HARRO

The Customer Magazine by Harro Höfliger

Edition 15 | 2025

Future since 1975

Harro Höfliger celebrates
50 years of pioneering spirit –
yesterday, today, and tomorrow.

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White Rabbit Studios

EDITORIAL

Dear readers,
Dear business friends,

For 50 years, customers and partners around the globe have placed their trust in excellent technical solutions made by Harro Höfliger. The anniversary celebration reminds us of how much we have achieved: from overhauling used cartoning machines and creating the first in-house designs to developing cutting-edge solutions that now set standards in the pharmaceutical industry. This success story fills us with pride and is a good reason, in this issue of HARRO, to look back at the beginnings of our company and its many important milestones.

The world has changed in leaps and bounds since the 1970s, but some things have remained – including our commitment to viewing our customers' products as the ultimate benchmark and to developing not just good, but the very best automation processes for their manufacture. Innovation has always been at the heart of what we do, driven by the creativity, passion, and experience of the people who develop, build and maintain our machines.

Each decade brought its own challenges and transformations, and we actively helped shape these developments. Today, for example, digitalization, global networking, stricter regulatory requirements, and sustainability aspects call for new and bold approaches. With comprehensive services and efficient, intelligent technologies, we help our customers stay one step ahead.

Our anniversary celebration motto, "Future since 1975", represents this commitment. We are ready for the next 50 years of innovation, development and shared success.

Your

Thomas Weller,
CEO at Harro Höfliger

Quick Note

20 years of the Satteldorf plant

In 2025, not only is Harro Höfliger celebrating its 50th anniversary as a whole, but Satteldorf also marks a special milestone: The first site outside the Rems-Murr district near Stuttgart opened here 20 years ago.

Around 45 employees work there today, supporting projects from design and pre-assembly through to line integration and making an important contribution to numerous Harro projects.

Over the years, the focus has been particularly on large-scale projects in the field of packaging, but solutions such as the MQS quality assurance system also play an important role. The portfolio in the area of labeling is currently being expanded.

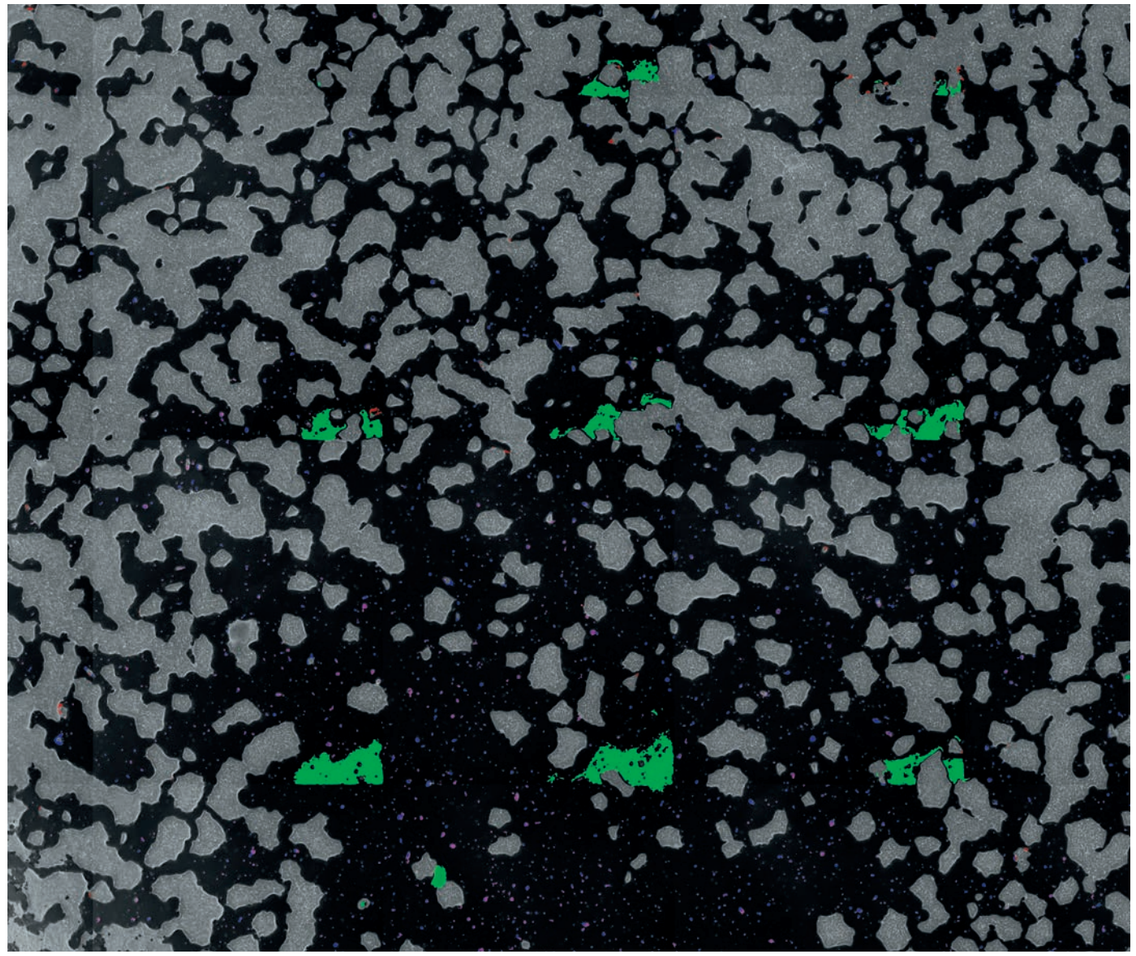
Anniversary week in Allmersbach

To mark its anniversary, Harro Höfliger held a week of events in May under the motto "Future since 1975". The Global Sales Meeting kicked things off by bringing together sales staff from around the world. The subsequent Pharma Symposium offered additional professional depth with high-caliber presentations on current industry developments. At Suppliers' Day, partners gained insights into the specifics of Harro technology and the special requirements of the supply chain. The week was rounded off with Career Day, featuring a wide range of opportunities for interested participants. Accompanying the various events, plant tours with exhibits, including Cartonetta, the first cartoning machine, illustrated the journey from the beginnings to the most advanced technologies.

New Modu-C LS: Advanced Protection

The new capsule filling machine combines reliable operator protection with easy handling and high mobility. Its Advanced Protection System (APS) provides maximum safety through an improved door seal, glove ports, and continuous negative pressure monitoring. As a mobile machine, the Modu-C offers flexible use in both laboratory and cleanroom environments – ideal for development departments working with new or sensitive substances. Interchangeable trolleys also allow the Modu-C to easily swap dosing systems and support seamless scale-up.

The cell microcosm



Atelier Lünig, Fraunhofer

Cells are not only the building blocks of life but also the key to new therapies. Particularly exciting in this context are "induced pluripotent stem cells", or iPS cells for short: They are generated in the lab by reprogramming normal body cells and have the ability to develop into any cell type.

Complex cell functions like these also form the basis for modern cell and gene therapies, in which cells are specifically modified to combat diseases at their root. Together, the Fraunhofer Institute for Production Technology and Harro Höfliger are driving the development of automated production processes to make these promising therapies accessible to a larger number of patients.

Find out more about the partnership starting on page 33.

SMART SELF-INJECTION

YpsoDose stands for patient-friendly injection at the push of a button. Harro Höfliger delivers the right assembly technology – precise, scalable, and future-proof.

All it takes is a small click. Once applied to the patient's skin, the device begins to hum softly, delivers the drug at a controlled pace, automatically retracts the needle at the end, and signals completion with a sound and light indicator: injection is finished. Throughout the entire process, the person can move about freely or even go about light everyday activities.

ONE DEVICE, MANY ADVANTAGES

We are talking about so-called patch injectors – wearable, prefilled devices that are gaining importance in the pharmaceutical industry. For modern therapies, which often require the safe delivery of expensive APIs, they offer several advantages: Besides greater convenience and fewer clinic visits, this also includes the precise delivery of drugs that need to be administered over an extended period.

A sophisticated example of this product category is YpsoDose, developed by the Swiss company Ypsomed. As a platform solution, it enables subcutaneous administration of a wide range of drugs, including highly viscous biologics. Thanks to its electromechanical drive, integrated sensors for skin-contact monitoring, and automatic needle handling, YpsoDose ensures precise drug delivery. Visual and acoustic signals support the self-injection process, making it as reliable as it is simple.

ADAPTED CARTRIDGE

An important contribution to safe and convenient application comes from the drug cartridge specially adapted for YpsoDose, whose sterile closure was developed by Ypsomed and is patent pending. It is equipped with a Tyvek® sterile barrier sealed onto the aluminum cap, as well as a plastic cap that reliably protects the contents from external influences.

Just before application, the patient removes the sterile barrier by peeling off a protective film. The well-thought-out product design makes this otherwise tricky step very easy to carry out, even for people with limitations. The tear-off tab attached to the sterile barrier is clearly visible thanks to a large ring, making preparation for the injection easy. After applying the patch injector to the patient's abdomen, two needles are positioned: one pierces the skin, while the other automatically emerges from the protected area of the device to puncture the cartridge septum. This ensures that the "fluid path" remains protected from pathogens and particles up until administration.

PLATFORM SYSTEM FOR RAPID MARKET LAUNCH

"Our name stands for self-medication," explains Philipp Richard, Manager Account & Business Development at Ypsomed, "because in Latin, 'ipso' means 'self' and 'med' stands for 'medication'. That is precisely where our focus lies: We want to enable people with chronic conditions to self-treat with simple and safe products – and thus lead a more self-determined life."

"Our name stands for self-medication."

Philipp Richard
Manager Account & Business Development
Ypsomed

Founded in 1984, the company from Burgdorf, Switzerland therefore relies on pre-developed platforms such as pens, autoinjectors, and on-body systems. This benefits not only patients, but also Ypsomed's pharmaceutical customers – after all, the platform approach reduces development costs and shortens time to market. "Once a certain level of technical maturity is reached, we adapt the device to our customers' drugs. Often, their products – in combination with the device – are ready

As a wearable injection system, YpsoDose ensures precision, safety, and tangible relief in everyday life.

Ypsomed AG

for market in less than two years," says Richard. The approach has stood the test of time: Numerous pharmaceutical partners around the world are now using Ypsomed's platform products.

Together with the YpsoMate 5.5 autoinjector, YpsoDose is among the newest additions to Ypsomed's portfolio, addressing an important development in the pharmaceutical industry. "There's a clear trend toward large-volume pharmaceutical forms, for example in the field of biologics. YpsoDose is suitable for a variety of applications with doses ranging from two to ten milliliters," emphasizes Philipp Richard. The huge potential is demonstrated by the large number of ongoing studies with large-volume medications.

TOGETHER TO SERIES PRODUCTION

Harro Höfliger was involved in the industrialization of the device from an early stage. It quickly became clear that the final assembly of patch injectors places special demands on precision and process control. Compared to established product classes such as pens or autoinjectors, the design is significantly more complex – and while many long-established injection systems can be assembled on familiar machine platforms, YpsoDose requires customized solutions. The Engineering & Innovation Services department therefore provided intensive support in process development, including proof-of-principle approaches. This made it possible to ensure at an early stage that the tricky assembly steps proceed correctly.

Building on this, the first pilot line for the final assembly of the patch injector is currently under construction. A flexible transport system with shuttles guides the individual device components from station to station. Pick-and-place robots, integrated camera inspections, and a labeler are also part of the setup.

The design focused above all on a safe process, as the valuable drug in the cartridge must under no circumstances be discarded without due consideration. The cycle rate of the machine is currently still of secondary importance – the pilot machine currently produces three to four products per minute. The subsequent scalability of the processes is more crucial. "The line is designed so that key process steps can later be transferred to high-performance machines," explains Ulrich Stahl, Director New Technologies at Harro Höfliger.

FAR-SIGHTED ASSEMBLY TECHNOLOGY

This shared forward-looking view has shaped the partnership from the very beginning. As early as 2017, Ypsomed received the very first Assembly Lab ever produced by Harro Höfliger for another product. It allowed automated assembly processes to be carried out on a small scale, especially for clinical trials and the flexible production of small batches – a decisive innovation, since previously only manual benchtop systems had been available on the market. Today, the system is in use at numerous companies worldwide. Ulrich Stahl summarizes: "When you consider the potential of patch injectors and how intensively we've been working together on innovative solutions around YpsoDose, it becomes very clear: Our partnership continues to be driven by a strong pioneering spirit."

SAFETY IN TWO STEPS

The patient peels off the film and applies the device.

The controlled injection is then triggered at the push of a button.

EXPERT OPINION: RETO MAFFIOLI ON YPSODOSE

"Technically complex, yet easy and safe to use."

