

HEARRO

The Customer Magazine
by Harro Höfliger

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**Finally,
breathe freely**

Fully automatic inhaler filling:
Kinnovata relies on
the growth market of China



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Dear Readers,
dear Business Associates,
There are very few companies, especially in the high-tech sector, that would not claim to have their finger on the pulse of the market, and to continuously offer their customers optimized, new, and above all “innovative” products. But what is merely new, and what is fundamentally novel with the pioneering force of a true innovation?

Innovation is an important part of our leadership culture and corporate strategy 2020, which is why we highlight the subject in this issue of “HARRO” magazine. Of course, by now Harro Höfliger has anchored innovation into the organization and established a management system that identifies ideas that have potential, systematically and efficiently guiding the development processes. We are already known for the fact that together with our customers we create new value-added products to meet their requirements. In keeping with our three core values: “Inventive. Qualified. Reliable”, we are resourceful, dependable and deliver top quality. That is why we want to consistently pursue ideas that have the potential to be genuinely innovative and economically successful. For instance, our universal XTray design for the delivery of surgical suture material is a very unique concept.

We intend to maintain our creative culture in spite of having grown to a substantial company, with approximately 1,100 employees. That is why we structure our departments in smaller teams, and give them the freedom and space to act as agile as a start-up firm. This approach results in unique machines and systems.

Your

Peter Claußnitzer,
CTO at Harro Höfliger

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Giving up was never an option

40 years ago, Wolfgang M. Rauch, Managing Director of Harro Höfliger Packaging Systems Ltd., met Harro Höfliger for the first time. Mutually simpatico from the beginning, a friendship developed, and a last-minute action turned into a successful business relationship.

Wolfgang Rauch does not make any promises he cannot keep. When the whisky distillery Drambuie wanted to commission a packaging machine in 1976, he declined, because he could not promise the desired delivery date. His frankness paid off: The customer decided, after a quick side-trip to the competition, to order the machine from Rauch's former employer anyway. A colleague in Germany advised to get in touch with Harro Höfliger, who might be able to help with this short-term order.

"I called and visited him together with my customer shortly thereafter," says Wolfgang Rauch. "At that time, Harro did not have an office yet. We discussed all the important points in a restaurant, and then he showed us the area in his car until it was time for the return flight."



For Wolfgang Rauch, problems are challenges which are to be overcome.

Harro Höfliger had eight weeks to build the machine. If he succeeded, he would receive a bonus of 15 percent of the purchase price. Of course, he succeeded. "Even if the last assembly work took place on the truck that the customer had sent to pick up the machine," Rauch says, laughing. "I really appreciate this in Harro – and it is something we have in common: We never give up."

This anecdote is a prelude to a partnership that has proved highly successful over the years, both on a private level and in business. On the advice of Harro Höfliger, Wolfgang Rauch founded his own company in 1981. Raupack Ltd., headquartered in Old Woking near London, initially operating as a representative for several manufacturers, and the very first order completed together with

Harro Höfliger was a resounding success. Chivas Regal ordered a labeling machine with an erector feature as well as the conversion of a cartoning machine, and ultimately bought a special system without having seen a reference or demonstration machine.

The tandem team Raupack Ltd. and Harro Höfliger GmbH made a name for themselves in the United Kingdom and Ireland, as problem solvers for complex projects and development projects in the food sector, in the pharmaceutical industry and in medical technology.

Wolfgang Rauch is continuously expanding his sales team. Since November 2012, Raupack Ltd. has been a 100 percent subsidiary of Harro Höfliger Verpackungsmaschinen GmbH. The sales and service branch with 14 mostly long-term employees under the leadership of Wolfgang Rauch, is responsible for several business sectors in the United Kingdom and Ireland.

Rauch is satisfied with his career: "For me, the purpose of work is to make a living, but also to find fulfillment – and I always did and still do." He is also very proud of his employees: "Usually I only act as a kind of flipper. I start the ball rolling and give it direction. I do not believe in excessive control. Anyone who wants to work independently, should be left to do so."



The successfully completed projects of Wolfgang Rauch and Harro Höfliger include the assembly of syringes. This led to the team's establishment in the British pharmaceutical market.

Asked about the joint recipe for success, Wolfgang Rauch says: "Harro and I have never succumbed to resistance. Our customers feel that they have partners who are trying hard, who can admit when something is not working as originally thought, but always find ways to complete an order."

Although his centre of life is in the UK, Wolfgang Rauch regularly travels

to the Harro Höfliger headquarters in Allmersbach im Tal. Every now and then there is still time left after work to indulge in a common passion with Harro Höfliger: Vintage cars. They started the collection together and to this day, the entire respectable fleet of historic treasures from Germany and the UK is parked in one garage. "We complement each other in many ways," says Rauch, laughing.

Harro Höfliger celebrates his 80th birthday



"Working and continually exploring new avenues", is his entrepreneurial motto. With technical understanding, perseverance and creativity, Harro Höfliger mastered a number of rather tricky challenges and always had a good sense for market trends and his customers' wishes. And he did so from the very beginning. As a man of action, in 1975 he quickly converted his garage to a workshop and dared to take the step into self-employment. In April, the passionate entrepreneur and namesake of this magazine turned 80 years old. Certainly, a milestone birthday, but no reason for retirement. Harro Höfliger has long since left the day-to-day business to others, but the senior partner is still present and active in his company of approximately 1,100 employees.

Even at the age of 80, he can frequently be found walking the factory floor. Technological challenges inspire Harro Höfliger to this day.

Excellent design

The new Human Machine Interface (HMI) by Harro Höfliger is not only multifunctional, but also exhibits exemplary design. This is confirmed by three prestigious design awards: Following the iF Award and the Red Dot Award, the intuitively operated human-machine interface also received the German Design Award 2017. For Fabian Elsässer, Head of the Central Automation Department, and his nine-member team, these awards are very high praise: "With our partner CaderaDesign, we wanted to develop a solution focused on usability, providing machine operators with comprehensive support for their tasks. And of course, we are all the more pleased that we received the most popular design awards."

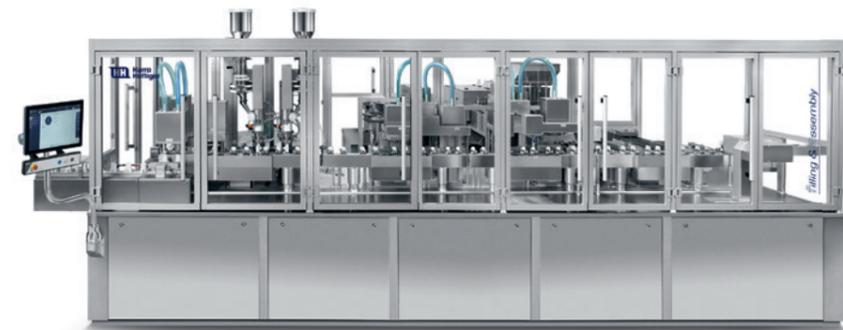


Great achievement: Harro Höfliger's second generation of the HMI has won all of the most important design awards.

