling system that is based on the standard labelling machine 132M HC and does not require any complex special design. According to Grifols' specifications, further components were added to the machine, such as a laser printer that produces a colour change on the labels, and a camera system that checks the printed labels. Grifols is happy with the solution and its implementation.

(to be continued on page 2)

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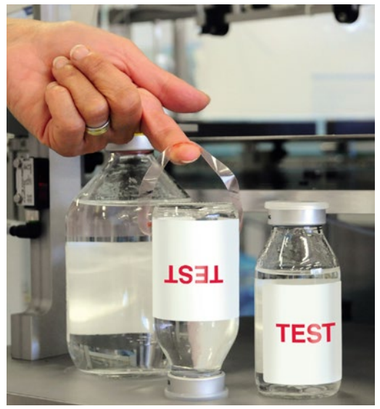
For over 20 years, HERMA labelling machines have been fulfilling the most demanding pharmaceutical industry requirements – reliably, accurately and quickly. The requirements are tougher than in any other industry. Especially now, when new regulations need to be met in many markets, e.g. in the EU, the US, China and numerous other countries, labelling technologies are enjoying a particular focus. Challenges like serialisation, aggregation, track & trace and tampering evidence must be solved quickly. An abundance of different technologies – for printing, identification, labelling and monitoring – must interact in a tightly confined space, so that maximum security can be achieved under extremely individual production conditions at each pharmaceutical company. In addition, there are often also country-specific characteristics and sometimes special labels. Aside from the pure transmission of information, the technologies will also need to carry out function tasks, thus adding another „complication" to the feed process. From now on, in *Labeling Businews*, we always want to demonstrate the range of possibilities – especially by focusing on concrete solutions that have already been realised. In addition, we will provide information about current topics in the industry as well as developments in the HERMA team. In the name of all pharmaceutical industry specialists at HERMA, I wish you a pleasant read.

Warm regards,
Martin Kühl
Head of Labelling Machines Division

"With HERMA's new 132M HC wrap-around labelling machine, we have clearly become faster and more flexible", explains Joost Kool, product manager at the pharmaceutical contract manufacturer Produlab.

(continued from page 1)

Thanks to its modular design, the wrap-around labelling machine 132M HC ensures excellent versatility while offering users many options for implementing individual equipment requests, e.g. regarding the choice of printing systems for variable data or data matrix codes and camera systems for code inspection. Another advantage of the modular design: users can adapt the wrap-around labeller 132M HC to various product formats in just a few steps. At the Grifols location, for example, glass bottles with diameters of 43 or 46 mm and a height of 70 or 80 mm are labelled. Thanks to its continuously rotating star wheel, the machine can label up to 100 bottles per minute.
"This project once again demonstrates the performance range of our rotating star wheel labelling machine that is unrivalled in its breadth", says Martin Kühl, head of HERMA's Labelling Machines Division. "We will extend the 132M product line in the future in order to provide customers such as Grifols with modular HERMA solutions for upcoming applications."



Short changeover times, reliable label application

Time is money – this principle applies in the pharmaceutical industry as well. When medication bottles of all kinds of formats and very different batch sizes need to be provided with labels, it is essential to be able to set up the labelling machine very quickly and flexibly. Because of this, Produlab Pharma is now using a HERMA wrap-around labelling machine.

300 bottles of a vitamin preparation for Bulgaria, 15,000 bottles of antibiotics for Germany, then another two mini-batches for the Greek market: Contract manufacturers and packagers for pharmaceutical products must be extremely flexible, quick to react as well as reliable. Take for example Produlab Pharma in the Dutch town of Raamsdonksveer in the vicinity of Breda. The company, founded in 1991, develops, produces and packages veterinary pharmaceuticals for a multitude of reputable European companies. This market has experienced significant growth for some time. And because the medium-sized company places great value on flexibility and customer-orientation, it has grown to 120 employees. Customers particularly appreciate the flexibility and customer-orientation of the company, which has its own lab for the handling of orders and can convert its production to different products quickly and reliably.
"We strictly work made-to-order, manufacture the products in large quantities and then label and package them," Joost Kool, project manager at Produlab, explains. "Time and precision are two important factors in this. In the past, our inline labelling machine often represented a bottleneck, because the set-ups and fine adjustment took much too long. With HERMA's new 132M HC wrap-around labelling machine, we have clearly become faster and more flexible – und all necessary printing and control systems were already integrated."