Reto Maffioli
Manager of Industry CollaboratioN
Ypsomed

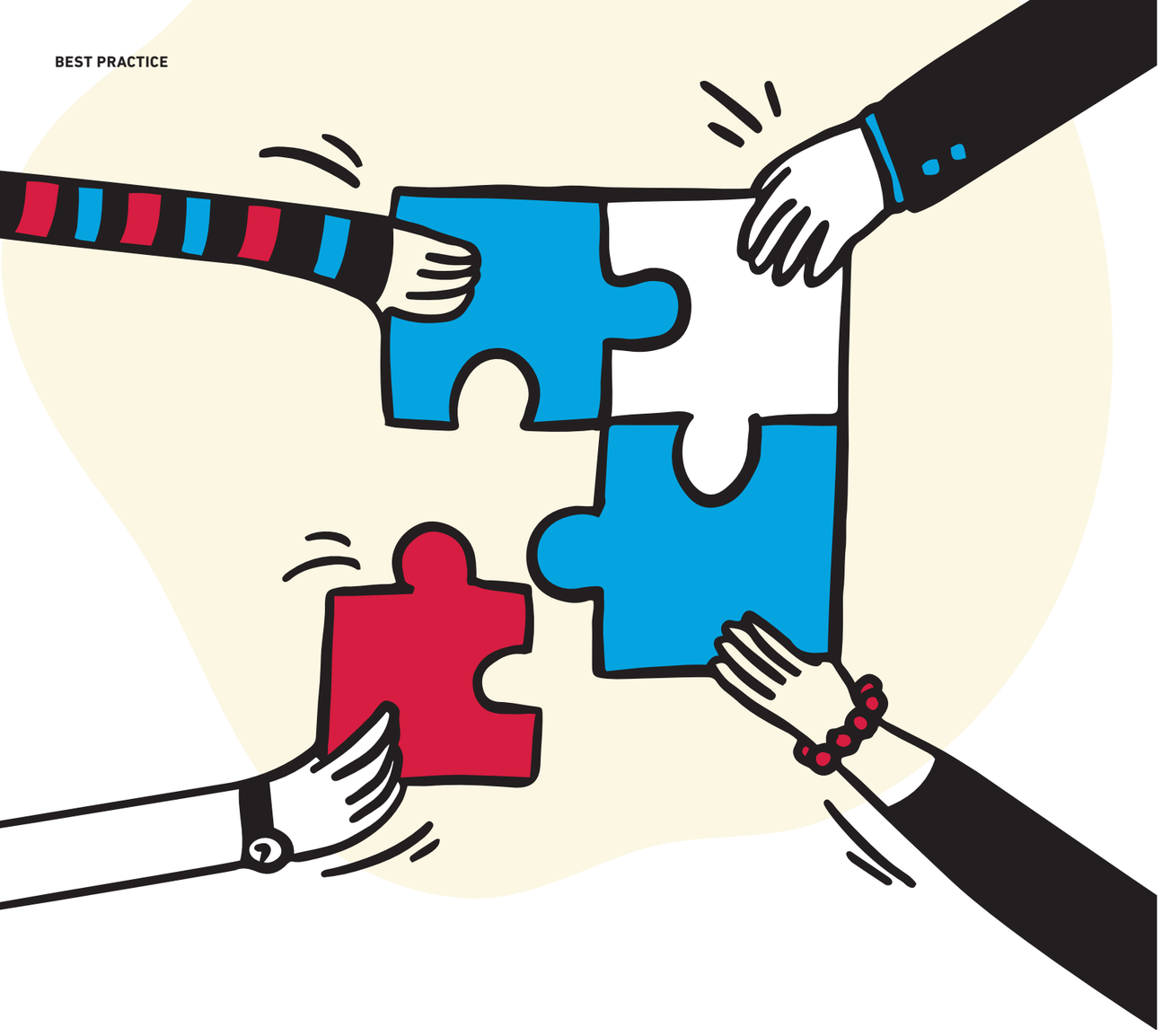
Reto Maffioli is Manager of Industry Collaboration at Ypsomed and leads a team that develops final assembly processes for the company's platform products. At the interface between product and process development, pharmaceutical customers, and cooperation with partners such as Harro Höfliger, he has a central perspective on projects – from the initial concept through to the finished series solution.

Mr. Maffioli, what in your view makes YpsoDose special?
Our aim from the very beginning was to develop a device that is easy for all patients to use – including those with limited motor skills. This very motivation has always driven us, even during challenging project phases: to design a technically complex product in such a way that it can be used simply, safely, and intuitively – thereby helping to improve the quality of life for people with chronic conditions.

Why did you choose to work with Harro Höfliger from the very beginning?
Our partnership goes back several years, during which we've successfully implemented a number of projects together for our shared pharmaceutical customers. So it was only logical to begin working together on YpsoDose as early as the design phase, carrying out a joint design for assembly assessment and proof of concept, among others. Thanks to this approach, we were able to design the final assembly processes from the very start so they are scalable for industrial production and ensure the product functions as intended. The product is designed to meet not only our own standards but, above all, the requirements of pharmaceutical customers and the needs of patients.

"The partnership continues to be driven by a strong pioneering spirit."

Ulrich Stahl
Director New Technologies
Harro Höfliger



BUILDING SUCCESS – STEP BY STEP

From replacing a capsule filling machine to forging a long-term partnership – this is, in a nutshell, the shared success story of Nordmark Pharma GmbH and Harro Höfliger.

Atelier Lünig

Since 2010, Nordmark Pharma GmbH – a medium-sized, owner-managed company founded in Hamburg in 1927 and now based in Uetersen, Schleswig-Holstein – has been using a Modu-C LS for accurate, count-based filling of small quantities of microfilm tablets into capsules. The work of Nordmark's around 700 employees focuses on biological and biotechnologically produced active ingredients and drugs. Nordmark also specializes in the development and manufacture of drugs based on biological active ingredients and is a global leader in the production of pancreatin and collagenase.

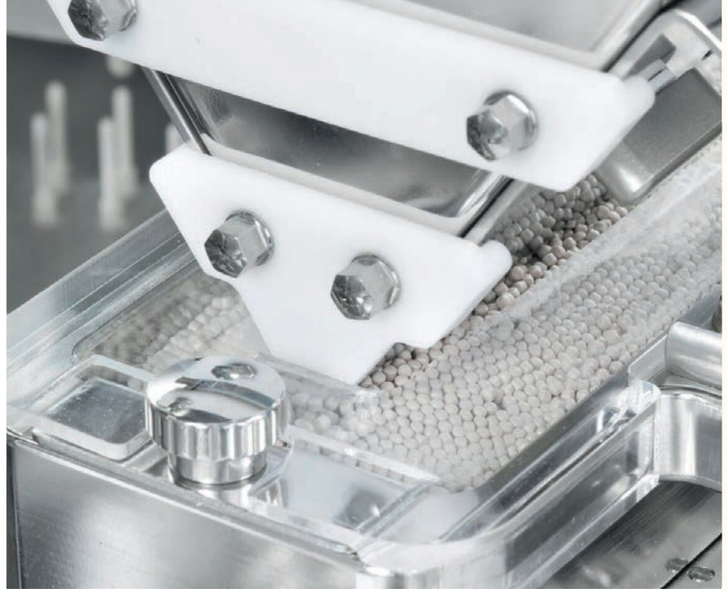
The positive experiences gained from working together formed the basis for a joint project launched in 2018 to replace an existing capsule filling machine at Nordmark with the high-performance Modu-C HS. Even before the purchase, the management of both companies had agreed on a long-term strategic partnership. Besides standardizing system concepts and leveraging synergies for maintenance and spare parts strategies, aspects such as technological expertise and a strong solutions-oriented approach were equally crucial for Nordmark.

IN CONSTANT MOTION

Daniel Müller, Director Sales Capsule Filling & Weighing at Harro Höfliger, reports: "The aim of the project was to provide an efficient and flexible solution for dosing microfilm tablets and pellets. Numerous preliminary tests in our cleanroom showed that volumetric filling with a pellet station also delivered optimal results for filling microfilm tablets." However, flow issues caused by the tablets, which were two and a half times larger than the pellets, initially posed challenges for Harro Höfliger's team of experts.

To counter this problem, vibrations were applied at various levels, keeping the product in constant motion during the filling process. "Faster changeover of the stations, simplified cleaning, and the ability to fill both pellets and micro-tablets on the same dosing unit are advantages of the Modu-C HS that ultimately convinced the Nordmark project team and tipped the scales in favor of our machine," says Daniel Müller.

The Modu-C with downstream Accura-C capsule checkweigher is used to manufacture the product portfolio in capsule sizes from 00el to 2.



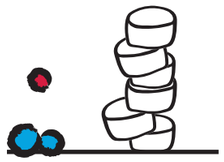
The flexible pellet dosing station also enables microfilm tablets to be filled into capsules with count accuracy.

The new Modu-C HS capsule filling machine with downstream Accura-C capsule checkweigher was delivered in 2020. Following successful commissioning and qualification in the first quarter of 2021, Nordmark began routine production. Since then, it has been used to manufacture the product portfolio in capsule sizes from 00el (elongated 00) to 2.

ACCURATE, COUNT-BASED DOSING

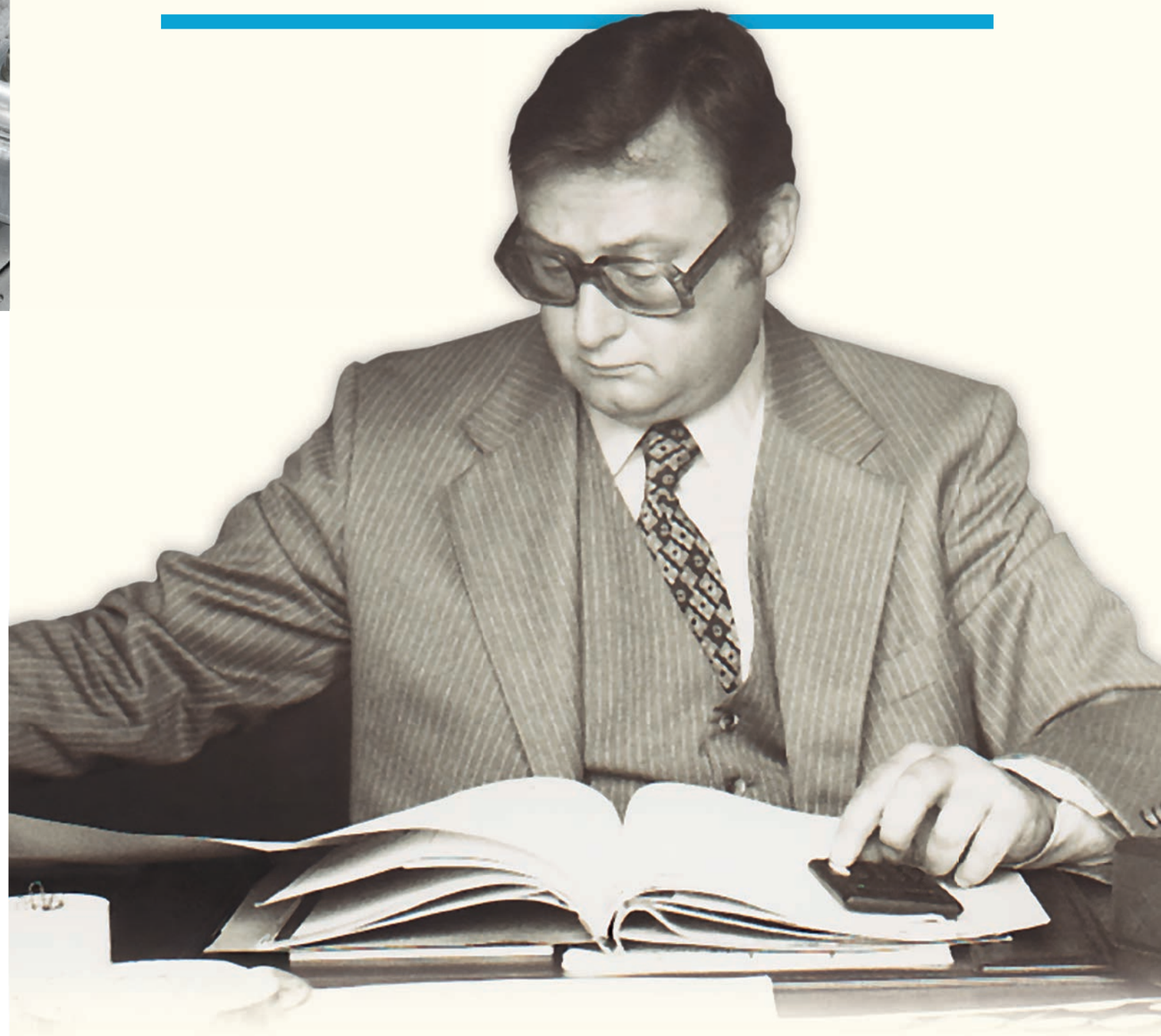
The implementation of the first machine equipped with the Accura-C checkweigher paved the way for expanding the close partnership. As part of the renewal and reorganization of its encapsulation equipment, Nordmark decided to replace the existing capsule filling machines with a further Modu-C HS, complete with a downstream Accura-C.

This machine is equipped with a trolley for accurate, count-based dosing of microfilm tablets. It also replaced the Modu-C LS that had been in use since 2010 – and continues the shared success story.



To prevent bridging in filling media, the product is kept in constant motion during the filling process by vibrations at various levels.

HARRO HÖFLIGER



Atelier Lünig

It all began in 1975 with Harro Höfliger, the company's founder and namesake. With his bold and astute decision to become self-employed in overhauled used cartoning machines. Over the decades, many other pioneering and equally courageous decisions followed. Recognizing market opportunities is one aspect. But to seize these opportunities, open up new business fields with innovation potential, and leave old ones behind, more is required: an attitude that embraces the spirit of the times, not stagnation. Building on what has been achieved, thinking ahead, and thus making new developments and growth possible. Harro Höfliger embodied this attitude, which shaped the entrepreneurial journey back then, shapes it today, and will do so in the future. He once described the development as follows: "It's like standing by a lake with a stone in your hand. The moment the stone leaves your hand and drops into the water, it creates ripples." These ripples do not end – they grow larger. 50 years: Future since 1975.