Inhaler Technology in China

Fast help in small doses

High levels of air pollution put a strain on people's health in urban agglomerations and industrial centers in China like nowhere else on earth. As a consequence, the number of respiratory diseases is rising steadily. For the administration of soothing active ingredients, the Chinese company Kinnovata is focusing on powder inhalers. The fast supply of inhalers is ensured by a fully automatic filling line developed by Harro Höfliger.



China is the largest market of the so-called “pharmerging” countries and the growth of the pharmaceutical sector is even above-average in the area of respiratory therapy. The reason for this is the high level of fine dust pollution in the metropolitan areas, and the resulting respiratory diseases affecting their residents. The demand for medication is high and this trend is set to continue. Tianjin Kinnovata Pharmaceutical Company Ltd., founded in 2013, specialized early in the production and filling of inhalers (Dry Powder Inhalers,

DPI). The active ingredients contained therein in powder form are used for the treatment of respiratory diseases such as asthma or COPD (chronic obstructive pulmonary disease).

When developing the necessary assembly and filling machines, Kinnovata deliberately banked on Harro Höfliger's know-how and experience. The fully automatic machine delivered in May 2016 produces two inhalers per cycle and up to 40 inhalers per minute. The assembly and filling process is complex. The bottom parts of the inhaler are stored on a

tray in a trayloader and fed to the assembly line just in time. All other individual parts are fed into the machine by gripper units and are gradually assembled to form complete devices. The machine has been designed in such a way that the individual parts are fed from the rear side. This makes it easier for operators and minimizes their movements.

In order to facilitate cleaning and to prevent the large-scale contamination of the entire process with active ingredient particles, the machine designers focused on and integrated the so-called walking

beam transport platform: The gripper units used for assembly and transport of inhaler parts do not advance through the machine but remain at their respective assembly station.

The powder is filled into both smaller round, and larger rectangular reservoirs. This is done without the need for time-consuming refitting – one of the major technical challenges that had to be overcome when designing the machine. Both fill quantities are controlled inline using weighing technology before the respective reservoir is closed with a lid. In addition, an integrated color sensor verifies the different colors of the two inhaler versions.

In the next step the laser coding is applied. For this purpose, the inhalers are removed from the transport grippers, rotated over the laser and marked from below. A camera checks the quality and completeness of the marking.

The staff and the managers at Kinnovata are very satisfied with the machine. Not only have they been convinced by the complex technology and implementation of the required process steps, but also by the seamless collaboration with Harro Höfliger. The best proof: Discussions are in progress about the manufacture of another filling and assembly line for a new generation of inhalers. ■



Jing Li, Managing Director at Tianjin Kinnovata Pharmaceutical Company Ltd.

Mrs. Li, why did you choose Harro Höfliger to develop your process?

"Harro Höfliger convinced us with their technical expertise. The machine concept they presented is excellent and fully implements our requirements. In addition, we were impressed by the numerous inhaler machines that Harro Höfliger has already implemented. This gave us the necessary assurance during our decision-making process. But technology was not the only decisive factor. The good cooperation with Harro Höfliger and their representative Rieckermann was also crucial for our decision. And as we can now see from the flawless operation of the machine, we made the right decision."

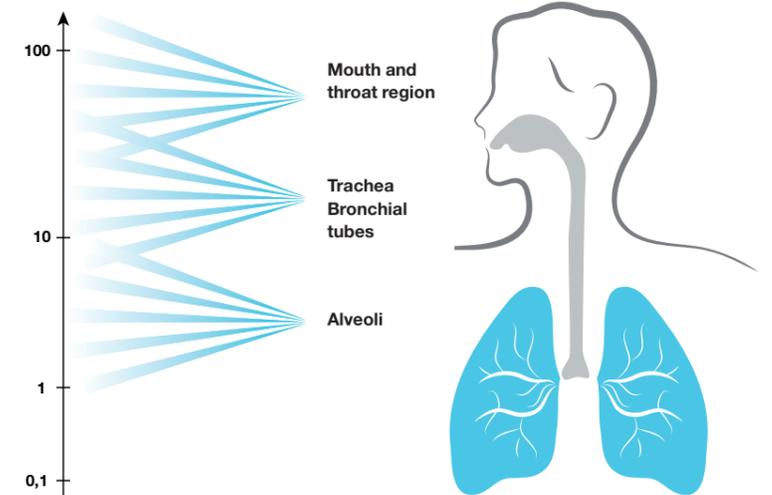
Dosing in the form of powder

Among the so-called "new administration forms", inhalation powder is regarded as the method of choice for the intake and absorption through the lungs (pulmonary) or through the nasal mucosa (nasal). The processing of micronized powder in a fully automatic system poses a very demanding challenge in pharmaceutical production, since the processing method depends heavily on the powder's physical properties. Particle size and geometry, size distribution as well as the surface structure of the particles affect the powder's flow behavior.



The effect of particle size

Powder inhalers have proven to be effective for the administration of active ingredients – for example in the treatment of asthma. The graphic shows how inhalation particles are deposited in the respiratory system depending on the diameter. With its micro-dosing systems, Harro Höfliger covers a wide spectrum of conceivable particle size distributions, starting at diameters below 1 µm.



