



Reliable drug production requires fast and GMP-compliant labelling

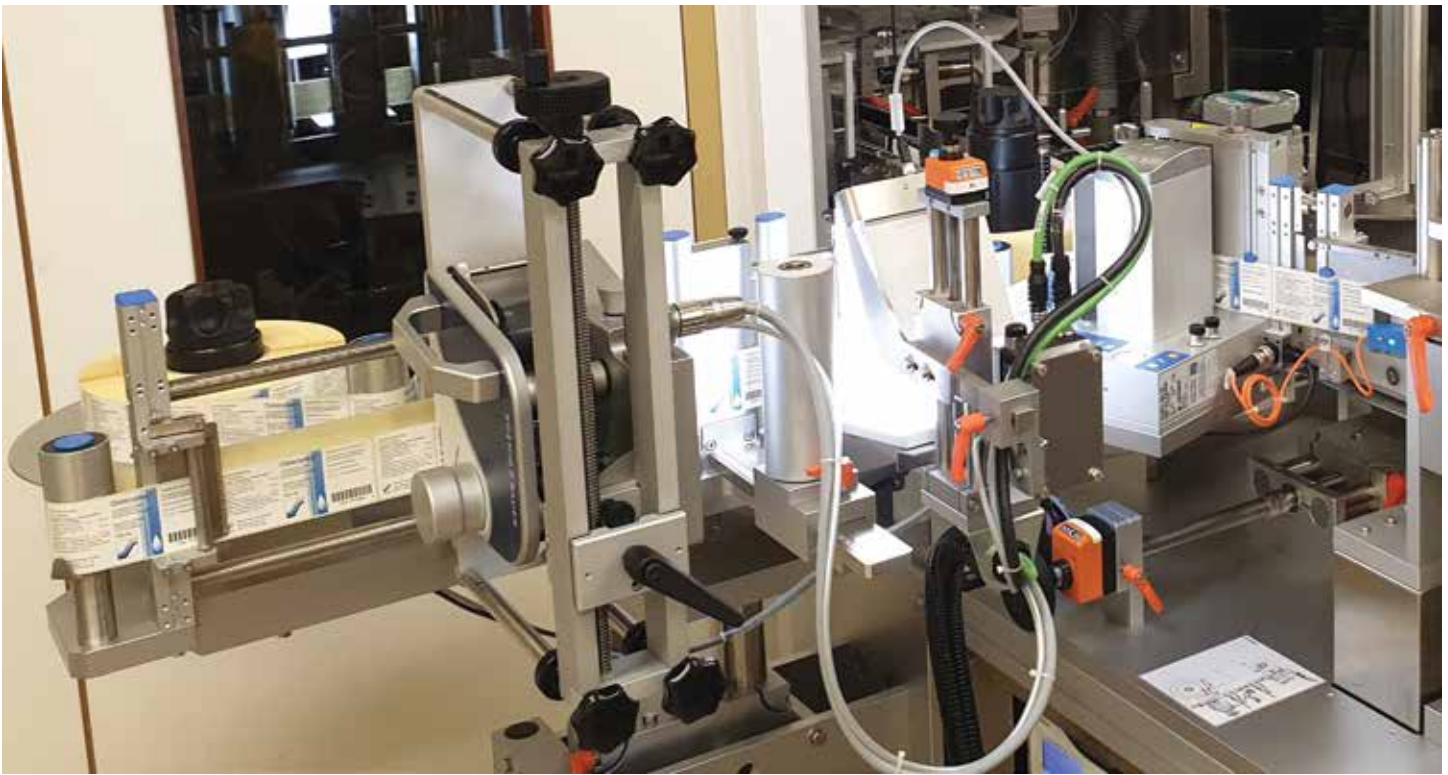
Steierl-Pharma modernizes and optimizes labelling processes with inspection technology from OMRON

Hardly any other industry is subject to such high-quality requirements and legal regulations as pharmaceutical companies. This applies to active ingredients, production and storage as well as to the labelling process. For example, the labels must be robust and stick reliably for the usability period of the drug of up to five years. Labels carry important information such as the name of the drug, active ingredient(s), manufacturer, and variable data such as expiration date, lot number, and serialization information, if applicable. Establishing a valid labelling process is key. At the same time, the

processes should also be as efficient, fast and sustainable as possible.

Steierl-Pharma GmbH from Herrsching (Bavaria, Germany) relies on the support of OMRON automation experts in this regard. By using a new labelling system with smart camera technology, Steierl-Pharma can label its pharmaceuticals with high process speed and reliability. The labels are printed with variable data on batch designation, expiration date and if required, the dispensing notice "Sample not for sale".

“As part of the challenge testing, we deliberately introduced mislabels, all of which were reliably detected”



Steierl-Pharma is a medium-sized pharmaceutical company in the field of naturopathy and produces medicines in liquid dosage form, in cylindrical glass containers. The product range of the company, which was founded in 1949 in Munich by a pharmacist, includes medicines for the musculoskeletal system, for lowering blood pressure, for relieving migraines or skin diseases, or for treating flu-like infections. In addition, the pharmacists at Steierl-Pharma are continuously researching new naturopathic therapies and the use of medicinal plants ineffective and well-tolerated preparations.