HOW IT ALL BEGAN

1970s

In 1975, Kodak makes technology history with the first digital camera. Muhammad Ali wins the now legendary "Thrilla in Manila" against Joe Frazier, and Queen rocks the charts with "Bohemian Rhapsody". Not in the headlines, but with a lasting impact: Bill Gates and Paul Allen found Microsoft, and Harro Höfliger starts his own company. The first headquarters – in Albuquerque as in Stuttgart-Untertürkheim: a garage.

FUTURE SINCE 1975?

Strictly speaking, the success story had already begun in 1951. With Harro Höfliger's decision to start an apprenticeship as a machine fitter at Höfliger + Karg. In his uncle's company, he gains experience in constructing and commissioning packaging machines. In 1968, he becomes technical operations manager at Allpack, a subsidiary of Höfliger + Karg, where he is responsible for production for several years. And in 1975 he is more than well prepared for the next step – self-employment.

MARIANNE HÖFLIGER

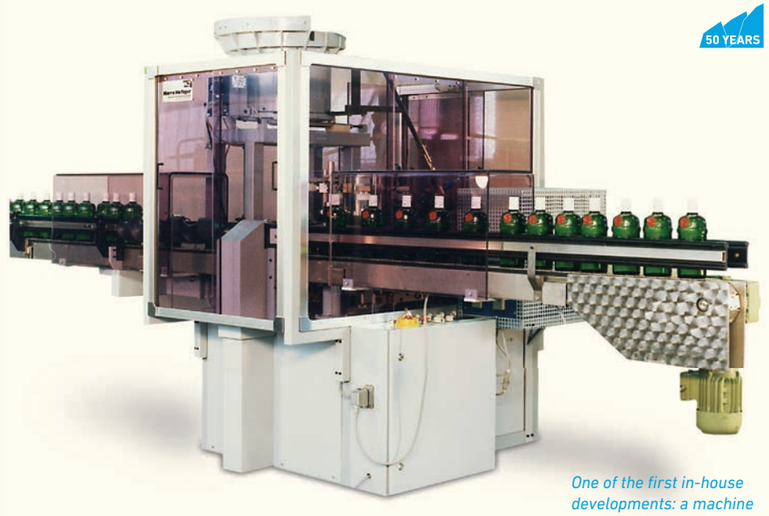
A BIG VISION IN A SMALL SPACE

In his home garage, Harro Höfliger initially refurbishes Höfliger + Karg cartoners and capsule filling machines and trades them. Not always to the neighbors' delight, as machine test runs regularly lead to power outages on all floors. In 1976, he relocates his company to Backnang. A wise business decision: In the region, unlike in the automotive stronghold of Stuttgart, there are still plenty of well-qualified workers available. And a decision from the heart: Harro Höfliger met his future wife Marianne, whose family in Backnang is rooted in skilled trades. She takes on the commercial side of the business, serving as both CFO and controller.

Another dedicated companion from the very beginning: designer and gifted inventor Manfred Reiser. With him, Harro Höfliger develops the first proprietary machines. Their creativity knows no bounds and includes a casting system for lipsticks, a testing machine for brake hoses, a sorting system for edible snails, and a sealing stamp machine. Brandy, bitter liqueurs, gin – the red seal promises quality. A British customer is thrilled with the line during acceptance, but somewhat disparagingly refers to the building – a former leather factory – as a "rat hole". But the site is soon to become history. By 1979, Harro Höfliger has become a limited company (or GmbH) with 19 employees. Assembly moves to Allmersbach im Tal. Sales, accounting, and purchasing are housed in the founder's private residence.

MANFRED REISER

MAKING POSSIBLE WHAT NO ONE ELSE HAS DONE BEFORE



One of the first in-house developments: a machine for applying decorative seals to fine spirits.

Food for little feathered friends that stands out at the POS with its triangular packaging.

The former leather factory in Backnang. An old building, where fresh, new ideas are born.

This is what positive growth looks like: the workforce in front of the new site in Allmersbach im Tal.

EVENTFUL YEARS

1980s

The eighties sound new and look it too: The CD brings crystal-clear sound into the living room. The Walkman allows people to enjoy music on the move, and Apple makes the computer small and user-friendly. And what do you fancy for your video night with MTV? A quick meal from a bag – perfectly packaged on a Harro Höfliger system solution for convenience products.

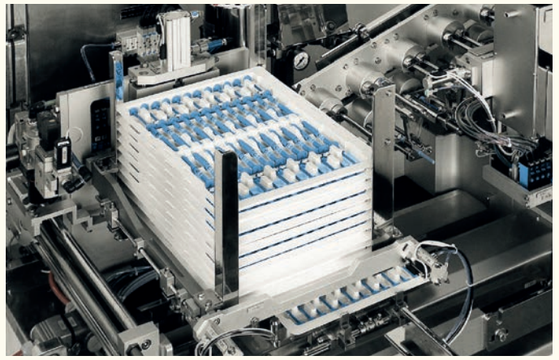
SUCCESS IN A POUCH

Instant soups or mashed potato, hot and cold beverages: The food market is in motion! Self-service markets are springing up like mushrooms, and convenience products fill the shelves. At Harro Höfliger, the potential is recognized and a system is developed for fully automated packaging in four-side sealed pouches. The innovation is the perfect "ingredient" for the first major market success.

At the same time, the company establishes itself as a systems provider. All individual steps are integrated into a machine solution: Dosing and feeding of bulk products, sealing into lightproof and food-safe pouches, packaging portion pouches into folding cartons or into outer cartons for retail: For the first time, customers receive everything from a single source.

ASEPTIC VENTURE

Meanwhile, Harro Höfliger and Manfred Reiser are already turning their attention to the pharmaceutical market and developing the first lines. Among them the KFM C, a capsule filling machine produced from 1980 to 2003. In 1988, the first line for assembling prefilled syringes with an oncology drug follows. The syringes are to be filled with a depot, assembled, and sterile-packaged – a task that the HH 20 accomplishes far better and faster in an automated process than manually. However, the customer also requires validation and qualification documentation. This is completely uncharted territory for Harro Höfliger. Looking at the documents, the company boss comments drily: "We are machine builders, not producers of paper mountains."



The HH20 filling and assembly machine for producing up to 20 syringes per minute.

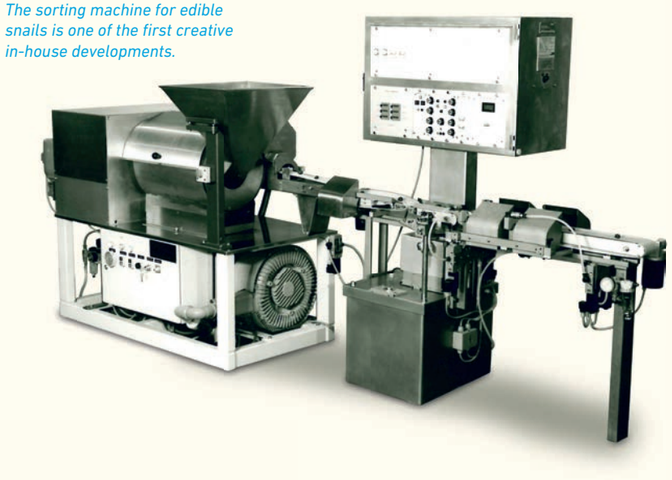
COMPETENCE IN LINE

This project is pioneering in many ways: It forms the basis for today's comprehensive expertise in sterile production and current line competence. Harro Höfliger develops additional components and expands the HH 20 into a fully automated complete solution: with a filling and sealing system for pouching, a cartoner with feeding and sealing station, as well as a labeling system.

An impressive sight: the first appearance at Interpack trade show in Düsseldorf.

HOT THING – PACKET SOUP! THE MARKET SMELLS OF CHANGE

The sorting machine for edible snails is one of the first creative in-house developments.



A new building for sales and administration allows the Höfliger family's private residence to become private again.

HIGHLIGHTS OF THE 1980s

- 1981: The first apprentice begins training as a machine fitter.
- 1983: Sales and administration move into the new building in Allmersbach im Tal.
- 1987: The first patent is filed. Manfred Reiser becomes Head of Design, Managing Director, and Partner.

NEW FOCUS ON PHARMA

1990s

The 1990s are connected, colorful, and boundless: The World Wide Web makes knowledge accessible. Cell phones become affordable and poularize texting (SMS) . The Spice Girls and Take That cause a screaming frenzy, while Harry Potter transports children into magical worlds of reading. The International Space Station (ISS) takes off in 1998. Harro Höfliger also sets its sights on a new target: the international pharma market.

Harro Höfliger is also designing efficient processes for packaging contact lenses in sterile single blisters, as well as for surgical sutures. The same applies to one of the most versatile pharmaceutical forms – the capsule. Here, the new KWS electronic capsule weighing system can be seamlessly linked with a capsule filling machine to form a productive unit.

The KWS electronic capsule weighing system with separate load cell weighs even the smallest quantities with high precision.

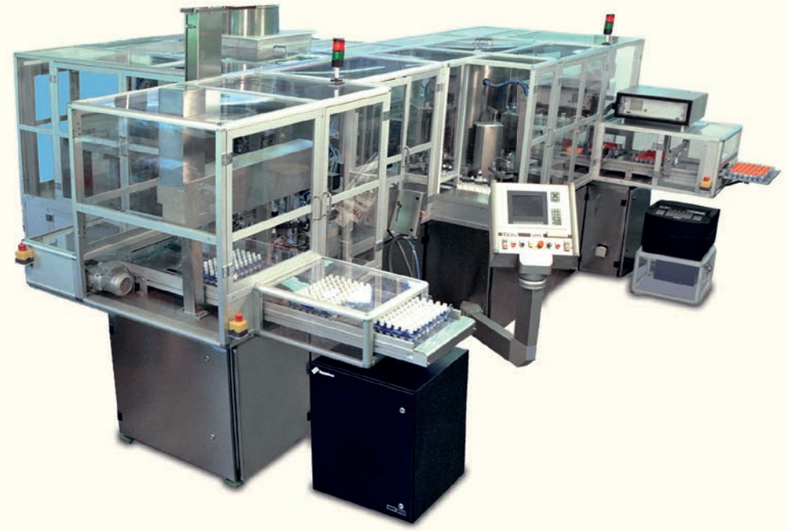
IN DEMAND: PROCESS COMPETENCE

In 1990, the company has around 100 employees and generates sales of 25 million DM. But the food market is getting tighter, the Deutschmark is strong – and standard machines are offered by other providers just as good and cheaper. And besides, as Harro Höfliger puts it, "a roast chicken in foil is a roast chicken in foil. There isn't much innovation there."

Pharma is completely different. Here, precision, safety, and uncompromising quality are paramount. This market needs exactly what Harro Höfliger does better than anyone else: High-tech mechanical engineering and innovative, specialized process solutions.

For example in the field of web processing and manufacturing of multilayer products. The first patch machine is developed for transdermal therapeutic systems (TTS) in 1991. Not just any line, but a five-lane high-performance system – a top seller in the expanding pharma portfolio.

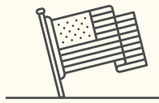
SPECIAL STRENGTH: INNOVATION



FROM ROAST CHICKEN TO BLOCK-BUSTER

Dosage forms and inhalation devices for the treatment of respiratory diseases today are as individual as the preparations. Whether soft mist inhaler (SMI), pressurized metered-dose inhaler (pMDI), or nasal applicators: Harro Höfliger develops the optimal process.

BIG IN AMERICA?



In 1994, everything is in place for doing good business in North America: The first foreign subsidiary is established in Doylestown, Pennsylvania. It is headed by Allen Shane, while today's CEO Thomas Weller coordinates the US market. "Everyone will give big cheer": This upbeat line from Leonard Bernstein's "West Side Story" doesn't come true immediately. When Harro Höfliger and Thomas Weller present to one of the major pharma players, they are met not with enthusiasm, but with a shrug: "Harro who?" Yet just two years later, other suppliers turn down a project for an insulin inhaler pump. Harro Höfliger, however, accepts the challenge, developing and building a line for dosing and assembling these sophisticated devices.

LOCALS FOR LOCALS

Quick on site, fully familiar with the machine solutions, and at home in the customer's language: What began in the US with a small service team continues to shape Harro Höfliger's customer service to this day. Currently, nearly 100 technical experts at nine locations worldwide provide support, ensuring productivity and process reliability.

THINKING BIGGER

The new millennium gets off to a record-breaking start: With Wikipedia, an unprecedented collection of knowledge emerges. Usain Bolt sprints into the history books in 9.58 seconds, and Airbus launches the A380, the largest passenger aircraft. Harro Höfliger also develops dynamically and establishes itself as a partner for expertise across the board.

2000s

The Modu-C LS capsule filling machine for the lab, for testing, and small batches – a modular design for individual configuration.

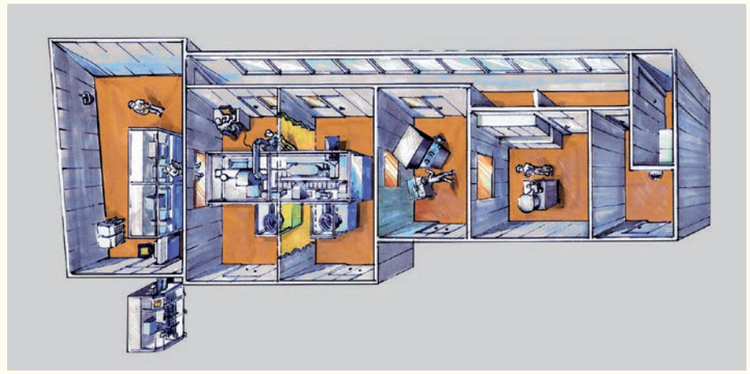
Signs of steady growth: The new Sales and Customer Center, completed in 2001, offers four floors for office and meeting space.