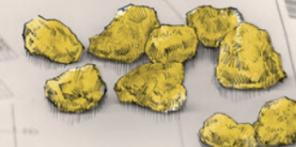
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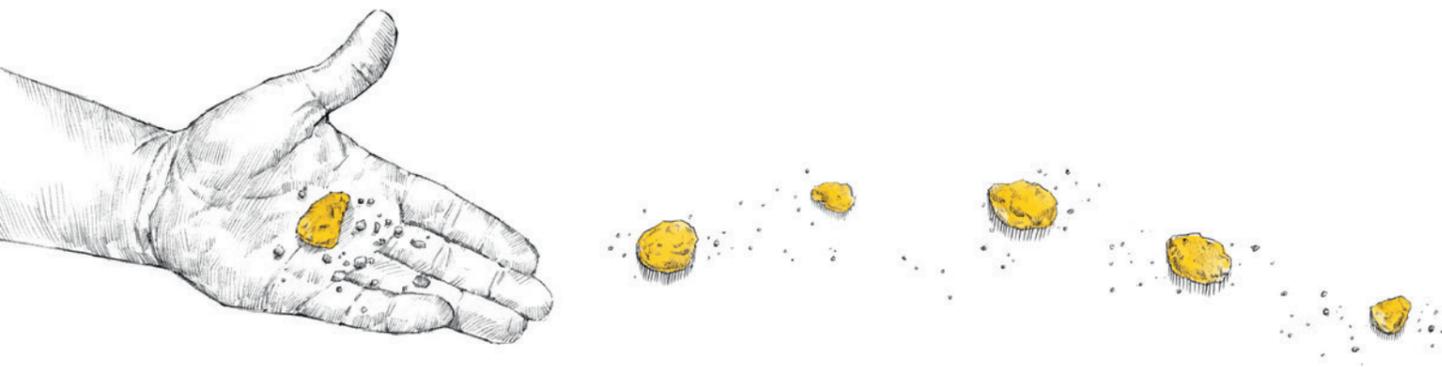


Sifting for golden ideas

For inspiration, creative minds need, above all freedom and space to think. In Harro Höfliger's business culture, the guideposts for all employees have been set so that besides the daily business, there is enough room for inspiration.

Hilmar Lüg, Bernd Schillendecker





Peter Claußnitzer, CTO at Harro Höfliger, carefully considers the concept of innovation: “The over-use of buzz words dilutes their core and degrades them into catch words. Most new products are not really innovative. Progressive, different and worthwhile are necessary but insufficient conditions for an innovation. An innovation should fundamentally change something,” Peter Claußnitzer emphasizes.

As a possible example for the near future he names the technology of Linear Motion Systems (LMS), such as Beckhoff XTS or Magnemotion linear transport systems, with independently driven

“New approaches must be introduced in close consultation with the customer. Because the customer appreciates creativity but does not like negative surprises.”



Thomas Weller, CEO

workpiece carriers. The reason: “Utilizing these transport systems essentially changes the design and the philosophy of a machine. That is why their use would be a genuine product innovation.”

One organizational innovation, still in effect today, is the incorporation of a “pharmacist” into the company structure. The resulting “Pharma Services” department at Harro Höfliger is the basis for many successful projects, and guarantees increased process reliability. The Pharma Services experts guide the customers in the selection, development and optimization of the processes from product infeed to packaging.

The first step is the characterization of active ingredient-containing original formulations, and the determination of the optimal dosing principle using a comparative product database. Utilizing test setups, critical processes are verified and tested well in advance. Finally, clean rooms make it possible to operate the new system with the original product under future environmental conditions. Therefore, Harro Höfliger not only builds machines, but is frequently an integral part of the development phase of new drugs.

Beyond the daily routine, new ideas constantly emerge regarding machines, systems and processes. So that they are not lost, Achim Wolf has set up the EIS (Engineering & Innovation Services) department at the Allmersbach im Tal headquarters. Their task is to systemize, structure and efficiently develop the process from the initial idea to market readiness. Thus, ideas with potential for innovation do not end up in some desk drawer, but are consistently moved forward in a controlled process and in multiple phases.

Innovation management as a systematic process, with transparent decisions and close project control is a building block of Harro Höfliger’s Strategy 2020. CEO Thomas Weller explains: “Our customers come to us because they

“Most new products are not really innovative. A true innovation should fundamentally change something.”



Peter Claußnitzer, CTO

know that we, as technology leaders, find the right solution for their particular task – even beyond the beaten path.”

It is therefore imperative that every market trend is recognized and analyzed at an early stage. However, emphasizes Thomas Weller, “new approaches must be introduced in close consultation with the customers. Because the customer appreciates creativity but does not like negative surprises.”

The key is the so-called co-innovation with the customer. For Peter Claußnitzer this has become the norm at Harro Höfliger: “Many good solutions are created together with our customers. We motivate and encourage each other to achieve excellence.”



More than 1,000 capable creative minds

Achim Wolf manages the innovation management team at Harro Höfliger. A conversation about tasks, challenges and successes.

What responsibilities does your team have, Mr. Wolf?

We are the first stop for an idea to become reality. After all, our company now has well over 1,000 proficient creative minds on the payroll – everyone can come to us with his or her sparking idea. First, we ensure that no flash of inspiration is lost. After all, there can be a real innovation behind every idea.

Do you also ensure a controlled process?

In four steps, we channel the flow from idea to innovation. First, an interdisciplinary team examines the feasibility of an idea. The innovation steering committee uses this expert opinion as a basis for whether or not an idea is pursued as a project. If in the next step, the project suitability is confirmed, the steering committee decides whether and in which application context the idea should be further developed. Next, it is determined which machine can be used for a new technology, or for which target customers the innovation can be considered.



How do you provide support to the originator of the idea along the way?