The Produlab range comprises solutions, suspensions, ointments and crèmes in sterile or non-sterile forms, which in most cases are filled in glass bottles and on rare occasions in plastic bottles. Glass bottles are currently still the solution of choice, since this primary packaging does not react with the medication. However, the bottles, which are made of moulded glass, have often turned out to be problematic in the processing: The material has small irregularities, is provided with fill level markings and must still be provided with standard and booklet labels reliably and precisely. "We used to have machine downtimes once in a while. But since time is a factor, we absolutely want to avoid this in future," Joost Kool explains. "Because when the labelling

At Produlab, HERMA's 132M HC inline labelling machine could eliminate a bottleneck in the production thanks to its high flexibility.

machine is at a standstill, it also slows down the entire line, which should actually be running 10 hours a day."

No more fine adjustments

After a thorough examination of several labelling machine providers, a HERMA solution was chosen: the 132M HC wrap-around labelling machine. It was integrated into the production line after a cleaning system, a sterilising tunnel and a filling machine, and so far, it has proven highly successful. "The different medication bottles now run through much faster – nobody is held up by the labelling anymore," says Kool. Unlike its predecessor, which required extensive user knowledge, the handling is now much easier. "As soon as the machine is running, it runs reliably. Fine adjustments during operation are no longer necessary. That is exactly what used to hold us up so much. A format change now only takes about 15 minutes. This means that we can change over quickly between the 14 bottle formats that we are currently processing. "This is important, because five batch changes per day are a frequent occurrence at Produlab. A special control feature was integrated in the labelling process: An invisible printed DataMatrix code that is read by an OCR camera is used to check whether the right label was applied. Next, the label is printed with a batch number that is also checked for correctness with a camera. All misprints are separated and not applied to bottles. The ERP connection of the machine is comprehensive thanks to made-to-order machine settings. When an order is started, the corresponding devices such as printers and camera monitors are activated and set automatically.