The focus on customer wishes and needs is summed up by the slogan introduced in 2001: ALL YOU NEED. It is the promise to offer more than high-tech mechanical engineering, production and packaging systems from the lab to high-performance, and more than comprehensive services. Harro Höfliger contributes its experience and expertise throughout the entire product lifecycle. A partner for innovations – from the initial idea to production designs, who implements highly specialized process solutions for pharmaceuticals, medical devices, consumer and home care products.

SHARED RESPONSIBILITY

When it comes to managing the company, Harro Höfliger also thinks further and bigger, distributing responsibility across more shoulders. For him, however, one thing is clear: "We are and remain a future-proof family business." After the death of Marianne Höfliger at the end of 2006, responsibility for this future therefore passes to Markus Höfliger as CFO, along with two long-standing managers: Peter Claußnitzer becomes CTO, and Thomas Weller CEO. Uwe Amann takes over HR, and Heinrich Havenstein Production. In 2009, Manfred Reiser, a brilliant development partner for decades, steps down from the Management Board.

In 2005, the Technical Center with GMP-compliant cleanrooms and a powder lab goes into operation, providing optimal infrastructure for Pharma Services and for trials with original products.



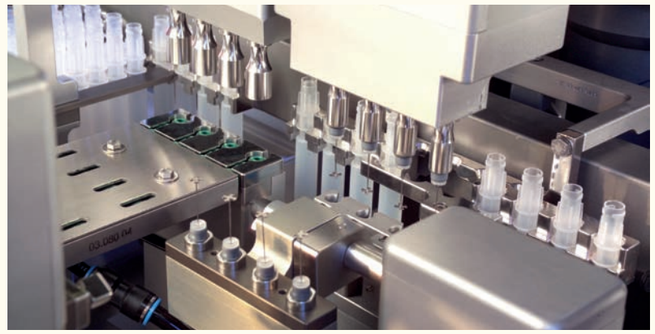
PHARMA SERVICES

In the 2000s, excavators are almost part of the vehicle fleet, with Allmersbach im Tal in a constant state of expansion and construction. A large parking lot makes way for the new Sales and Customer Center. In addition, a new design building is constructed along with a multifunctional building with offices, assembly areas, and the cleanrooms for Pharma Services.

Since 2003, Pharma Services has paved the way to high process and product safety for new formulations and innovative devices. The best formulation, the right dosing method? These questions are addressed early on by the interdisciplinary team from Research, Development and Mechanical Engineering, enabling efficient, risk-minimized process development.

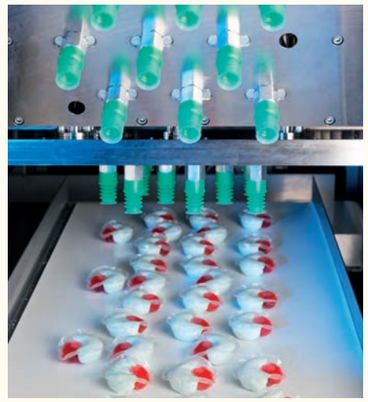
EVERYTHING FROM A SINGLE SOURCE

Web processing, assembly or packaging? Customers are increasingly calling for "and". The first large pharmaceutical lines are developed, integrating all the necessary technologies into a complete solution – for the production of dual-chamber syringes, for example. From feeding the filled syringe bodies to assembly, labeling, packaging and inspection, all steps are highly automated.



Atelier Lünig, Tom Philippi

A FAMILY BUSINESS OF INTERNATIONAL STANDING



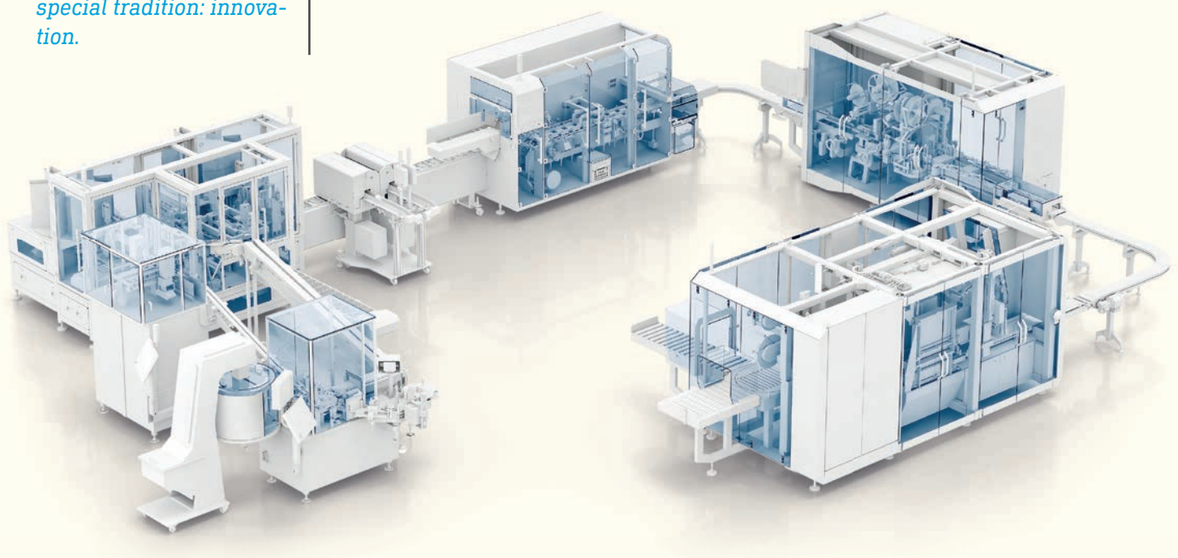
Forming, filling, and sealing of the water-soluble films used for detergent or dishwashing tabs.

TRADITION: TRANSFORMATION

2010s

Following on from the Millennials, Gen Z arrives in the 2010s – digital natives at home in both the virtual and the real world. They wish to work with purpose, ideally in a medium-sized company like Harro Höfliger. The company embraces the founder's culture of respect, creates added value for society, and combines growth with a special tradition: innovation.

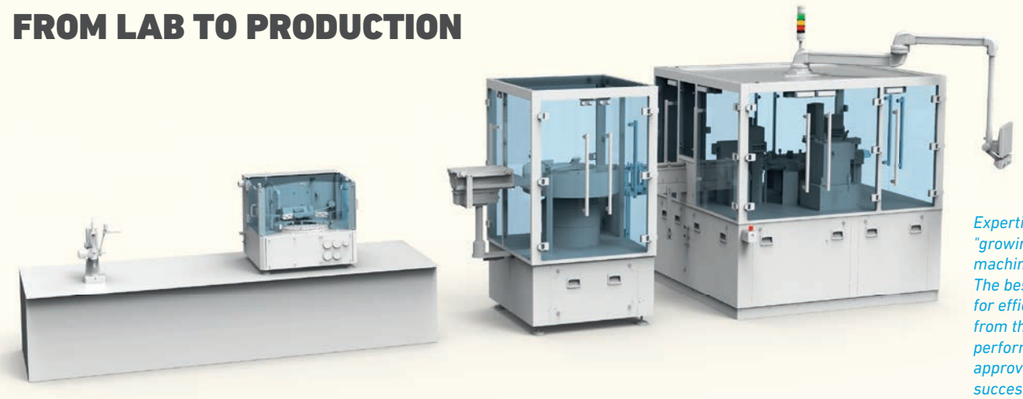
THE FLEXIBLE WHOLE



Harro Höfliger consistently carries forward what began in the 2000s. Additional modular machine platforms such as the MOT are developed. With this assembly machine, complex devices – such as dry powder inhalers (DPI) – can be loaded with capsules, blister strips, cartridges, or reservoirs and joined with precision. In addition, the MOT can be expanded into a complete system with feeding and handling systems, as well as modules for filling, labeling, inspection, and packaging, and can be equipped with barrier technology for cleanroom requirements.

At the same time, the market demands maximum efficiency delivered by turnkey lines with end-of-line packaging. An example of this is a line for Christmas-scented "gingerbread patches" for stomach discomfort relief. The herbal remedy is traditionally Chinese, while production – in the millions with web processing and packaging of four-side sealed pouches into folding cartons – is highly automated and innovatively "Harro".

FROM LAB TO PRODUCTION



Expertise and a "growing-with-you" machine portfolio: The best conditions for efficient scale-up from the lab to high-performance, from approval to market success.

Excellence United

The Community of Experts

Combining competencies and providing best-in-class coverage of the value chain in the pharmaceutical, medical technology, and process industries: That is the goal of Excellence United, the strategic alliance founded in 2011. Today, Fette Compacting, Glatt, Harro Höfliger, and Uhlmann offer not only perfectly coordinated production solutions but also a global service portal for excellent remote support.

THE MAGICAL MILESTONE

The number of employees has doubled within just a few years. By 2016, Harro Höfliger has 1,000 employees – and space is getting tight. New capacity for manufacturing and logistics is created in Aspach, while assembly starts up at Plant 5 in Backnang. Internationally, additional sales and service locations are added: the UK subsidiary near London and the Indian subsidiary in Bangalore.

"WE ARE AND REMAIN: A FUTURE-PROOF FAMILY BUSINESS, APPEALING TO EMPLOYEES AND PARTNERS."

Harro Höfliger

Raff Digital, Atelier Lünig, Janine Kyofsky, Geffken GmbH

THE HARRO SPIRIT LIVES ON

Harro Höfliger passes away on May 12, 2019, at the age of 82. Markus Höfliger, his son, takes over as Chairman of the Supervisory Board, established in 2018. He is remembered as a visionary who had the gift of inspiring people with his ideas in a lasting way. Someone who created a motivating corporate culture in which everyone makes a difference together, lives the "Harro spirit", and carries it into the future.

In the fifth decade after its founding, Harro Höfliger is still consistently pursuing one goal: Making possible what no one else has been able to do before. This means more than process solutions for established products, innovative pharmaceutical forms, and formulations. The focus is also on personalized medicines, groundbreaking treatment approaches such as cell and gene therapies, and even more comprehensive support for customers throughout the entire product lifecycle.

READY FOR WHAT'S TO COME

SINCE 2020

An area of innovation with great potential: pharmaceutical 3D printing for personalized medication.

NETWORKED COMPETENCIES

Harro Höfliger complements its core competencies with strategic investments for technologically leading solutions along the entire value chain. The US company Experic is the partner for formulation samples and clinical studies. DiHeSys (Digital Health Systems) is working on pharma-compliant 3D printing of individualized active ingredient combinations in a tablet.

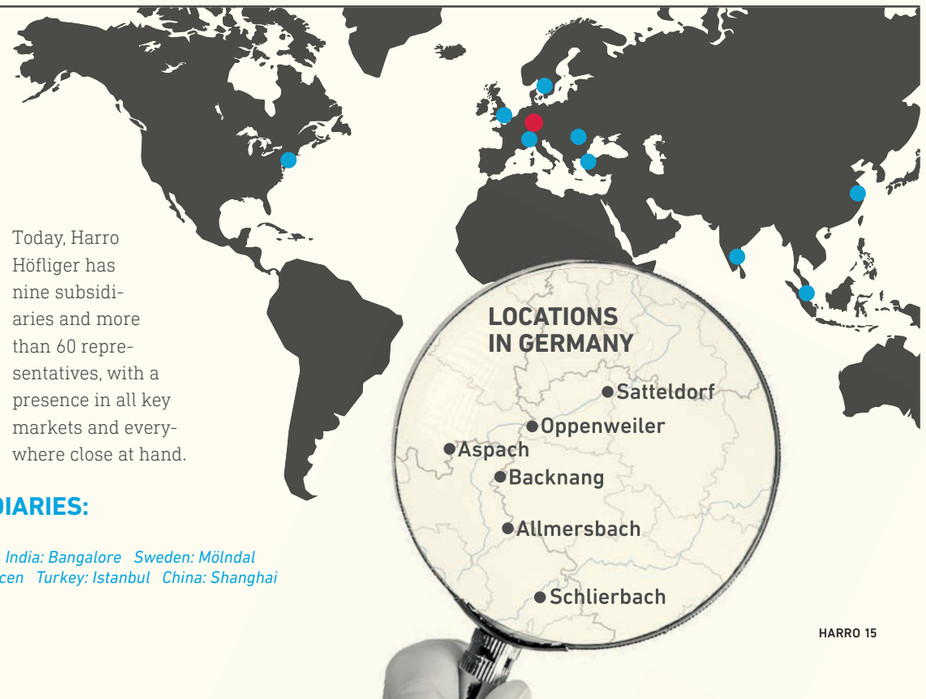
MARKET-READY WITH A SYSTEM

The service portfolio is consistently expanded to support customers even more comprehensively: Established in 2018, Device Services contributes its technical solution expertise at an early stage in product development, to optimize applications, and ensure scalability for commercial production. Harro Höfliger's experts also provide support with the approval process for the EU market.

ON A GROWTH TRAJECTORY WORLDWIDE

How do you measure success? From the growing number of dots on the world map, for example. Two new sites for manufacturing and assembly were added in Germany in 2022 – Oppenweiler and Schlierbach — followed by a production facility in Hungary in 2024.