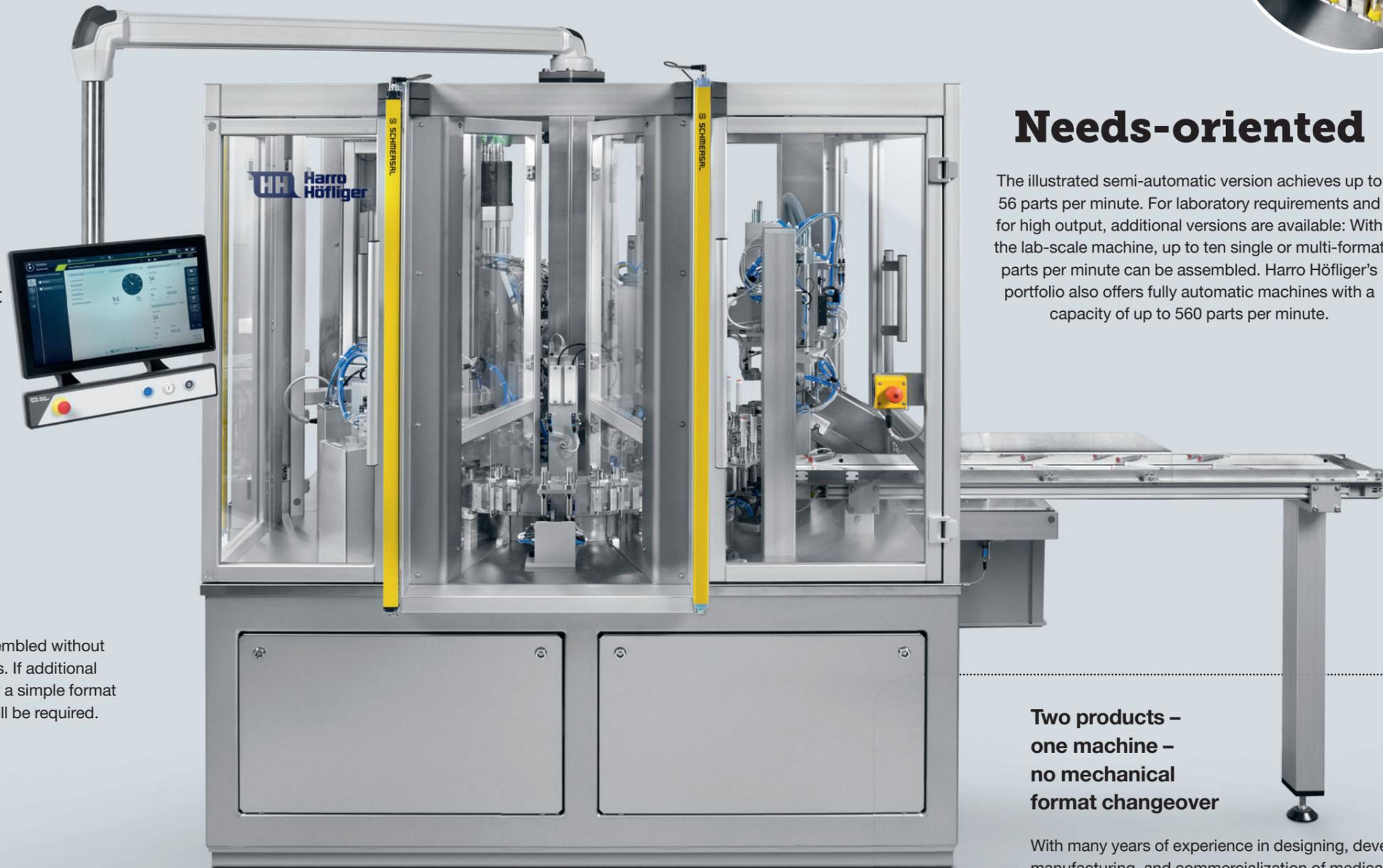
In the classic role as a coach, we clear the way. We set priorities, provide the necessary resources, and ensure continuous communication regarding the project status. With full support from management, we can also identify other employees who can function as promoters at the appropriate time. Last but not least, we make decisions transparent and ensure close project control.

Are there examples in which innovation management has already proven itself?

The XTray, a universal concept for the delivery of surgical sutures, is one example. Likewise, our DiscFiller – a table unit that can be used to fill up to 60 cavities of a disc with inhalation powder in one dosing cycle – is the result of our dedicated innovation management.

One for two

The new semi-automatic assembly machine for pens and auto-injectors stands out with its flexibility. For the first time, two different products can be manufactured on one platform – without the need for mechanical format changeovers. With this semi-automatic solution, Harro Höfliger speeds up market access for their customers at an early stage.



Ergonomic

The machine's proven GMP-compliant design makes operation and cleaning easy. For manual loading, up to two operators have direct access to the insertion point at the rotary table.

Needs-oriented

The illustrated semi-automatic version achieves up to 56 parts per minute. For laboratory requirements and for high output, additional versions are available: With the lab-scale machine, up to ten single or multi-format parts per minute can be assembled. Harro Höfliger's portfolio also offers fully automatic machines with a capacity of up to 560 parts per minute.

Expandable

The machine concept allows subsequent automation at any time. For example, conversion from semi-automatic to fully automatic mode is possible, in case of increasing production demand. The integration of additional technologies such as labelers, and connections to downstream equipment such as cartoning machines is also possible.

Fast

Pens and auto-injectors are assembled without mechanical format changeovers. If additional versions are to be processed, only a simple format change command at the HMI will be required.

Safe

All critical processes are automated. Pressing and joining operations as well as function checks are fully monitored as with a high-performance system.

Standardized

The semi-automatic machine also is equipped with Harro Höfliger's proven Human Machine Interface (HMI). It goes without saying that it fulfills the CFR part 11 requirements for FDA-compliant electronic signature. Customers benefit from the comprehensive service including service portal and remote maintenance.

Two products – one machine – no mechanical format changeover

With many years of experience in designing, developing, manufacturing, and commercialization of medical devices, BD supports customers in the rapid market segment of new products. BD Physioject™, a disposable auto-injector (right), was developed following extensive studies and considering user experience. It received the Ease of UseSM commendation from the Arthritis Foundation® for its ease of handling. The auto-injector can be used in combination with BD Neopak™ and BD Hypak™ for Biotech 1ml Long pre-fillable glass syringes. BD Vystra™ disposable pen is designed for simple and comfortable administration of liquid medical agents with variable dosing regimens. It can be customized according to customer-specific requirements.



„Better safe than sorry“

When producing highly potent or toxic products, customized barrier technology is required in order to protect product, operator and environment. Bernhard Brugger, aseptic and containment expert at Harro Höfliger, is talking about the challenges.



A wooden mock-up (left) is used to simulate operation. The findings are implemented on the machine (right).

Is it correct to speak about containment instead of barrier technology?

Brugger: No, even if the two are often equated. The generic term is barrier technology. If we talk about product protection, we are in the field of aseptics. However, if we look at operator and environmental protection, we are talking about the issue of containment. Confusion is also caused by the fact that in the German-speaking countries the term containment only refers to the enclosure, whereas in the English-speaking countries it means the entire process, including handling and interface difficulties.

Is Harro Höfliger active in both fields?

Yes, with a great deal of commitment since the establishment of our department in 2008. After all, highly active ingredients, for example, in cancer therapy or in hormone treatments are used more and more frequently. Independent market researchers expect an annual average growth of the HPAPI-market

(High Potency API) of almost 15 percent between 2015 and 2022. So, there is a lot of potential. On the other hand, increasingly complex active ingredients are processed, which often cannot be terminally sterilized and therefore have to be processed aseptically.

What kind of aseptic issues do you address?

There are clear guidelines for aseptic machines like the FDA guidance “Sterile Drug Products Produced by Aseptic Processing“ or the EC-GMP guidelines. Basically, it is about the aseptic processing of sterile products. Germs, viruses and spores, in other words, all sorts of contaminants have to be kept away from the product. We implement isolators, open and closed RABS (Restricted Access Barrier System) with integrated laminar flow systems. Due to rapid transfer ports or active and passive mouse-holes, interfaces no longer constitute a problem. Naturally, we have also mastered complex proces-

ses with strict temperature or humidity control requirements, as well as under an inert gas atmosphere. For example, we implemented a system in which cryo pellets are filled under a nitrogen atmosphere.