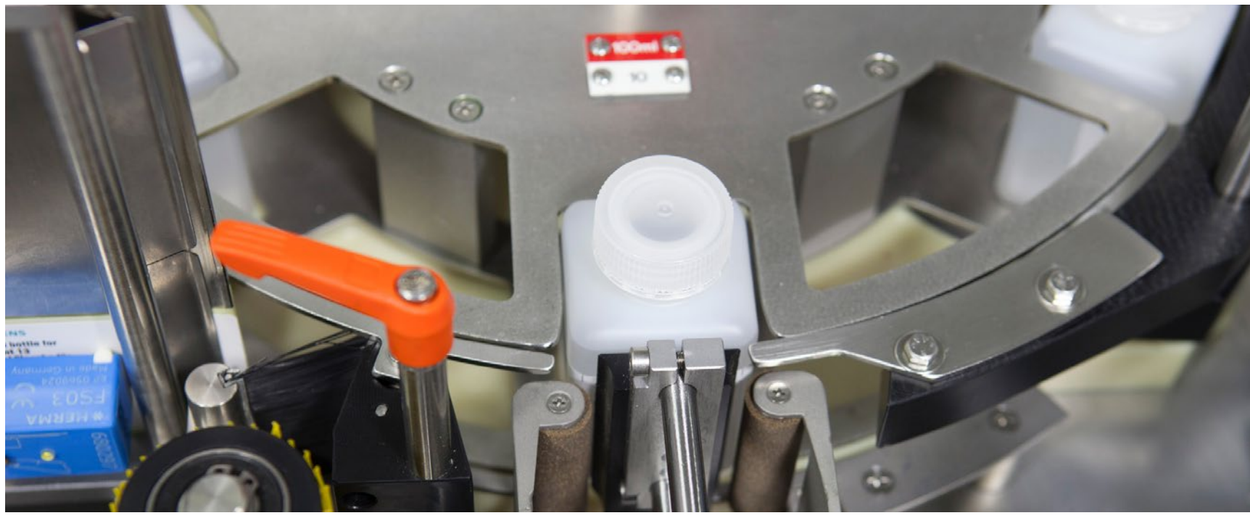
Quick format changes

Despite its versatile performance range, this HERMA system is not custom-made, but rather a standard model with all typical advantages such as cost-efficiency and reliability. Thanks to its modular design, the 132M HC wrap-around labelling machine ensures excellent versatility while offering users many options for implementing individual equipment requests, e.g. regarding the choice of printing systems for variable data and camera systems for print and code control. Another advantage of the modular design: Users can adapt the 132M HC wrap-around labelling machine to all required cylindrical product formats in just a few steps. At Produlab, the product portfolio comprises bottles with a diameter of 23 mm and a height of 46.8 mm to bottles with a diameter of 68 mm and a height of 136 mm – each with different label formats and types. Thanks to its continuously rotating star wheel, the machine can label up to 200 bottles per minute.

"An optimal set-up"

"Our business is running well – we already have to resort to overtime on occasion, and in the foreseeable future, we are planning to convert to a two-shift operation," Kool concludes. "For this increase in productivity, our new HERMA labelling system is an optimal set-up."

Bottom right picture: After labelling, Produlab packages and ships the medication bottles all over Europe.



A label for three sides

Four-sided containers require non-standard and relatively unusual U-labelling.

HERMA labelling machines once again reinforce their performance within the healthcare and pharmaceutical sector: as the world's largest company specialising in clinical diagnostics, Siemens Healthcare Diagnostics has now opted for a HERMA 040M wrap-around labelling system. It is part of a completely new filling and labelling line at the company's Marburg, Germany, site. The HERMA system applies labels to four-sided plastic containers for diagnostic fluid at the company's site with a single label on three sides, so-called U-labelling. The crucial factor in the decision was not just the high precision of the HERMA system. It could also be integrated into the relatively restricted space available without any compromise in terms of performance or ease of use thanks to its compact design. "The modular structure of the HERMA system from proven standard components guarantees a high level of reliability, but is flexible enough at the same time that we were able to easily implement a number of individual special requests," confirms Jens Geisel, Project Manager at Siemens Healthcare Diagnostics. The diverse portfolio of the Siemens Healthcare Diagnostics products includes a large selection of analytical systems for clinical chemistry, immunodiagnostics, hematology, hemostasis, microbiology, diabetes, urine chemistry, blood gas analysis and molecular diagnostics as well as laboratory automation. The company employs around 14,000 people worldwide and has its main European production site in Marburg.

Intermittent rotary star for high precision

Siemens Healthcare Diagnostics places great value on top product quality and 100% on-schedule deliveries to its customers. This also places particularly strict requirements on the labelling process. The intermittent rotary star enables the HERMA 040M to apply labels extremely reliably and precisely to around 60 plastic containers per minute. The system is controlled via a touchscreen. This only displays the menu items that are actually needed and therefore does away with a confusing array of buttons. In addition, the housing that also has an ergonomic design and the extra smooth and thus easy to clean surfaces guarantees maximum security and optimum ease of use in operational practice.

As the world's largest company specialising in clinical diagnostics, Siemens Healthcare Diagnostics has opted for a HERMA 040M wrap-around labelling system.

No scope for manipulation

How to use safe and efficient tamper-evident labels? In this interview, HERMA product manager Ulrich Fischer provides answers to the most important questions.