Today, Harro Höfliger has nine subsidiaries and more than 60 representatives, with a presence in all key markets and everywhere close at hand.



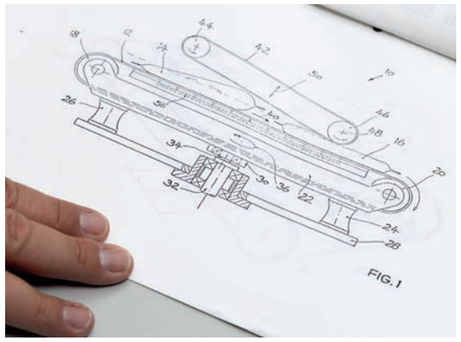
INTERNATIONAL SUBSIDIARIES:

UK: Old Woking USA: Doylestown, PA India: Bangalore Sweden: Mölndal Switzerland: Reinach Hungary: Debrecen Turkey: Istanbul China: Shanghai Singapore

Experic, Janine Kyofsky, Atelier Lünig

WHO INVENTED IT?

The first patent for Harro Höfliger was filed in 1987. The "levelling device" for sealing machines ensured the flawless appearance of pouches filled with instant soup.



The levelling device invented by Manfred Reiser.

The Harro Höfliger trademark is also registered in the United States of America.

Uneven filling of flat pouches was a problem in the 1980s. In automated packaging of soups or sauces, powdery, granular, and larger components often ended up randomly distributed. This led to pouches of varying thickness – making subsequent stacking in cartons difficult. Existing mechanical solutions for flattening the filled four-side sealed pouches were unsatisfactory, as the contents all too often crumbled in the process.

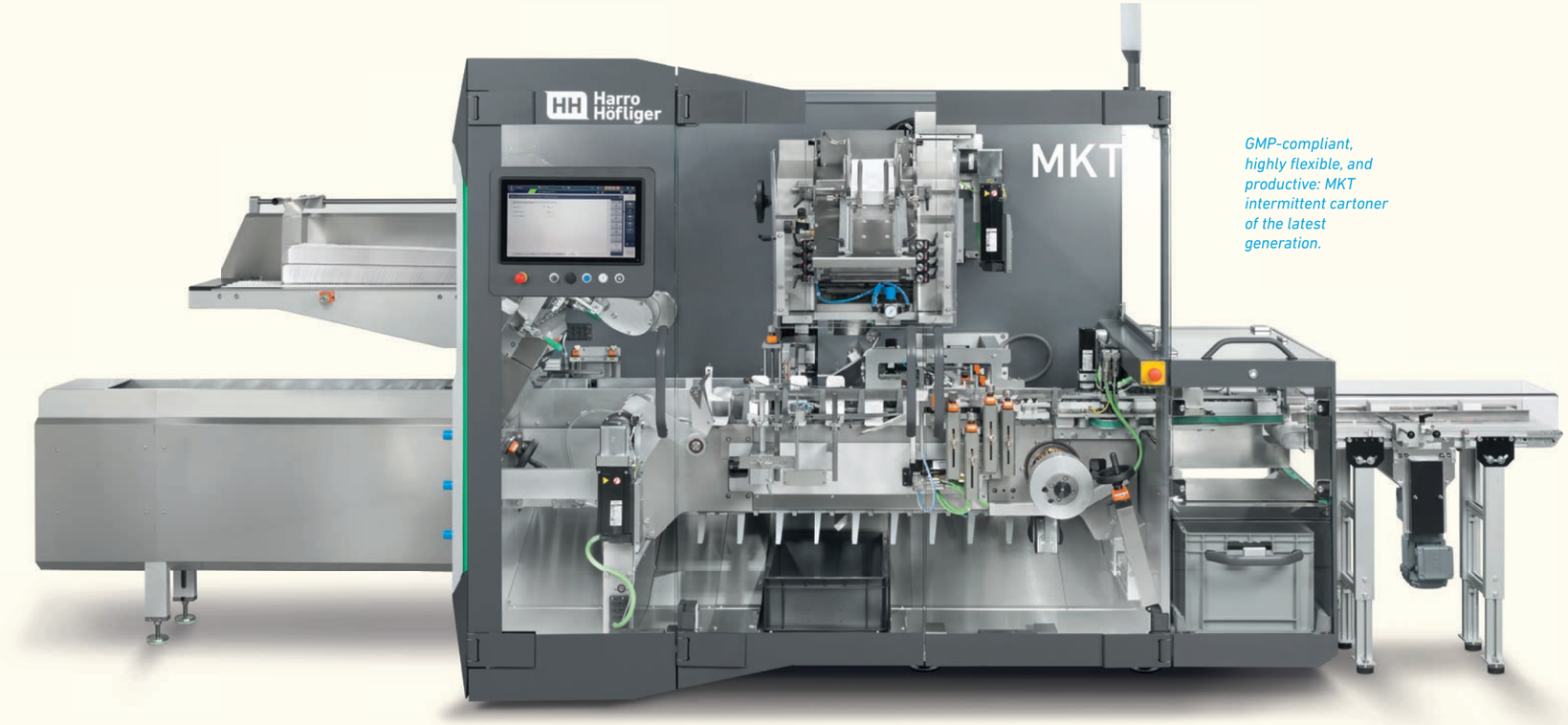
Chief Designer Manfred Reiser took a close look at this process step and in 1987 developed a "device for levelling pouches sealed on all sides and filled with food particles of different types and sizes". Operating with a controlled oscillation mechanism, it was granted as Harro Höfliger's first patent on January 7, 1990, under the number EP 242594 B1.

Many more innovations and patented technical inventions were to follow. To date, Harro Höfliger has filed 255 patents (national and international) and German utility models (or "small patents"). Browsing the archive reveals an impressive treasure trove of information and knowledge. The number of intellectual property rights granted for the various countries is significantly higher, of course. In addition, 16 trademark applications (national and international) have been registered.

The creative ideas from Harro Höfliger contribute to Baden-Württemberg's reputation as a region of inventors and innovators, helping keep this federal state unchallenged at the top of Germany's patent statistics for years.

THE POWER OF DNA

Whether in biology or in business – growth from within begins with DNA. Studies show that market leaders maintain this focus and continue developing it. Harro Höfliger's DNA is cartoning and packaging machines. Every modular, high-performance solution today incorporates more than 50 years of experience.

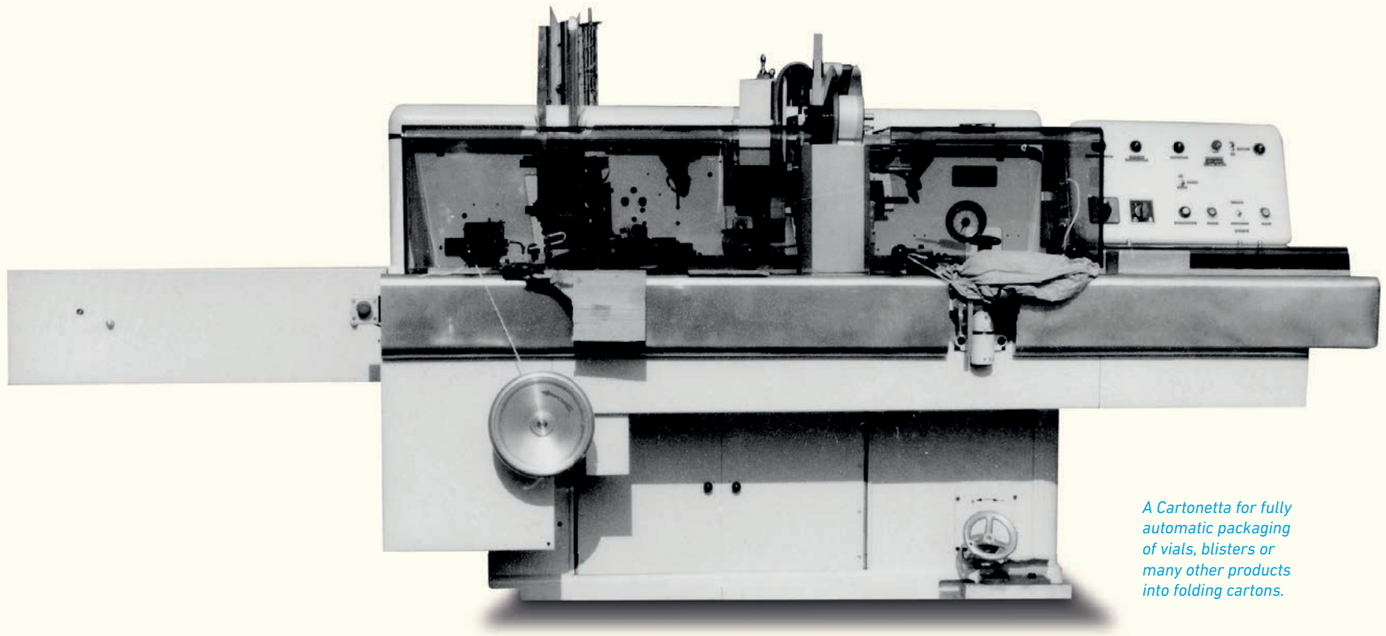


GMP-compliant, highly flexible, and productive: MKT intermittent cartoner of the latest generation.

Cartonetta / MKT

The Cartonetta from Höfliger + Karg is a bestseller with around 5,000 units built in the 1950s and 1960s alone. Compact, flexible, easy to operate: These features made the horizontal cartoning machine a market success for decades, and thanks to its robust design, it became a flagship product for Harro Höfliger. First in Untertürkheim, later in Backnang and Allmersbach, lines manufactured at all times were professionally overhauled. Resale platforms reveal just how long a Cartonetta can stay productive in packaging: "Horizontal cartoning machine, 1974. Cartoning machine for blister packs or vial trays, 1985. Compact cartoning legend, 2001, like new".

The horizontal, intermittent MKT exemplifies the evolution of packaging technology at Harro Höfliger: The first generation was launched in 1995, the latest in 2023. During this time, the packaging portfolio has grown. Today it includes machines and technologies for packaging a wide range of products in folding cartons, wallets, and outer cartons, as well as other packaging formats. The basis for a precise and sustainably efficient process is the modular machine concept. It enables rapid format adaptations, customized closure variants and the integration of product-specific feeders, plus the possibility to adapt the current best process to new requirements and products at any time.



A Cartonetta for fully automatic packaging of vials, blisters or many other products into folding cartons.

Atelier Lünig

FROM RECIPE TO PROCESS

Harro Höfliger's Pharma Services have stood for safe process development since 2003 – from the idea to production. Co-founded by Dr. Karlheinz Seyfang, they form the basis for market-ready innovations and consistent product quality.

Four cleanrooms and a powder lab have been providing optimal conditions for trials with API-containing products since 2005.

Dr. Karlheinz Seyfang knew early on that he wasn't going to become a traditional pharmacist. It wasn't advising customers from behind the counter that appealed to him, but the processes behind the scenes: How are tablets pressed? How does powder arrive precisely into a capsule? What sounded dry to others was pure fascination for him. Pharmaceutical analytics, dosing systems, technology, and mechanical engineering became his career focus – for almost two decades at Harro Höfliger as well.

The connection with the company began in the 1990s with an idea: Together with a contract manufacturer, Dr. Seyfang developed a rotary capsule check weigher. The technology was as convincing as its developer. The licensed pharmacist joined Harro Höfliger in 2003, taking on the task of building up the new Pharma Services division. "I found the perfect combination of pharmacy and engineering mastery here – and I was immediately captivated."

Dr. Seyfang saw himself as a mediator between Sales and pharmaceutical or medical technology companies. For him, the interdisciplinary interaction of pharmacy and technology, as well as research, development, and mechanical engineering "changed everything – for us and our customers. If you know how the product really behaves, dosing becomes reliable, the manufacturing process is right from the start, and it can be scaled up for mass production."

Janine Kvofsky

Space for additional analytical systems: The second lab has been in operation since March 2022.

"A HIGHLIGHT? ONE IN PARTICULAR – DOSING 0.12 µL OF GOLD POWDER WITH DNA COATING FOR A VACCINE INJECTOR, WHICH WE ACCOMPLISHED USING THE VACUUM DRUM FILLER."

Dr. Karlheinz Seyfang
Head of Pharma Services
2003 to 2022

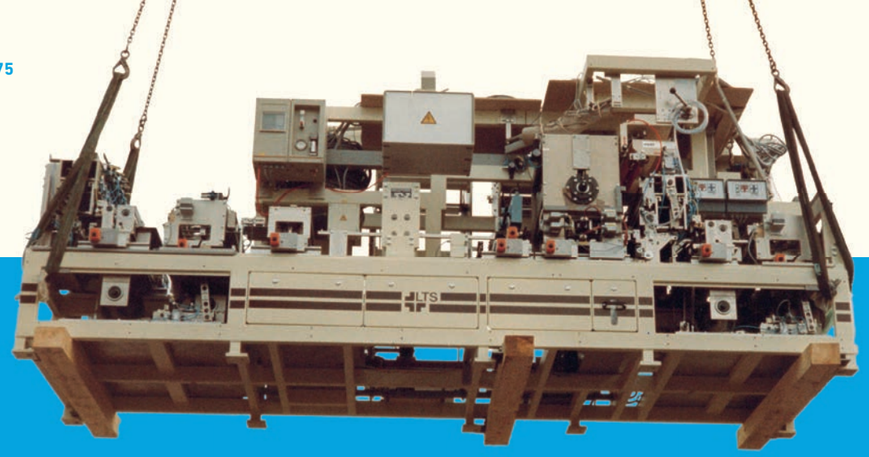
The new Technical Center began operations in 2005 with four GMP-compliant cleanrooms and an adjoining powder lab. Trials with original APIs could now take place in a practice-oriented setting – a novelty in the industry at the time. This test environment was a crucial step toward efficient product development and assured quality. Machine qualifications and factory acceptance tests have also been carried out here under controlled conditions ever since.