What role do people play in this?

A double role – because people are the main disruptive factor on the aseptic side. Just think of germs and particles such as skin dander, clothing abrasion or sweat drops. On the other side, when processing highly active ingredients, containments are required to protect us from these substances.

How do you determine the protective measures?

An important, but not the only aspect is the OEL-limit (Occupational Exposure Limit) that has been established and must be met. Many questions have to be answered first. What properties does the product have? How long does the operator work on the machine per day?

What is the concentration of the active ingredient in the final product? What external interfaces are involved in the process? What intervention methods does the operator need? Only when all these factors are known, can we determine the probability of exposure and design the containment solution.

What tools do you use?

Naturally, we use all modern tools such as computer-aided design (CAD), computational fluid dynamics (CFD) and virtual reality. In addition we build wooden mock-ups of the entire machine. This is necessary to simulate operation. Together with our customers, all conceivable process steps are simulated, including setup, troubleshooting, and cleaning. These trial sequences often take several days. Then we work out the ergonomic details. With this method and using realistic weights, operators can test the system through glove ports and judge whether this is manageable in their daily work routine. ■



Bernhard Brugger, Department Leader Design & Development Isolators & Containment Systems at Harro Höfliger,

previously spent his study time in the cleanroom. His long-term experience gathered at the Fraunhofer-Gesellschaft paved his way in aseptics and containment. After having worked in various positions in the industry – always close to the topic – he came to Harro Höfliger in 2008 where he founded the barrier technology department. Today he manages a team of nine employees.

Operator Protection: Proven in Practice

In response to growing market demands from pharmaceutical companies, Harro Höfliger designed a containment concept for their capsule filling machines.



The Containment concept of the Modu-C MS provides reliable technology for operator and environment protection.

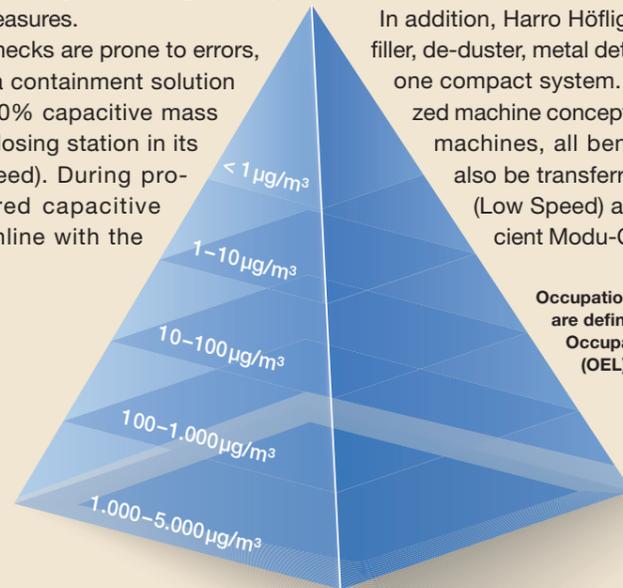
This containment concept offers the highest process stability and a validated safety level up to the OEL value of $0.1 \mu\text{g}/\text{m}^3$ during production. In order to achieve this low OEL level, the development focused on consistently minimizing powder dust. In addition, particular attention was paid to interface optimization (e.g. empty capsule feed). A simple cleaning concept complements these measures.

Since gravimetric checks are prone to errors, Harro Höfliger offers a containment solution with an integrated 100% capacitive mass control for the drum dosing station in its Modu-C MS (Mid Speed). During production, the measured capacitive value is compared online with the

scale value in order to meet the customers' accuracy requirements.

For simple cleaning during product changes, Harro Höfliger prefers dry cleaning. The benefits: No bacterial growth caused by moisture, no disposal costs for contaminated water, and reduced incrustation, facilitating the removal of powder particles from the machine surface.

In addition, Harro Höfliger combines capsule filler, de-duster, metal detector and sampling in one compact system. Due to the standardized machine concepts of the capsule filling machines, all benefits mentioned can also be transferred to the Modu-C LS (Low Speed) and the even more efficient Modu-C HS (High Speed).



Occupational Exposure Bands (OEB) are defined on the basis of Occupational Exposure Limits (OEL).

Helmar Lünig, Tom Philipp



Fast route to point of action

For the production of their fast-acting nasal applications, M et P Pharma AG has been relying on Harro Höfliger as their competent partner – from developing the device and the pilot machine for filling and sealing, all the way to high-speed production.

The corporate slogan “The Nasal Company” puts it in a nutshell: M et P Pharma is a specialist for nasal applications. The Swiss Company concentrates on the intranasal administration of molecules that are effective in the brain – neurotransmitters and hormones, for example – are administered by means of thixotropic oil formulations. The

fascinating part is that the nasal and olfactory mucosa, blood capillaries and nerve pathways are the small back doors through which these active ingredients can pass directly into the brain, past the powerful blood-brain barrier.

The nasal applicator is as innovative as the concept – a mono-dose container made from polyethylene with a convex

“For challenging tasks such as the manufacture of a completely new application device, it takes a system manufacturer like Harro Höfliger who develops the necessary processes with a creative approach.”



Udo Mattern,
CEO at Met P Pharma AG,
Emmetten (CH)

Parts infeed
Each of the four vibratory bowls conveys up to 150 top and bottom parts per minute into the line.

Pick and place
By means of a linear pick and place unit, eight correctly oriented bottom parts each are inserted into special workpiece carriers.

IPC removal
An integrated process control ensures that all applicators meet the highest quality demands.

Ultrasonic welding
Four ultrasonic welding stations ensure the 100 percent tight and secure joining of the applicator parts.

Liquid filling
The gel dosing station fills four bottom parts with the thixotropic oil formulation.

Alignment
A robot places about 110 correctly positioned parts per minute into the workpiece receptacles using suction grippers.

Completion
A transfer unit with four suction grippers places the flat top parts onto the filled bottom parts.

liquid reservoir and twist-off pin closure. “For the administration of centrally acting molecules it is imperative to use a perfect combination of active ingredient, formulation and applicator,” explains CEO Udo Mattern. “Our container guarantees a simple and accurately dosed application.” Harro Höfliger has been involved in its development from the very beginning. After all, it was necessary to find tailor-made processes for handling, bubble-free filling and sealing of these brand-new devices.

A milestone on the route to commercial production was the semi-automatic pilot line, which M et P has been using for cli-

nical trial drugs and test samples since 2012. The practical experiences gathered with this line were directly integrated into the design of the high-speed machine that Harro Höfliger developed in parallel, with an upscale factor of 1:10.