What exactly does the EU prescribe with respect to tamper-evident labels?
In contrast to serialisation, for which the requirements have been extensively described in the EU guideline 2016/161, the prescriptions with respect to the anti-tampering marking have been very vague. At least the DIN EN 16679 standard shows the range of possibilities. It's not a long list.

What would be permitted, for example?
For the current pharmaceutical folding boxes, four solutions in particular are available. These are folding boxes sealed with glue, special folding box constructions, shrink-wrapping and seal labels. Expensive blister display packages are in principle conceivable for folding box packaging, but they don't make sense for practical and economic reasons. Flexible packaging with plastic and/or aluminium foil and a sealing edge would in practice remain the exception rather than the rule. In addition there are manipulation characteristics that would hardly play a role for folding box packaging, for technical reasons alone, such as the sleeve or similar elements.

What are the criteria by which a pharmaceutical company should decide on the most appropriate solution?
Of course this always depends on the individual case. It should be considered, however, that when implementing the anti-manipulation mechanism, a pharmaceutical company will not experience any positive side effect beyond having met the guideline itself. For pharmaceutical manufacturers or contract packers, this would mean that a maximum level of security must be achieved, but at the same time great value must be placed on an economically feasible implementation, since no other benefit is currently apparent.

What does this mean in concrete terms?
To be able to continue to use the existing folding boxes, when you look at cost/benefit aspects, the use of seal labels is particularly interesting, specifically given the fact that labelling technology has matured and corresponding know-how is already widely distributed in the pharmaceutical industry.

Doesn't one need special materials for these purposes? And doesn't that represent a cost factor?
In the past, that was certainly the case. In order for seal labels to work reliably, often very special materials are used, such as foils that virtually dissolve when someone attempts to manipulate them, or so-called "void" labels that irreversibly unveil a piece of text when an attempt is made to open the container. Aside from the costs involved, these special materials also exhibit weaknesses when using machines to process containers at high speed.

So what are the ideal properties of seal labels?
The most economically feasible and technically useful protections against manipulation would be completely conventional rectangular or round labels – maybe with an additional safety perforation. The decisive factor for this use is the pressure-sensitive adhesive. It must be highly resistant to water, hot air and different solvents. Only then is it guaranteed that the conventional label cannot be removed from strongly lacquered folding box packaging without visibly destroying itself or the carton surface.

Is this a vision of the future, or an option that can be realised today?
HERMA has a separate, very successful business division that deals with the development of self-adhesive materials for different challenges. At HERMA, such pressure-sensitive adhesives are now available for universal use, that is to say for very different surfaces. With the innovative HERMAsuperPerm 63S adhesive, for example, one and the same seal label variation can be used for a multitude of packaging materials and surfaces. This solution is already in use in the pharmaceutical industry, for example at a very well-known manufacturer of folding boxes and labels. That is why it's worth looking at the label as a manipulation marker more intensively, even if that's not one's initial focus.

What do you mean by that?
Even in the previously named variations, labels can play an important role – as an additional anti-manipulation marker. For example, this is the case for folding boxes with an adhesive seal based on hot glue. It is current practice of product forgers to dissolve hot glue by adding heat, then removing or exchanging the product and replacing the original folding box again. Such manipulation attempts make corresponding seal labels immediately recognisable.

However, a seal label must first be attached safely and reliably. What is important to keep in mind when selecting the most suitable labelling system?
Hardly any other industry has to deal with such complex requirements regarding product information and labelling as the pharmaceutical industry. It's hardly surprising that, when it comes to the labelling of pharmaceutical products, decision-makers still accept that corresponding systems must out of necessity have a custom design. They grit their teeth while they're doing it, because every production manager knows the disadvantages of such a procedure. Actual special machines are expensive and often lead to special problems. Because when it comes to individual systems, most of the time there is no extensive practical experience to fall back on.