The recipe for success then as now? A common language. Most co-workers have a background in the pharmaceutical industry and know what really matters – whether it is regulatory requirements, process validation or formulation development.

Dr. Seyfang has been retired since 2023. Dr. Elke Sternberger-Rützel has taken up the baton of pharmaceutical expertise and technical knowledge as Division Leader Pharma Services. Building on modern analytical methods, a comprehensive product database and continuously growing experience, she and her team develop efficient processes for new formulations and innovative devices.

WHAT PHARMA SERVICES OFFER

- Analysis and processing of original active ingredients
- Testing and optimizing dosage methods at an early stage
- Development of scalable processes based on data
- Precise coordination of formulations and technologies
- Achieving market readiness in a targeted and regulatory-compliant manner



TECHNICAL PREMIERE

Peter Claußnitzer, CTO of Harro Höfliger, reflects on a milestone in his professional life and in the company's machine portfolio.

As a young mechanical engineer, I started my career at Harro Höfliger 35 years ago. Even back then, I was given challenging tasks. Designing solutions from scratch on a blank sheet of paper and seeing them through to production and customer implementation until they worked reliably – that's what inspired me after years of rather academic studies! My first project was the first ever Harro machine for manufacturing transdermal therapeutic systems (TTS or transdermal patches).

The five-lane high-performance line delivered in 1992 produced nicotine patches for smoking cessation at a rate of 90 cycles or 450 products per minute, and packaged them in four-side sealed pouches. For me, that first design remains an unforgettable experience, even though over the course of my career I've worked on many other exciting, innovative projects and accompanied them as a designer, project manager, and CTO. The customer sent me back the machine type plates after the line was decommissioned – after almost 30 years of stable operation, during which we had supported it with regular service, a format adjustment, and minor retrofits.

For me personally, the decades at the company passed very quickly. The work here has shaped and changed my life. I had the opportunity to play an active role in the company's development and to experience our growth from 100 to 2,300 employees. For that, I am eternally grateful to Harro – to the person and to our company.

"This first construction remains unforgettable to me."

Peter Claußnitzer
CTO
Harro Höfliger

Alongside developing precise processes for handling sensitive web materials, we were also faced with the challenge of accurately dosing the API – in this case liquid nicotine – and applying it evenly onto the substrate material. The technical solutions from back then have since been continuously developed and refined for a broad portfolio of oral and transdermal applications, as well as sophisticated products for wound care. We have now built over 450 similar machines.

"THE PROCESS IS CRUCIAL"

An anniversary is not only an occasion to look back on history, but also to focus on the future. An interview with Thomas Weller, CEO at Harro Höfliger.

Mr. Weller, which trends do you think will influence Harro Höfliger in the coming years?
Our markets pharma and medical technology are, by their very nature, highly innovative. They are increasingly shaped by digitalization, AI, and the pursuit of flexibility. One example is on-body devices with smart sensor technology, which serve as valuable healthcare tools and make everyday life easier for many patients. In addition, demand for personalized therapies is on the rise – for our customers this typically involves small-batch production and more frequent format changes. Not least, energy-efficient, eco-friendly production processes are gaining in importance, since our customers – like us – are progressing toward climate neutrality.

You mentioned individualized therapies. Can you give some examples?
Every person is unique – and every illness is too. That's why I consider personalized medicine to be one of the most important markets of the future. Modern diagnostic methods now make it possible to gather more data and thus offer tailored concepts for prevention and treatment. If the dosage is precisely adjusted to the patient, this reduces potential side effects and improves treatment compliance. In oncology, for example, there are new treatment methods based on a person's modified cellular or genetic material – another truly individualized approach.

What does that mean for production processes?
Conventional production processes often lack the flexibility needed for customized combinations of APIs or dosages. For oral applications, for example, 2D and 3D pharma printers – which we have developed together with DiHeSys (Digital Health Systems) – enable the patient-specific production of medicines. New methods in the field of cell and gene therapy also place high demands on production and aseptic filling into bags. The aim here is to manufacture these complex biological products quickly and efficiently through standardized, automated processes. Our cooperation with the Fraunhofer Institute for Production Technology puts us in a very strong position in this field.

At the heart of every innovative solution is the customer's product.

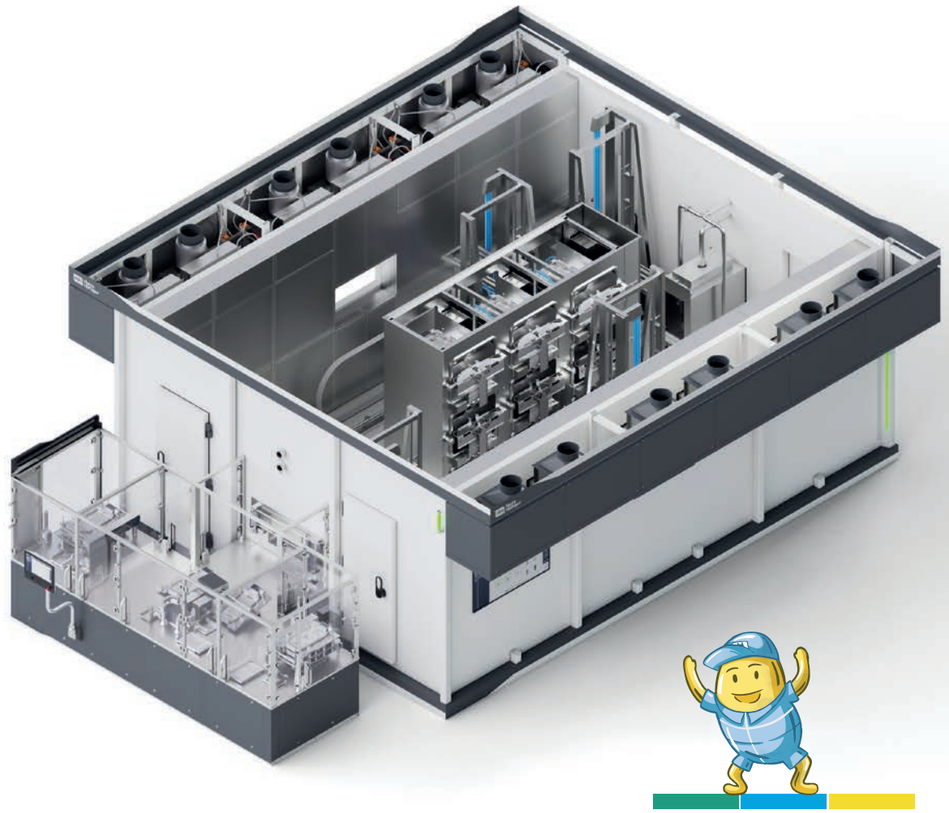
How do these trends affect the development of production lines?
We're increasingly focusing on modular designs with decentralized control – for example, in product assembly on our new MOD Flex platform, enabling our customers to produce small batches during the approval phase and to handle launch quantities. As a mechanical engineering company in the pharmaceutical market, we face the challenge of developing highly complex, regulatory-compliant lines that can be seamlessly and safely integrated into digital production environments. The opportunity lies in offering innovative solutions that deliver added value for our customers – like our "Harro Digital" products, which turn machine data into specific recommendations for action. This opens up new business fields and strengthens our position as a technological leader.

"PERSONALIZED MEDICINE IS ONE OF THE MOST IMPORTANT MARKETS OF THE FUTURE."

Harro Höfliger has also grown strongly worldwide. What role is internationalization set to play for the future?
Our international growth is driven by the clearly defined goal of providing customer proximity and direct on-site support. With our "locals for locals" strategy, we're establishing production, service, and sales sites worldwide. We're also investing in new capacities, such as currently at the Debrecen plant in Hungary and in Bangalore, India. These sites expand our production capabilities.

You've accompanied the Harro Höfliger story for over three decades. What makes it special for you?
What's unique for me is the focus on the customer's product, in line with our philosophy: "The product defines the process." For me, that's the key to staying successful in a rapidly evolving market. Our commitment to offering our customers innovative solutions for their product will continue to drive us forward. Of course, we build machines – but we're not the only ones. What really sets us apart are the underlying processes – for our clients' satisfaction and for securing our economic future.

WHAT MAKES CELLS HAPPY



The Apic, White Rabbit Studios, Andreas Streicher

Fraunhofer IPT and Harro Höfliger are jointly driving the advancement of cell and gene therapy production. Fusing scientific expertise and GMP-compliant mechanical engineering enables production that is both automatable and scalable.

Cell handling requires the utmost precision. One key challenge lies in transferring critical steps into safe, reproducible processes.

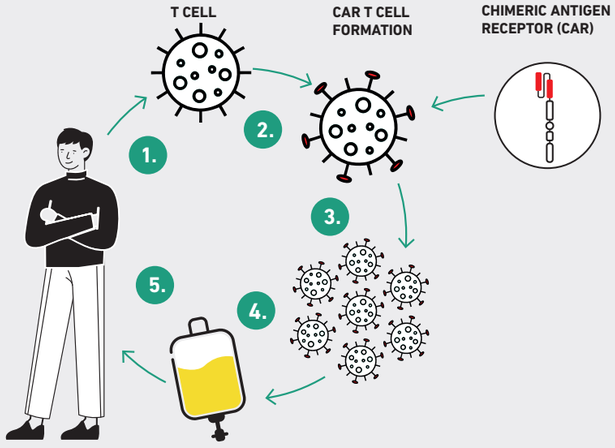
Cell and gene therapies have the potential to revolutionize the field of medicine. Rather than merely treating symptoms, these approaches aim to eliminate the causes of diseases. This is achieved by activating the human immune system or by repairing genetic defects. "Ultimately, it's always a matter of getting cells to produce specific proteins," explains Bastian Nießing, Head of the Bioadaptive Production Department at the Fraunhofer Institute for Production Technology (IPT) and an expert in these modern therapies. "Cells and their functions are specifically modified for this purpose, for example, by repairing genetic defects or by modifying the body's own cells."

CAR T cell therapy is a well-known and established example. T cells – white blood cells that serve as part of the immune defense – are separated from the patient's blood and modified in the laboratory for this purpose, so that they can identify and destroy specific cancer cells. This approach has achieved impressive success in the fight against various types of blood cancer. In addition to treating cancer, cell and gene therapies can also be used to fight autoimmune diseases or to repair tissues and organs – the possibilities are as diverse as they are promising.

GREAT POTENTIAL, GREAT CHALLENGES

Despite the potential of these new therapies, their originators face significant challenges, primarily related to the complex production process. It begins with the extraction of relevant cells from the patient's or donor's body. The cells first undergo genetic modification and preparation for multiplication before being cultivated in bioreactors. As these are individualized therapies involving living material, the entire process requires particularly precise and careful handling.

CAR T CELL CYCLE



AdobeStock, White Rabbit Studios, Andreas Streicher

1. First, blood is drawn from the patient.
2. T cells are isolated and specifically modified.
3. Modified CAR T cells multiply.
4. The patient then receives the cells back via infusion.
5. Inside the body, CAR T cells identify and destroy tumor cells.

Bastian Nießing: "Cells always vary from person to person, which makes the creation of these therapies so complex. The processes are currently carried out largely manually, however, which makes them both error-prone and time-consuming. There are also strict regulatory requirements and extensive documentation." All these factors drive up costs – often several hundred thousand euros for a single application.

"Our approach is to transfer scientifically sound solutions into practice."

Bastian Nießing
Head of Bioadaptive Production
Fraunhofer IPT

SCIENCE MEETS PLANT ENGINEERING

A continuously rising demand accompanies these challenges. Both aspects make it increasingly essential to transition from manual to automated, scalable production. This breakthrough is now possible through a collaboration that combines two perfectly complementary strengths: the scientific expertise of Fraunhofer IPT and Harro Höfliger's practical experience in building GMP-compliant systems.

The Institute for Production Technology is part of the Fraunhofer-Gesellschaft (Fraunhofer Society), the largest European organization for applied research and development services. It specializes in developing technologies and processes for industrial applications. "Our approach is to develop scientifically sound solutions that can be applied in practice," explains Bastian Nießing. "For the last ten years or more, an important focus has been the automated production of cell and gene therapies. We concentrate on developing demonstrators and concepts that can later be transferred into industrial solutions."

The research institute relies on collaboration with Harro Höfliger to commercialize these solutions. Christian Kollecker, Director Sales Aseptic Processing: "With our pharmaceutical focus, we've specialized for many years in building scalable GMP systems – an ideal prerequisite for working with Fraunhofer IPT to take the production of cell and gene therapies to the next level."

Thanks to the combination of scientific expertise and industrial machinery competence, customers receive an end-to-end solution that covers the entire process from the initial concept to the ongoing maintenance of tailored machines – always with a focus on enabling the automation of previously manual processes. The procedure is divided into three main steps:

First, Fraunhofer IPT provides a comprehensive consultation. The aim is to design a scalable production process and identify opportunities for automation. This is followed by system planning, in which Fraunhofer IPT and Harro Höfliger jointly develop an individual project plan and the machine concept. In the third step, Harro builds a tailored line that integrates the previously defined processes into a GMP-compliant system.