Product conservation, reproducibility and tight ultrasonic welding of the injection molded parts proved a particular challenge. Ultimately, the solution resulted in the optimization of the device design. Instead of the original “butterfly” shape with a hinge, two separate plastic halves are now used, which are joined in four welding stations at lightning speed. The wavelike

contour of the welded edge reinforces this precise and homogeneous connection of the top and bottom part. Furthermore, a small separating strip around the cavity of the bottom part prevents leakage of the oil formulation and protects against particles – in addition to dust extraction during the sealing process.

In the fall of 2016, M et P put the fully automatic line into operation. It is an oval motion machine in an eight-lane version with an output of 200 devices at 25 cycles per minute. From two vibratory bowls each, both the bottom parts with the bulbous molding and pin, as well as the flat top parts are fed

to the line as bulk material on a belt conveyor. A camera detects the position of the parts. Only correctly positioned halves advance to the suction grippers, which deposit eight bottom parts each into workpiece carriers. A rotary piston pump with a four-way dosing head alternately fills four bottom parts each with active ingredient containing oil. This is followed by the transfer of the upper parts and the servo-driven welding. In addition to the tightly focused camera inspection, an in-process control with fail part ejection ensures the perfect quality of the applicators. ■

Even more diverse

Additions to the portfolio of the Excellence United partners: Besides Harro Höfliger's Modu-C HS, capsule manufacturers can now also benefit from the FEC40 by Fette Compacting.

Since first being patented in 1846, the two-part hard capsule has had a stellar career. Among the most common dosage administration forms, it now ranks second after the tablet and demand is growing steadily. For filling of capsules with medication, especially with inhalants, Harro Höfliger has continuously expanded its machine program for more than 30 years. Today, the Modu-C, with three out-

put levels, low-speed, mid-speed and high-speed, enables capsule production with a multitude of fill materials and combinations. In addition to technologies for research and development, Harro Höfliger also offers customized solutions, special applications, and all components for complete turnkey systems in the high-tech market.

Last year, the product portfolio of the Excellence United partners was expan-

"The FEC40 is a good example for the positive impulses that Excellence United can contribute towards product development in the future."



Olaf J. Müller,
CEO LMT Group
Division President Fette Compacting

"Our customers benefit from our collaboration: The FEC40 is proof of the synergies in all areas and the performance capability of our alliance."



Thomas Weller,
CEO Harro Höfliger

LMT GmbH & Co. KG, Helmar Lünig, Tom Philipp

ded once more. With their new capsule filling machine for large volumes, Fette Compacting, the market leader for tablet presses, now covers the high-capacity pharmaceutical market and the booming dietary supplement sector. The FEC40 fills up to 400,000 capsules per hour with powder or pellets.

During their collaboration in the development stage, Harro Höfliger and Fette Compacting agreed that, beginning with the FEC40, Fette Compacting would position themselves in the market for standard applications whereas Harro Höfliger would continue to offer solutions for

special applications involving extraordinary engineering skills.

The partnership constitutes a solid basis. When developing the core technologies such as powder and pellet dosing, Fette Compacting was able to benefit from Harro Höfliger's transfer of knowledge. Furthermore, the close cooperation among the Excellence United partners ensures the compatibility of individual components. For example, Harro Höfliger's weighing machine Accura-C can be seamlessly integrated into the production line to complement an efficient high-speed capsule production. ■

About Fette Compacting



Fette Compacting is the world's leading provider of integrated solutions for industrial tablet production. Since 2016, the product portfolio offered by the technological and global market leader has been supplemented to include highly-efficient capsule filling machines. The company specializes in high-performance machines for the pharmaceutical industry. Its range of products and services comprises tablet presses and capsule filling machines, tools and processing equipment, as well as maintenance, training and consultation services.



	Fette Compacting FEC40	Harro Höfliger Modu-C Family
Output	High-performance sector, 400,000 capsules/h	„From Lab to Production“ 8,000 up to 200,000 capsules/h Special applications Customized solutions
Main markets	Pharmaceutical market, dietary supplement sector	Pharmaceutical market including inhalation
Fill material	Powder, pellets	Powder, pellets, tablets, micro tablets, liquids and combinations thereof
Dosing method	Tamping pin, pellet station	Tamping pin, pellet station, drum filler, dosator, liquid station
Cleaning / Changeover	Dosing stations are completely interchangeable; tamping pin station is removed by means of disassembly support without drives	Flexible change trolley with up to 4 filling units
Operator protection		Containment, dry cleaning



Reliability creates trust

Customized machines are the core business of Harro Höfliger. Our customers not only expect us to come up with elaborate technical solutions, but also with seamless project implementation and ongoing transparent overview of the project. Professional project management provides the basis. How exactly this is handled within the company, and what specifics need to be considered is explained by individuals responsible for the respective area.



How is the quality of project management processes ensured?

For the past year or so, Harro Höfliger has been offering project managers an extensive qualification program. The certified project manager training is carried out in accordance with the guidelines of the German Society for Project Management (GPM, Deutsche Gesellschaft für Projektmanagement) and the International Project Management Association (IPMA). Building on experiences gathered, after completion of a project I always invite everybody involved to a so-called Lessons Learned Meeting. In this review, we reflect on the entire project in order to identify strengths and weaknesses from an organizational and technical point of view. These findings provide a perfect source of information for my colleagues for future projects. Our goal is to avoid the same mistakes in new projects. Although mistakes are “permitted”, they are not to be repeated.

Markus Hänle, Project Manager Sales

Why is project management so important for Harro Höfliger?

Our orders are technically very demanding and time frames are usually tight. Therefore, it is necessary that everything is structured and transparent. Consequently, at Harro Höfliger project management means that all individuals responsible for a project work together in a team. To this end, across all divisions, we clearly define responsibilities and tasks within the project. This enables project teams to work efficiently without compromising our most precious asset, the creativity of our employees. Professional project management is a solid pillar for us, because it assures the reliability of process operations and thus the high quality of our products. This is what our customers rely on.

Günter Ziarnetzki, Head of Project Management



What are the responsibilities of a project manager?

First and foremost, I am the direct contact for my customers. Additional core tasks include project planning, conducting design reviews, managing project processes and regular reporting. During the planning phase I prepare a schedule defining the sequence of required work activities which I coordinate internally and also with the customer. I clarify open points, answer questions on requirement specifications and make sure that the order is clearly defined for all parties involved. That way everyone gets the information they need. When a project is close to the Factory Acceptance Test (FAT), it is my job to perfectly plan the forthcoming customer visit so that customer acceptance and dispatch can proceed according to schedule.