How can this be circumvented?
One possibility to avoid the disadvantages of custom-built machines while still being able to solve a very comprehensive range of special responsibilities, for example tamper-evident labelling, is to go with a modular construction. We have perfected these at HERMA. This means that individual function modules, partly manufactured in very large quantities and thus proven in the field, can, depending on customer requirements, always be combined in new ways, with the objective that any system resulting from it is not only up to meeting standard challenges, but also extraordinary ones.

Name some examples of such function modules.
These include labellers, printing systems, control systems, ejectors and sensors. Let's take the example of labellers: it's the core of every tamper evidence system. In a modular construction, the aim is to always keep its geometry constant. Even after ten years, an uncomplicated exchange is still guaranteed, for example against a more powerful model. This then results in a high degree of reliability. At HERMA, we build the labellers with the same basic shape several thousand times a year.

How do you manage to react to current changes?
At HERMA, the electronics and software are completely integrated in the labellers. Keeping them up to date has practically no influence on the device geometry. The individual units of the labeller, such as winders and unwinders, separating systems and label sensors are in turn also manufactured in large quantities. To maintain high flexibility on the users' side, it is enough to maintain these units in different forms: For example in right-oriented/left-oriented models, for different winding diameters, label types and widths.

What are the special challenges that need to be solved in tamper-evident systems?
A high level of precision is required. It's about applying rather small tamper-evident labels sideways to the insertable tags in such a way that they jut out about 50 percent above the body of the folding box either upwards or downwards. A mechanical folding rail then presses the two protruding label parts by 90 degrees and spring-loaded foam materials press the labels so that the insertable tags are firmly connected to the bodies of the folding boxes.

What is the process to ensure that a tamper-evident label was really applied?
To optimally ensure the presence of the anti-manipulation marker, two control units are necessary. A light barrier on each side of the folding box checks for the presence of a protruding label part, a second pair of light barriers checks whether the label still protrudes after the pressing or whether the pressing was successful. If an error is detected, a slider, controlled over a shift register, invariably separates the packaging in question.

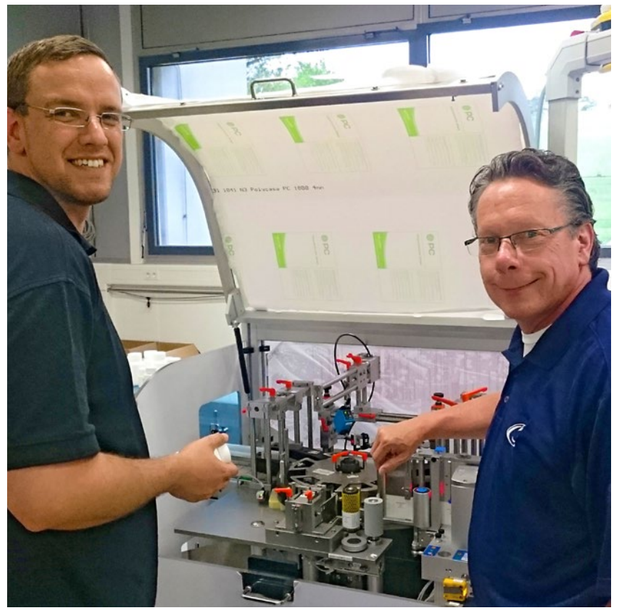
What happens if the seal labels are transparent?
If transparent seal labels are used, the pressure-sensitive adhesive can be set with luminescent particles so that a UV sensor can detect the difference between a folding box and a label. This makes it possible to directly check the successful application of the seal labels. If the seal labels are printed, either a contrast scanner or a camera system can be used for this monitoring function. If none of these procedures work, gloss sensors can be used to detect the difference between the gloss of the folding box and the gloss of the seal labels and thus determine the presence of the labels.

New line for twice the output

Thanks to a newly designed assembly line, HERMA is now able to double the production capacity for label applicators at its Deizisau location if required. The new line ensures an optimal production route, from the assembly of the drive unit to shipping.