During the so-called seeding process, the cells are introduced into bioreactors. They then pass through an airlock to the expansion mansion.

A LUXURY HOTEL FOR CELLS

The Happy Cell Factory was created through close collaboration between the two partners. It's a platform for the production of cell and gene therapeutics that covers all production steps – from cultivating and expanding cells to providing the product – with precision and minimal human intervention.

"The name Happy Cell Factory reflects the philosophy that healthy, 'happy' cells form the basis for successful therapies," explains Christian Kollecker. "Only under optimal conditions and with precise handling can they thrive and multiply in a way that enables them to fulfil their role in these vital therapies perfectly. So we like to compare our Happy Cell Factory to a luxury hotel for cells, in which they should feel completely at ease."

The first pilot line is currently under construction. The process begins with the "check-in", i.e manual loading of cell bags and empty bioreactors. The cells are introduced into these bioreactors, where they can then multiply and grow. Positioned on special trays, the bioreactors glide smoothly through the various modules. A special lifting system – the "concierge" – then transports the cell material into the heart of the line. This incubator, the "expansion mansion", consists of several "hotel rooms", one for each cell culture. This allows multiple batches to be processed simultaneously on the line. Cell activation now occurs in the hotel room: The cells receive growth factors that optimize their responsiveness for subsequent processes. In the next step, transduction, viral vectors are introduced to trigger the genetic modification. The cells thereby develop the specific properties required for the therapy. Preassembled multi-use sterile connectors are used for aseptic fluid transfer during these steps to minimize the risk of contamination.

OPTIMAL CONDITIONS FOR GROWTH

Following this comprehensive preparation, the cell culture is ready to grow unhindered. "The hotel rooms are designed so that each cell batch expands under the best possible conditions," explains Christian Kollecker. "We keep the rooms at a constant temperature of 37 degrees, the optimal temperature for cell growth. At the same time, we continuously monitor all key parameters such as temperature, pH, oxygen content, and CO_2 concentration, and transfer them to a digital batch report in an automated process."

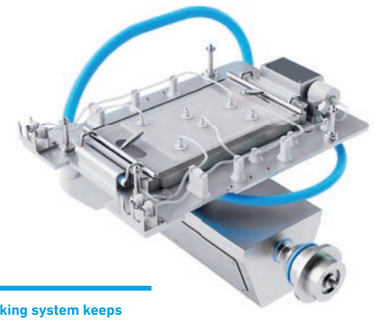
Throughout their entire stay in the hotel room, a rocking system keeps the cells in gentle motion. This ensures even nutrient distribution and helps prevent clumping. "Besides these comprehensive 'massages', we also offer excellent room service in our cell spa," the expert goes on to say. "A sophisticated perfusion system ensures that the used cell culture medium is removed and replaced with fresh medium. This ensures that the cells are always optimally supplied with nutrients." Throughout the entire expansion process, samples for quality control can be taken automatically without requiring the system to be opened.

Once the cells have reached the desired quantity, a concierge steps in again to guide them toward the "check-out" area. By tilting the bioreactor, the medium can drain into a separate bag. The cells are then separated from the other components.

Transport through the various modules takes place automatically. In the hotel rooms, multiple cell batches expand in parallel.

AUTOMATION AS THE KEY

Each step is reproducible and strictly compliant with GMP, which minimizes human error, reduces waste, and enables continuous data acquisition. "Automation is the key to mastering the variability of the starting material. With the Happy Cell Factory, we process every batch under precisely regulated and controllable conditions," says Bastian Nießing, clearly satisfied.



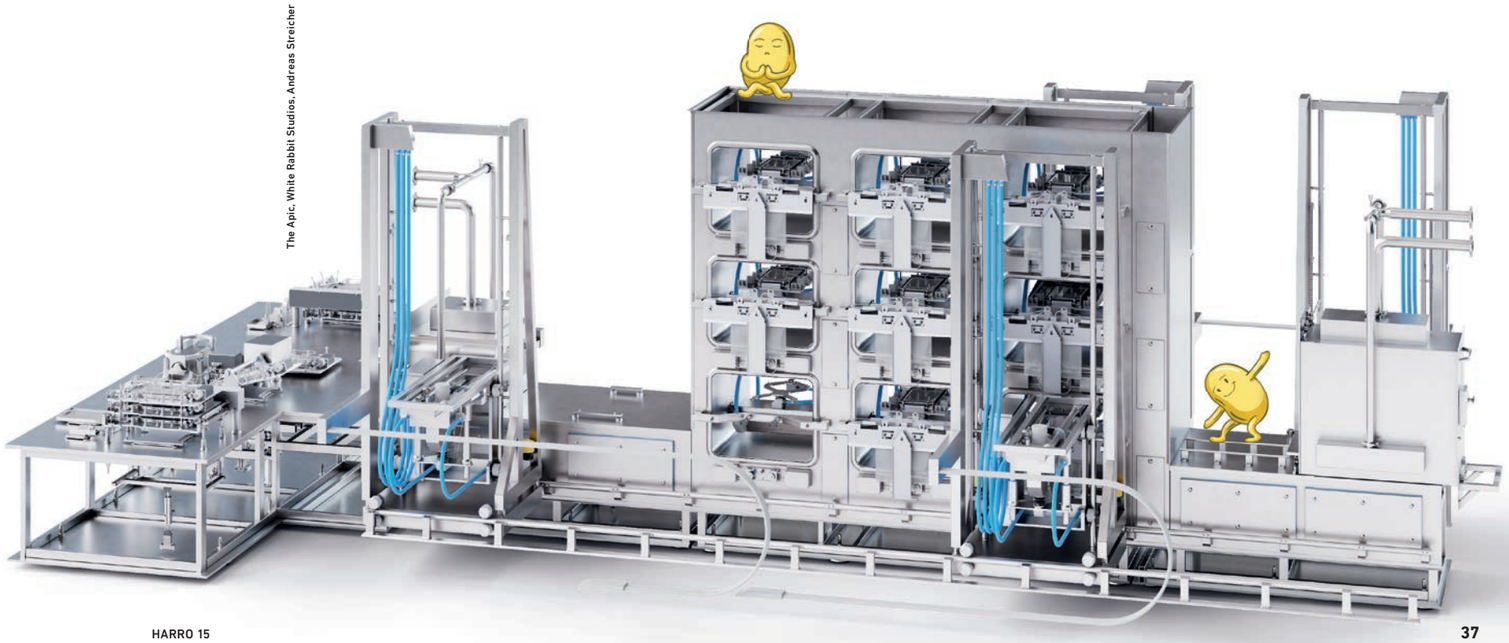
The rocking system keeps the cells in gentle motion, ensuring even nutrient distribution.

"The Happy Cell Factory is like a luxury hotel for cells."

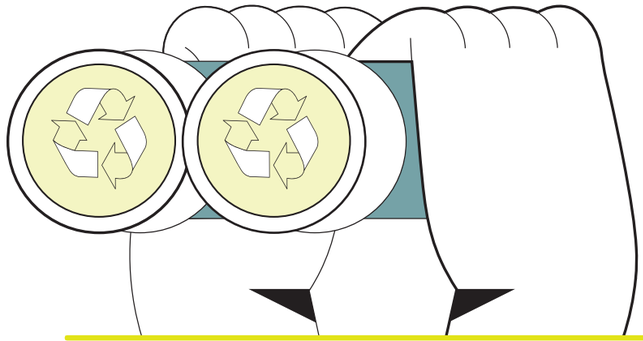
Christian Kollecker
Director Sales Aseptic Processing
Harro Höfliger

Thanks to continuous parallel processes rather than prolonged serial operations, throughput also increases significantly. The pilot line, with its output of one cell therapy per day, is, however, just the beginning. Future models of the platform are to be scalable, ranging from compact tabletop versions to high-speed systems, with an output of up to 25 batches per day. Some of these advanced lines will cover the entire "vein-to-vein" process – from thawing the apheresis bag through cell selection and expansion until final product delivery to the patient. However, the flexibility of the platform also underscores its future viability, as modules, software, and sensor technology can be adapted to different cell types and therapies.

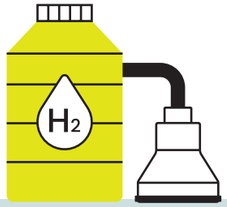
Christian Kollecker, therefore, has a positive outlook on the continued collaboration with Fraunhofer IPT: "By combining scientific expertise with technical sophistication, we help ensure that in the future, tailored, vital therapies will be available to far more patients." This way, working with small cells could soon make a significant contribution to global healthcare.



The Apic, White Rabbit Studios, Andreas Streicher



SUSTAINABLY INTO THE FUTURE

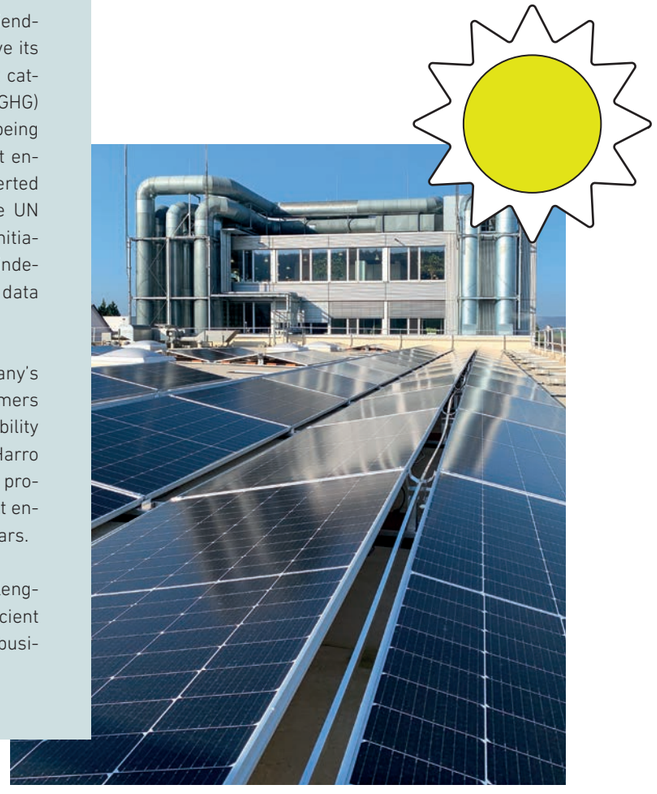


Sustainability is not a short-term trend, but one of the greatest challenges of our time. Because it's about nothing less than preserving the natural basis of life for future generations.

Harro Höfliger uses environmentally friendly technologies at all its sites to achieve its net-zero targets in the Scope 1 and 2 categories from the Greenhouse Gas (GHG) Protocol by 2035. For example, a pilot plant is being built at the Allmersbach im Tal headquarters that enables heating and cooling systems to be converted to self-produced hydrogen. As a member of the UN Global Compact and the Science Based Targets initiative (SBTi), Harro Höfliger has its climate targets independently validated and makes its environmental data available to the Carbon Disclosure Project (CDP).

But the commitment goes far beyond the company's own climate-neutral transformation. Many customers are also working hard to achieve their sustainability goals in line with the Paris Climate Agreement. Harro Höfliger supports them with optimized production processes, innovative technologies and measures that ensure that their machines can be used for many years.

Aligning ecological and economic goals is challenging, but also presents opportunities: Resource-efficient solutions reduce costs and ensure sustainable business success.



ECO DESIGN

Harro Höfliger is continuously optimizing its systems to lower resource consumption and raise energy efficiency, and develops alternative, practical mechanical engineering concepts based on eco design principles. The company is among the pioneers in special machine construction by integrating ecological factors early in the development phase. Team-oriented cooperation with the customer plays a decisive role here.

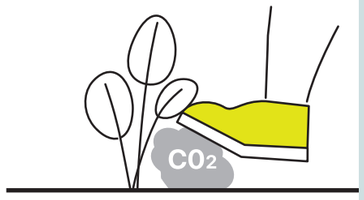
Many different parameters are optimized in the process. One example is material selection: Additive manufacturing methods and specific lightweight design of moving components, such as shafts or grippers, save raw materials and energy. Innovative drive systems and intelligent control design also significantly reduce power consumption. By digitally combining electrical and pneumatic systems, Harro Höfliger always uses the optimal medium for moving machine components. Sealing is a prime example of resource-efficient technology: Conventional processes rely on energy-intensive heat sealing, but in some cases, products made from water-soluble film, such as dishwasher tabs, can also be sealed with water.

Another focus is on optimizing the manufacturing processes. A digital twin makes it possible to test the efficiency of machines and processes even before the component is manufactured. Modular designs facilitate maintenance, repair, and replacement of stations, e.g. when switching to new products or formats. Intensive operator training also helps ensure efficient machine operation and reduces the use of spare parts.

PRODUCT CARBON FOOTPRINT (PCF)

What impact does a machine have on the environment? The Product Carbon Footprint (PCF) provides transparency here and is determined by Harro Höfliger on request. The calculation model is based on the Greenhouse Gas (GHG) Protocol and takes into account all processes from resource extraction and manufacturing through to the point at which the machine leaves the plant (cradle-to-gate). It includes not only the company's own CO_2 emissions but also those from the upstream process chain. This allows customers to identify the extent to which the line contributes to the PCF of their own end products. This transparency also facilitates compliance with regulatory requirements.