Caroline Mildenerger, Project Manager Sales



Why are there two project managers for every project?

We rely on a well-coordinated dual leadership. As “technical project manager” I concentrate primarily on the technical implementation and achievement of the technical project objectives whereas the “sales project managers” keep an overview of the “big picture”. They plan, control and initiate corrective measures if something gets “out of control”. Moreover, they are in constant contact with the customer. This creates transparency, both internally and externally, and forms the basis for a trusting customer relationship. Naturally, I am also always at the customer’s disposal for technical questions.

Thomas Joos, Technical Project Manager Design



Tom Philipp

Why are there special project managers for foreign customers?

Many customers speak English well, however, discussing questions in their mother tongue is still a major advantage. Cultural differences – for example differences in etiquette – and people’s mentality are also to be considered. I myself am Chinese and therefore responsible for our customers from China. I know what conduct is expected of me, how I have to react to difficulties and how I can avoid misunderstandings in advance. The same applies to my colleagues whose mother tongue is Russian or Arabic. Through correct and clear communication, we avoid difficulties and save time. In addition, this creates a very special relationship of trust with our customer.

Yuan Su, Project Manager Sales



How do customers respond to the international project management at Harro Höfliger?

“When Chinese companies undertake investments with German suppliers, they expect language barriers and different ways of thinking. Harro Höfliger, however, convinced us otherwise. During initial meetings, we were quickly assured that language would not be a stumbling block for the project. We have worked very well together with Ms. Su and with a focused approach. She is Chinese, speaks our language and knows our ways of thinking. This has had a very positive effect on the course of the project. If I had questions, she could quickly provide answers or clarify issues. I had the feeling of being understood, and this is important for the safe implementation of the project and for me personally.”

Dabing Hu, Production Manager, Respirant Pharmaceuticals



Dabing Hu and Yuan Su after the successful machine acceptance at Harro Höfliger.

Fill quantity control with an X-ray vision

When filling highly potent powders for inhalation purposes, tiny amounts of active substances have to be dosed with precision. Harro Höfliger, always meticulous, is now also using X-ray technology for verifying the quantity of powder filled in blister strips. The use of the X-ray module enables 100 percent verification of the dosed mass – fully automatic, in-line and in a closed container.

Normally, the verification of powder filled blisters is done by means of destructive random sampling: An aluminum strip is removed from the process and opened in a separate test unit. If the net weight of the weighed dry powder deviates from the defined set value, the dosing process must be re-adjusted and the random test repeated afterwards. This may result in production losses and delayed batch releases.

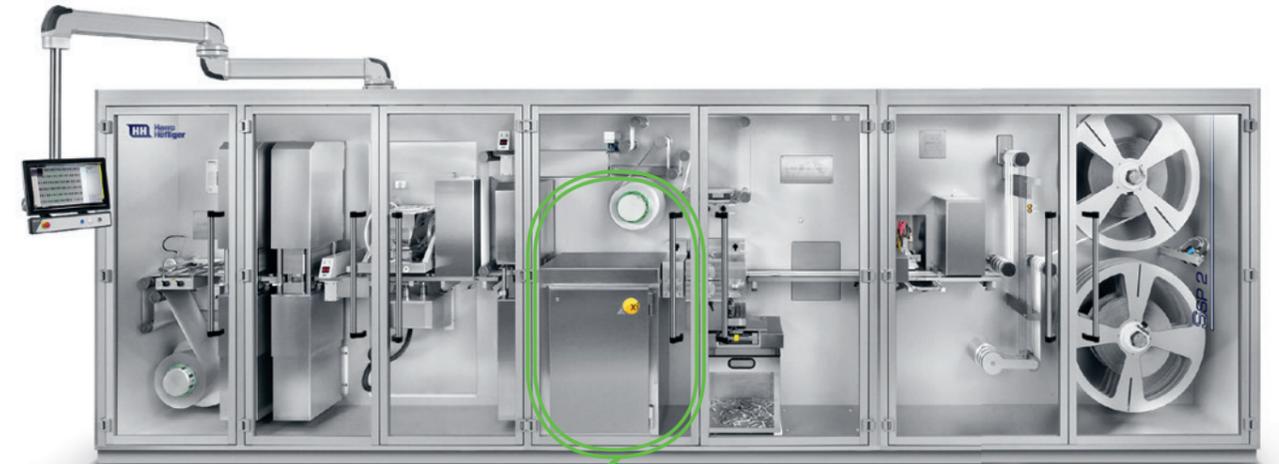
When such OOS incidents (Out Of Specification) happen, short reaction times are crucial for pharmacists. Harro Höfliger therefore now offers an integrated X-ray module for continuous quality control in their blister machines with membrane filling technology. An X-ray beam penetrates the sealed powder cavity and strikes a flat panel detector, converting the intensity distribution into a digital image with a range of gray-scale gradations. Light and dark colors correlate with the respective amount of radiation energy absorbed by powder and aluminum film.

If the absorption rate of the empty blister strip and the powder mass are known in the reference pattern, the software sets

the gray value in relation to it. That way the system can be calibrated. For every new product with a different composition, the correlation value of fill quantity and gray value is determined and the system calibrated again. The powder mass is verified by Harro Höfliger's IPC-checkweigher for blister strips. After programming the new coordinates, a fill quantity control with automatic trend control for the complete batch duration is possible. At the same time, seamless data recording facilitates a smooth batch release.

The system reliably verifies fill quantities down to 5 milligrams and without changing machine speed. On the model SSP2 blister machine for small series, 60 to 80 cavities per cycle are inspected, at up to 15 cycles per minute. The minimal radiation intensity has no impact on the active pharmaceutical ingredient or the operator's health. The new X-ray technology will not only be used in future blister machines, but existing machines can also be retrofitted. Another plus: The system detects damage to the aluminum blister and detects foreign particles in the powder cavities. ■