"With the new line, HERMA underpins its goal of being a leader in the field of process and manufacturing excellence": Martin Kühl, head of the HERMA Labelling Machines division.

Everything is in flow – on the shortest possible route: in HERMA's new assembly line for label applicators, the production capacity can be almost doubled if required.



Training in Deizisau: Michael Schmidt (left) shows William Ingraham, who now works as a service technician at HERMA's new subsidiary in the USA, how to operate a machine.

Peter Goff (on the right), previously Sales Director of HERMA UK, has been appointed Managing Director of HERMA US Inc. – here he is at the official start, together with Martin Kühl, Head of the HERMA Labelling Machines Division.

Go West! HERMA USA off to a good start

HERMA has now created the conditions required for a considerable increase in the production volume of label applicators at their Deizisau location. "We have inaugurated a production line with a brand-new design, and are therefore now able to almost double our capacities if required", says Martin Kühl, head of the Labelling Machines division. "This enables us to fulfil the sharply rising demand from customers without making any structural changes to our buildings before our move to Filderstadt in 2019." In addition to increased capacities, HERMA also aimed at further optimization of efficiency and quality processes. "With regard to that, HERMA is once again sure to set new standards in our field", says Kühl. This likely also applies to production figures: in the course of the last year, more than 3,000 HERMA 400 and HERMA basic applicators left the production facilities for the first time.

Workstations for top quality

There are firm plans for further growth: "The new production line has a very flexible design, which allows us to double-staff workstations during times with a high workload in order to increase production." For that purpose, the synchronized assembly line which used to be arranged in a semi-circle has now been re-designed as a linear assembly line. "This makes it much easier and faster to manoeuvre especially large modules", explains Giancarlo Lipari, who is responsible for HERMA's new line and played an important role in its development. On top of that, the height of all workstations can now be freely adjusted electronically by each individual employee for the first time. "The tasks involved in production require the utmost precision and quality. The fact that workers can now adjust their stations exactly according to their requirements has been proven to improve concentration", says Lipari. Moreover, state-of-the-art LED technology provides daylight-like, fatigue-reducing lighting and prevents disruptive heating from above.

Integrated high-voltage test

The new station for high-voltage tests is a special highlight. Unique in this form, the high-voltage test station was built exactly according to HERMA's specifications. "Since the test station is directly integrated into the assembly line, applicator modules can simply pass through it on their mounting frame", explains Lipari. "Previously, the modules had to be lifted onto special testing tables which were not part of the assembly line." The packaging of the applicators is now also integrated into the assembly line. "This results in the shortest possible production route – from the assembly of the drive unit to applicators that are ready for shipment. We thereby underpin our goal of being a leader in the field of process and manufacturing excellence", says Kühl, summing up the new possibilities.

On July 1, 2016, HERMA US Inc., the new HERMA subsidiary in the USA, commenced business operations. It focuses exclusively on the distribution and service of label applicators and labelling machines. HERMA US is headquartered in Fairfield, New Jersey – this location ensures optimal connections with customers and local sales partners, since many pharmaceutical and consumer goods manufacturers have production facilities there. Peter Goff, who will contribute valuable experiences from his years as the sales manager of HERMA UK, has been appointed managing director. Sales and service staff members have been hired and have undergone training courses in Deizisau and at HERMA UK – the team, which consists of six members, did therefore turn into a unit. Peter Goff explains the background of the newly founded subsidiary: "We register high demand for HERMA labelling technology in North America. The proven HERMA 400 in particular already has many buyers. Our own warehouse in Fairfield enables shorter delivery times and faster service – crossing the Atlantic brought us so much closer to our customers." The new subsidiary also enables HERMA to increasingly focus on complete labelling machines, such as the HERMA 132M, the HERMA 362E, and the tamper-evident labelling system for healthcare applications. These models present great potentials that can be tapped through direct sales in the USA.

Modular concept.
Versatile integration.
Efficiency benefits.

Innovative Labelling

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