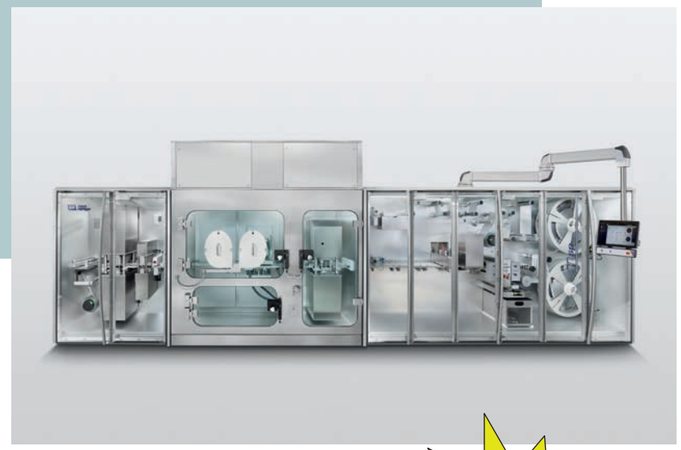
Throughout the service life of Harro Höfliger's lines, the emissions they cause contribute only minimally to the PCF of the customer products produced on them. The detailed breakdown of emissions arising in the various life cycle phases helps identify relevant levers for improving the carbon footprint.

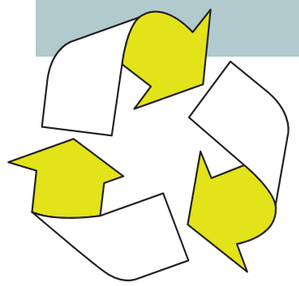


Atelier Lünig

CIRCULAR ECONOMY

Many products become sustainable by remaining in use for as long as possible and, at the end of their life. by being regarded and used as a valuable resource. Harro Höfliger's high-quality machines are designed for high efficiency and a long service life. Both can be extended through regular maintenance as well as hardware and software upgrades. Used machines can be overhauled and modernized. Early identification of discontinued components by Customer Service allows alternatives to be used to extend the utilization phase. This way, customers not only benefit ecologically but also from greater investment security.



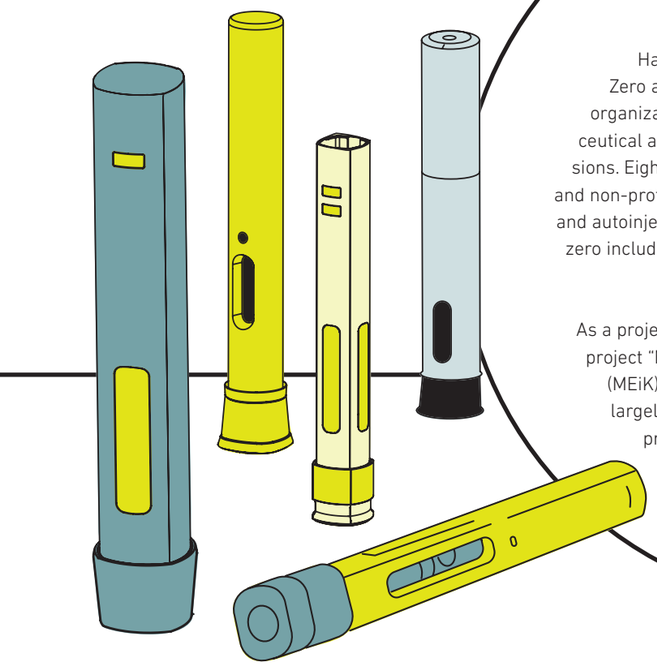


Retrofitting upgrades proven machines to the current state of the art – a sustainable and cost-effective alternative to purchasing new equipment.

PARTNERSHIPS AND PROJECTS

Harro Höfliger has been active in the Alliance to Zero as a founding member since 2021. This non-profit organization aims to facilitate the transition of the pharmaceutical and biotech sectors towards achieving net-zero emissions. Eight companies work together with research institutions and non-profit organizations to make injection devices such as pens and autoinjectors more sustainable. Interim goals on the way to net zero include the reuse and recycling of individual parts instead of their disposal.

As a project partner, Harro Höfliger also supports the research project "Medical single-use products in the circular economy (MEiK)" at Pforzheim University. The aim is to develop a largely climate-friendly, high-quality material recovery process for medical devices with a high plastic content in Germany.



CLARITY ASSURED

If the function of the eye's lens is impaired, intraocular lenses can help restore clear vision. Harro Höfliger offers the right technology for their packaging.

The lens of the eye plays a key role in our ability to see: It gathers incoming light and focuses it precisely on the retina – ensuring sharp perception of the surroundings. Clear eyesight suffers when the lens no longer functions properly. This is the case with cataracts, for example. The lens gradually becomes cloudy, allowing less light to reach the retina. Intraocular lenses (IOLs) can be a solution here. Implanted in the eye, they replace or support the natural lens.

„With multi-format machines, we can respond flexibly to the variety of products."

Jochen Stein
Director Sales Eye Care Technologies
Harro Höfliger

Harro Höfliger offers specialized technology for packaging these small visual aids. "We've been active in the ophthalmic sector for many years, particularly with contact lenses and eye drops," explains Jochen Stein, Director Sales Eye Care Technologies at Harro Höfliger. "It was therefore a logical step to begin working with intraocular lenses."

One challenge in their packaging is the variety of lenses. They come in different strengths, some include an applicator, and country-specific certificates and other inserts must also be taken into account. Jochen Stein: "To accommodate this diversity, we rely on multi-format machines. This makes it possible to switch quickly between different batches and formats."

The machines carefully package and serialize each lens. By using various methods, including a wide range of camera inspection systems, Harro guarantees high quality and complete traceability to meet the strict standards for the implants – and thus ensures clear vision for patients all over the world.

Atelier Lünig

EVERYTHING IN FLOW

Convenient monitoring of urological health parameters at home – that is the mission of the start-up Streamcheck. Harro Höfliger's Device Services supported the path to market approval of their smart medical device.

A conversation among friends on vacation. Prof. Dr. med. Stefan Siemer reports on his daily work at the Clinic and Polyclinic for Urology and Pediatric Urology at Saarland University and concludes: "If our male patients didn't wait to see a doctor until they have complaints and made better use of preventive care, we could start therapy early and prevent many an operation. But very often urological check-ups are a taboo subject." This message resonates with entrepreneur Sebastian Heidrich. His idea is to devise a user-friendly technical solution that helps people to regularly monitor important health data from the comfort of their own home and seek medical advice if necessary.

"Competent support, always with a clear drive toward the goal."

Sebastian Heidrich
Founder of Streamcheck

Siemer and Heidrich, together with marketing specialist Sebastian Janus, founded Streamcheck GmbH as a start-up in Vierkirchen, Saxony in 2023. The name says it all: The diagnostic product, developed by an interdisciplinary and steadily growing team, consists of the device and a special cup, and measures the flow rate and volume of urination. An integrated test strip reveals important biomarkers in the urine – such as protein, glucose and nitrite. All data is recorded, analyzed and stored in a smartphone app.

"If urine flows noticeably slowly, this may indicate a condition affecting the prostate, urethra, or bladder," says Prof. Dr. med. Stefan Siemer. "As a diagnostic procedure, uroflowmetry is established in all urological practices. However, our approach is preventive: If urinary flow is measured regularly at short intervals, let's say once a month, the first signs of health changes will not go unnoticed. The same applies to biomarkers. If, for example, the device detects white blood cells in the urine, this may indicate inflammation. In either case, it's a signal for users to have any irregularities checked by a doctor."

THE CHALLENGE OF CE MARKING

The innovative Streamcheck system has also attracted the interest of specialist practices and clinics. Harro Höfliger came into play to accelerate the process of market approval as a medical device in the European Union. "We moved forward purposefully and energetically, fine-tuning the technical details. But all the regulations, standards, guidelines and directives to be considered for certification were completely new territory for us and presented us with some major challenges," explains Sebastian Heidrich.

Jan Schikora, Regulatory Affairs Expert at Harro Höfliger's Device Services, is very well acquainted with the regulatory pitfalls and knows how to overcome them:

Sebastian Heidrich, Prof. Dr. med. Stefan Siemer und Sebastian Janus have a common goal: safe and easy regular health checks that can be conducted at home.

Streamcheck GmbH

"We not only advise on the development or optimization of devices, but also on all matters relating to approval. Conformité Européenne marking is required for the European market to confirm that the product functions properly and meets all relevant safety requirements."

To obtain the CE mark, manufacturers must undergo a comprehensive conformity assessment procedure and identify the applicable legal framework themselves. Jan Schikora: "We offer support for the entire process, from advising on the correct procedure to preparing the required technical documentation, which includes classification, product description, information on performance, safety, data protection, and numerous other details. Assigning a medical or diagnostic product to one of the various risk classes correctly right from the start is important and saves time."

Jan Schikora, Regulatory Affairs Expert at Harro Höfliger, supports manufacturers of medical devices throughout the entire CE marking process.

"Meaningful data also help us doctors."

Prof. Dr. med. Stefan Siemer
Founder of Streamcheck

Sebastian Heidrich confirms this. "We benefited from Jan Schikora's extensive regulatory expertise. His well-structured, results-oriented approach contributed to a smooth process and the rapid approval of our smart device in the fall of 2025. Ultimately, we were able to save resources and valuable time, which we invested in providing people with even more precise technologies for their healthcare."

THE STREAMCHECK DEVICE

A trip to the bathroom can provide important insights into the health of the urinary tract and prostate. The Streamcheck system allows users to conveniently collect such valuable information at home. A smartphone app evaluates the data and, if any irregularities are detected, prompts users to repeat the test or consult a physician. The device's small camera is only activated briefly: for identification and calibration before use and then again after urination to record the biomarkers. All sensitive personal and medical data is stored and managed securely and in compliance with data protection regulations in a database.

Streamcheck GmbH

SIX QUESTIONS FOR STEFAN BERNSAU

Microneedle array patches (MAPs) with thousands of minute needles could provide an alternative to conventional vaccinations. Harro Höfliger has been engaged in this pioneering technology for several years. Stefan Bernsau, Director Needle Technology, on current developments.

Mr. Bernsau, what are you working on right now?
We're currently collaborating with Micron Biomedical, a US-based company, on an entirely new concept for manufacturing "dissolvable microneedles". This type of microneedle is made entirely of dried vaccine and requires a special form of dosing as well as the appropriate drying concept. As the drying process can't be accelerated by raising the temperature, we're testing other physical processes.

In addition, together with VAXXAS, an Australian start-up, we're designing a high-performance line for the aseptic production of coated microneedles, also for vaccine delivery. We're currently in the phase between fundamental development, carrying out tests, and building a pilot machine.

These developments are lengthy processes – because microneedles involve an entirely new technology, and that now presents major challenges for us as mechanical engineering company.

Can you tell us about some of these challenges?
In commercial manufacturing, strict sterility and quality standards apply, also at high output levels. The automated process has to take place in an aseptic environment. On top of that, there are extremely demanding steps such as precisely coating the needles with vaccine and then drying them to ensure they all retain their shape. Aspects like these increase the complexity of developing the new production lines.

"It's part of Harro's DNA to engage with emerging, promising technologies such as MAPs."

Stefan Bernsau
Director Needle Technology
Harro Höfliger

The product model shows that MAPs are equipped with many tiny "needles".

How can Harro help unlock the potential of MAPs?
With our many years of experience in aseptic processes and our global network in the microneedle sector, we're in a unique position to help drive the development of potential production technologies around MAPs. After all, it's part of Harro's DNA to engage with such emerging, promising, and future-oriented technologies.

How do you – and your customers in turn – benefit from the still very new microneedle business segment?
Special requirements, such as those in the field of microneedles, often lead to innovative solutions. This is one of our great strengths: Unlike many other mechanical engineering companies, we cover a very broad spectrum of business areas and technologies with the corresponding process expertise. A key advantage for our customers is that we're in a position to apply the technologies or methods developed from one area in other areas as well. Of course, always supported by the relevant confidentiality agreements. This means we also work with different teams here to ensure separation between the projects.

MAPs have the potential to significantly simplify vaccination campaigns.

MAPs AT A GLANCE

Microneedle array patches (MAPs) contain thousands of microscopic needles that are coated or filled with a vaccine. They effectively deliver the vaccine antigens into the upper skin layer (dermis and/or epidermis), where the API is either released locally or enters the body via the bloodstream.

MAPs have the potential to simplify vaccination and healthcare provision in low- and middle-income countries:

- Administration without preparation as a single dose
- Painless, simple use through self-application or by minimally trained personnel
- Immune cells are targeted directly, so the vaccine dose can be reduced
- No cold chain required in most cases

There's still no product on the market. How do you rate the chances of success for this technology?
The development has been in progress for a while now. More and more experts from research, development, and industry around the world are dedicating themselves to this technology. After all, vaccination with MAPs offers a range of advantages over conventional injection with syringes. To name but a few: It's painless, because the microneedles only penetrate the top skin layer, the dermis. It can be self-administered, and infections at the injection site can be avoided. Its simple application makes vaccination far easier – a big advantage, for example, in a pandemic. Eliminating the need for a cold chain also cuts logistics and storage costs, sometimes dramatically. This is a major advantage, especially for global distribution.

How do you think this technology will change the market?
Different institutions are currently researching various possible applications – so there's a wide range of potential uses. We keep a close eye on these developments and we're very excited about future applications. I'm convinced that MAP technology will impact the market.

Strict sterility and quality standards apply in the manufacture of the small patches.

IMPRINT

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