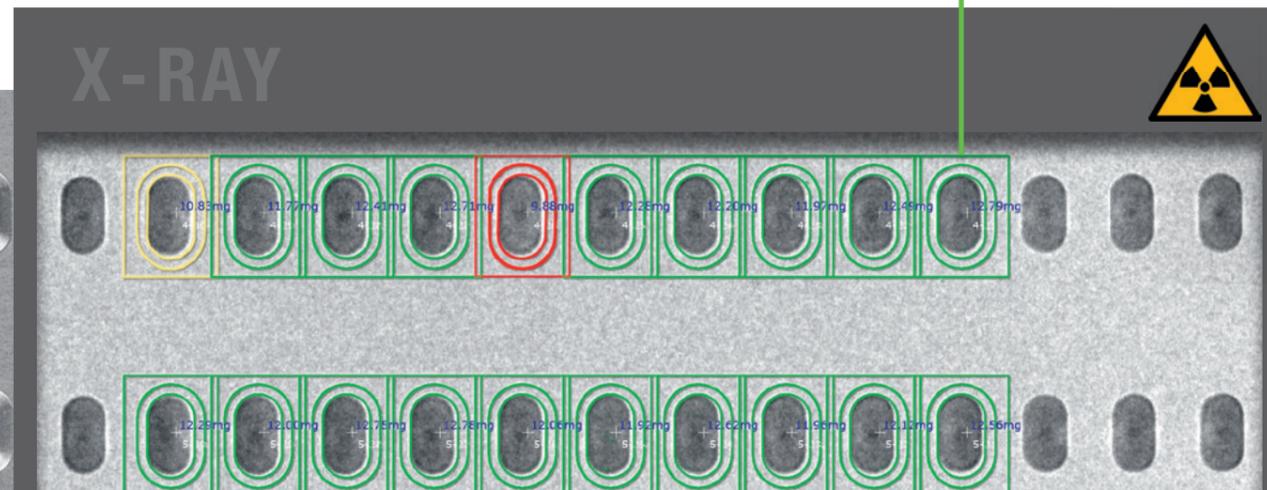
Helmar Lünig



Compact and safe integration of the X-ray module in the Blister Machine SSP2. Convenient operator control via the HMI operator panel.

X-ray – This is how it works

Whether used for luggage control or at the doctor's office: X-ray images are practically a part of everyday life. Inspections and screenings benefit from the fact that the absorption of X-rays passing through matter varies. More or less attenuated, they then strike an X-ray film or a modern detection system, which converts the information into a digital image. The gray scales reflect the degree of absorption. Thus, our radiolucent muscles appear almost black, and the robust bones white. In addition to material density, attenuation also depends on the atomic number in the periodic table: Due to their higher number of electrons (aluminum: 13, iron: 26), metals absorb less radiation energy than organic substances (carbon: 6). A measure of attenuation is the gray-scale value. The higher it is the more rays are registered by the detector.



The fight against antibiotic resistance

With Sorbact®, ABIGO Medical provides a unique wound dressing that prevents and treats infections, fighting the global threat of antibiotic resistance. Now ABIGO gears up further, with significant investments in their production facility.

In 1989, the brothers and entrepreneurs Jan G. Smith and Leif Smith founded ABIGO Medical AB, with a focus on delivering innovative methods of infection control and to reduce the use of antibiotics. ABIGO is a company with a substantial international presence and a continuing strong growth. Its products are sold in 70 countries, with a current turnover of about 30 million euros. The company's workforce consists of more than 130 employees.

"Sorbact® is one of ABIGO's key products and offers fantastic opportunities, particularly in view of the global challenges of infections and antimicrobial resistance," Jan G. Smith, owner and CEO at ABIGO Medical explains. Sorbact® is a wound dressing that prevents infections and helps to reduce the need of antibiotics, hence lessening the risk of spreading multi-resistant bacteria. Excellent results in international studies com-



The founders and owners of ABIGO Medical, Jan G. Smith (left) and Leif Smith (right).

bined with many years of clinical experience, has led to a sharp increase in the use of Sorbact®.

In order to meet the strong demand, ABIGO has invested 3 million euros in an expansion of the production facility, now 5,000 sqm and inaugurated in November 2016. The strong and continuous growth requires close partnership in all aspects of the product process. Harro Höfliger is a close companion to ABIGO for the production of the Sorbact® dressing. "Together we have grown over the past few years and we have established a lot of trust," says Hartmut Thier, leader of the Harro Höfliger web converting team.

ABIGO's Plant & Production Director Fredrik Stenbäcker affirms the good cooperation between the companies: "At ABIGO we promote a down-to-earth corporate culture without the hectic frenzy of continuously focusing on quarterly performance. We believe that people are buying from people. That's why we highly appreciate that cooperation with the Harro Höfliger team always take place on a professional and pleasant basis. And we feel outstanding loyalty."



This is a close collaboration that pays off for both sides. The first web converting machine type PMK in 2010 was followed by a second line in 2012. The third machine for the Askersund site, near Gothenburg, has already been ordered.

"The PMK's modular machine concept offers perfect prerequisites for a flexible and optimized sequence of core processes such as coating, sealing, cutting, punching and packaging," Fredrik Stenbäcker explains. Format changeovers or machine options with different numbers of components can be easily implemented due to the PMK's modular design. According to Jan and Leif Smith, the fight against infections and antibiotic resistance is of utmost importance. It is an incredibly large area and there are a multitude of applications for the innovations owned by ABIGO. "We have barely scratched the surface," Leif Smith says. ■



Rapid changeover to other product variants is possible due to the modular design of the PMK.

About ABIGO Medical



Founded: In 1989 by brothers and entrepreneurs Jan G. and Leif Smith

Products: Non-prescription, prescription drugs, food for medical purposes and medical products

Headquarter: Gothenburg, Sweden

Production: Askersund, Sweden

Annual turnover: 30 million euros

Global representation: 70 countries

Number of employees: 130

Visit us:

CPhI

Tokyo, Japan
19.04. – 21.04.2017

ICE USA

Orlando, USA
25.04. – 27.04.2017

Interpack

Düsseldorf, Germany
04.05. – 10.05.2017

Biotechnica

Hannover, Germany
16.05. – 18.05.2017

FCE

Sao Paulo, Brasil
23.05. – 25.05.2017

ExpoPack Mexico

Guadalajara, Mexico
13.06. – 15.06.2017

Interpex

Tokyo, Japan
28.06. – 30.06.2017

ERS

Milano, Italy
09.09. – 13.09.2017

IranPharma

Teheran, Iran
12.09. – 14.09.2017

Inhalation ASIA

Hongkong, China
13.09. – 15.09.2017

PackExpo/Healthcare

Packaging Expo
Las Vegas, USA
25.09. – 27.09.2017

Powtech

Nuremberg, Germany
26.09. – 28.09.2017

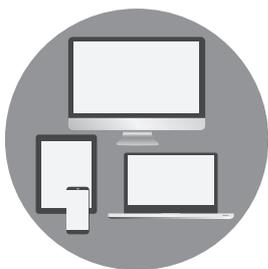
Maghreb Pharma

Algiers, Algeria
03.10. – 05.10.2017

CPhI/P-Mec Europe

Frankfurt, Germany
24.10. – 26.10.2017

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internet presence:
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