3,600 units pass through production line in one hour

The producer has the legally required manufacturing license for medicinal products as well as the GMP certificate. Such Good Manufacturing Practices (GMP) certification guarantees process

integrity in drug production and conformity with applicable regulations. When it comes to filling and packaging the drugs, Steierl-Pharma uses a production line designed for around 3,600 units per hour. It consists of a filling and capping machine, a labeller, and a packaging machine. The line ensures a continuous and seamless process consisting of filling and closing the bottles with a dropper insert and a screw cap. The closed bottles then leave the cleanroom and enter the labeller, where they are labelled and then packed in a folding box together with an information leaflet in the packaging machine.

Challenge: Avoiding unintentional machine stops and read errors

In 2019, a project team at Steierl-Pharma began initial considerations to introduce a replacement for an already older labelling machine. "The labelling machine used until

then already had a smart camera-based inspection system to check the identity of the label and the variable data (batch name and expiration date). However, this had two drawbacks: First, labels were repeatedly misread as bad labels, and second, bad units were not rejected, but the labelling process was stopped. However, this meant that when the machine stopped, the bottles backed up into the filling machine, so that it also stopped, and the packaging machine ran empty. "So we had a, bottleneck in our process," reports Steffen Wegner, Managing Director of Steierl-Pharma GmbH.

Requirements: Precision and speed

Wegner explains: "That's why we worked with the manufacturer HERMA to find a suitable inspection system. The focus here was on high reliability and good pricing."

The aim was to develop a labelling machine that on the one hand met the high requirements in the GMP area, but on the other hand, also ran without interruption during regular operation. One of the central criteria was that the new inspection system should work particularly precisely: bad units such as an incorrect or illegible barcode as well as batch or expiry date errors should be detected reliably, the keyword being sensitivity. At the same time, Steierl-Pharma wanted a high level of specificity: the system should only detect actual bad units as such and eject them from the process. But that's not all: with an output of around 60 labels per minute, the inspection system only has a time window in the range of milliseconds for the complex inspection tasks.

FHV7 smart camera supports testing and quality control

The central component here is the inspection system. Wegner explains: "We decided on the OMRON FHV7 smart camera after a test on our label material on site, supported by an OMRON application engineer. We were effectively supported by OMRON throughout the entire development process up to commissioning and qualification of the machine and beyond." With the help of the FHV7, the HERMA labelling machine at Steierl-Pharma checks the identity of the label based on the pharmaceutical code and verifies batch and expiration via OCV (Optical Character Validation) for compliance with the specifications. The FHV7 series smart camera provides illumination and image processing functionality for enhanced visual inspections. Due

to its world-first multi-color light and a powerful high-resolution 12-megapixel camera, only a single FHV7 camera is needed to perform high-precision visual inspections of the production line.

During the performance qualification, which is part of the qualification of new machines in the pharmaceutical environment, the project managers involved were surprised by the extremely high specificity of the FHV7. "We could not believe how extremely reliable the OMRON FHV7 inspection system is. As part of the challenge testing, we deliberately introduced mislabels, all of which were reliably detected – but with a throughput of some 10,000 labels, not a single good label was incorrectly read as a bad label," reports Wegner. Even single faulty units could cause a lot of trouble in the GMP environment. By using the new camera, such situations do not occur, and the machine outages caused by the incorrect reading of actual good units can also be prevented.

Another advantage of the OMRON camera, in addition to its hardware, is the software, which is intuitive to use and does not require lengthy training. "I also really like the option of a customizable user interface, and so do the users. There is only one window in which, for example, the target code, batch designation and expiration date can be entered. Code verification and Optical Character Validation (OCV) can also be performed. It's all very clear and simple," explains Wegner. The software runs on any current Windows system and communicates directly with the

FHV7 via the local network. Wegner also praises the high inspection speed of the OMRON system. The complex individual inspection of a label takes just 80 milliseconds: "That's impressively fast."

Inspection system and support

"We are very satisfied with both the new labeller and especially OMRON's inspection technology. In a highly regulated environment such as the pharmaceutical industry, manufacturers must be able to fully rely on the technology that is used – also to be able to successfully complete the qualification. This is the case with us," Managing Director Wegner sums up. "The cooperation with the sales and application team was and is also excellent." Since the company has had such a good experience with OMRON, it is planned to convert an existing packaging machine to OMRON inspection technology within the near future.

About Steierl Pharma

Steierl-Pharma GmbH is a renowned and modern manufacturing company for homeopathic complex remedies, which was founded in 1949 by the pharmacist and chemist Hans Steierl in the Munich district of Pasing. Today, the company is based in Herrsching (Ammersee). Here, there is space for drug production and packaging, laboratory, shipping, warehouse, and administration. Thanks to constant modernization, the company complies with strict pharmaceutical regulations. Steirocall® is one of the company's most important drugs. The range of medicines covers the indications musculoskeletal system, endocrine system, cardiovascular system, kidney/bladder and nervous system. www.steierl.de.

About OMRON Corporation

OMRON Corporation is a global leader in the field of automation based on its core technology of "Sensing & Control + Think". OMRON's business fields cover a broad spectrum, ranging from industrial automation and electronic components to social systems, healthcare, and environmental solutions. Established in 1933, OMRON has about 30,000 employees worldwide, working to provide products and services in around 120 countries and regions. For more information, visit OMRON's website: automation.omron.com