

O-COM

THE OPTIMA MAGAZINE

Flexible. Sophisticated. Integrated.

Various diagnostic
applications,
holistic solutions

Your partner for reliable diagnostics



Gerhard Breu
Chairman,
Optima Pharma Division

Dear Readers,

From personalized medicine to clinical chemistry or even criminology, the possible applications for diagnostic products are diverse – and very important. Because reliable diagnostics are the primary step towards successful therapy and problem solving in many fields.

The dynamic and innovative market environment of our customers and partners shapes the requirements for high process quality and flexibility. The trend is clearly moving towards higher levels of integration and complete lines.

In this issue, you will find out how we can support you as an experienced partner with our turnkey approach. To provide insight into our expertise, we spoke to Christian Müller, Director Sales Diagnostic Global. He is familiar with the technical requirements and explains the many advantages of Optima's turnkey solutions for the diagnostic sector.

What does this look like in the "real world"? Learn more by reading our case studies – including successful customer projects such as a system for Maxwell cartridges with high processing flexibility and fast delivery for Promega. We also look into the future: My colleague Dr. Stefan König, Managing Director of the Optima Group, talks about ideas and trends for sustainable machine and packaging solutions.

Enjoy reading!

Yours,
Gerhard Breu

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Turnkey for diagnostics

Diagnostic applications increasingly require comprehensive expertise that goes far beyond filling and closing. This is what Optima Pharma specializes in with its turnkey solutions. In an interview, Director Sales Diagnostic Global, Christian Müller, talks about the services, background and customer benefits.



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In addition to personal protective measures, it was diagnostics that mitigated the spread of the Covid-19 virus. Micro-dosing and high performance are two central features of the new system – and Promega already had a "role model".



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Technology transfer

In 2016, Optima Pharma has developed a specific production line for the filling of four very different media of a diagnostic product from bioMérieux. Because of the principle of "never changing a running system", the company has decided to purchase a duplicate of this system for its Chinese production site in Suzhou.

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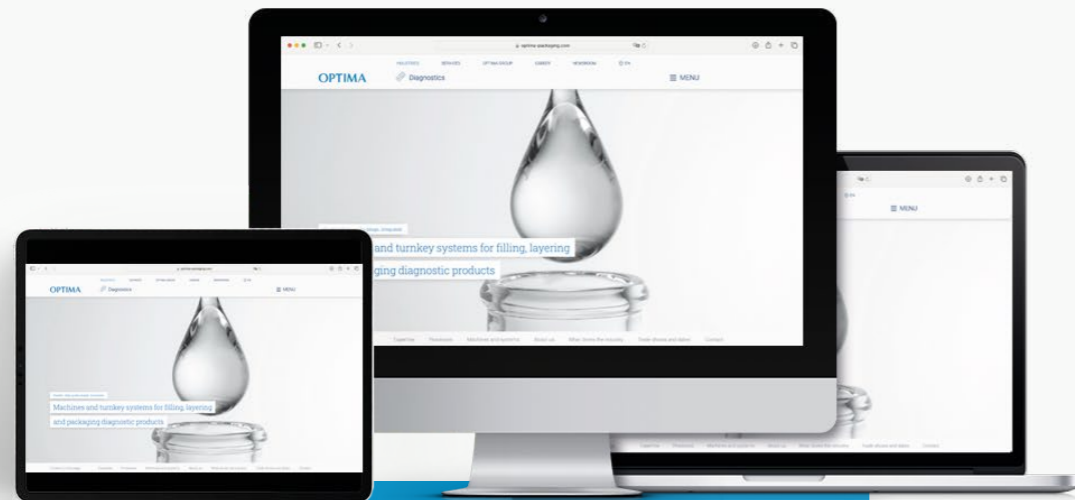
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The big website relaunch

Content growth of up to 1,000%: Optima's new website offers a state-of-the-art design and even more targeted information for customers and prospects. Whether they are seeking information on aseptic filling, isolator and containment, freeze-drying or cell and gene therapy – visitors to the site will find information on all of Optima's solutions for the pharmaceutical and biotech industry. They will also find additional information on our sustainability efforts, service portfolio, success stories and interviews with Optima experts.



OPTIMA on course for growth

Optima is strengthening its claim as a technology leader and strategic partner and can look back on another successful business year 2022. Optima has retained the flexibility of a family company and combined it with the performance strength of a group. That is why the company now has over 7,000 customers, from start-ups to large company groups. Optima generates the majority of the revenue abroad, with exports accounting for over 85 percent. About 3,000 people are employed worldwide at 20 locations. Over 2,500 in Germany and over 2,000 of these in Schwaebisch Hall.

Shaping a sustainable future

Sustainability is part of the Optima Group's corporate DNA. This results in valuable practices, such as conducting regular sustainability management ratings, including those from EcoVadis, to identify opportunities for improvement early on. As part of the Carbon Disclosure Project (CDP), the group provides environmental data for better transparency. In addition, Optima focuses on CO₂ reduction targets based on the Science Based Targets initiative (SBTi) methods that are proven effective and support the goals of the Paris Climate Agreement.



Clear approach with new company mission statement

To provide orientation for the many new employees and customers, Optima updated its mission statement. **"We care for people"** defines a clear mission, vision, principles and values. With its technologies and solutions, Optima makes a valuable contribution to improving health and safety and creating a better quality of life. The vision is to be the best partner for filling, packaging and production systems for challenging products. The group has also committed to the values that characterize the daily cooperation within the team: reliability, partnership, commitment, focus on solutions and a human approach.



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Interview

with Christian Müller



Christian Müller is Director Sales Diagnostic Global at Optima Pharma.

Turnkey for diagnostics: high-tech solutions for complex requirements

An increasing number of diagnostic products and projects require comprehensive expertise that goes far beyond filling and closing. Optima Pharma specializes in the development of turnkey solutions and takes central responsibility: multiple systems – from one source. The o-com editorial team discusses the services, background information and customer benefits with Christian Müller, Director Sales Diagnostic Global at Optima Pharma.



Diagnostics is becoming increasingly important in modern medicine. How does this effect the technical side? What are the requirements for diagnostic turnkey projects?

We see considerable variety in our line of work. For instance, we are currently working on a project for cancer diagnostics, a personalized medicine that demands extremely high dosing accuracy. The crucial substances for the reagents, the antibodies, are obtained through elaborate animal husbandry. Specific requirements of a diagnostic product like this lead to functions we integrate in-line. This can include minute dosing quantities, vacuum closing, leak tests, air-drying systems, freeze-drying, palletizing, or the assembly of the containers, among many others.

And diagnostics extends beyond medicine.

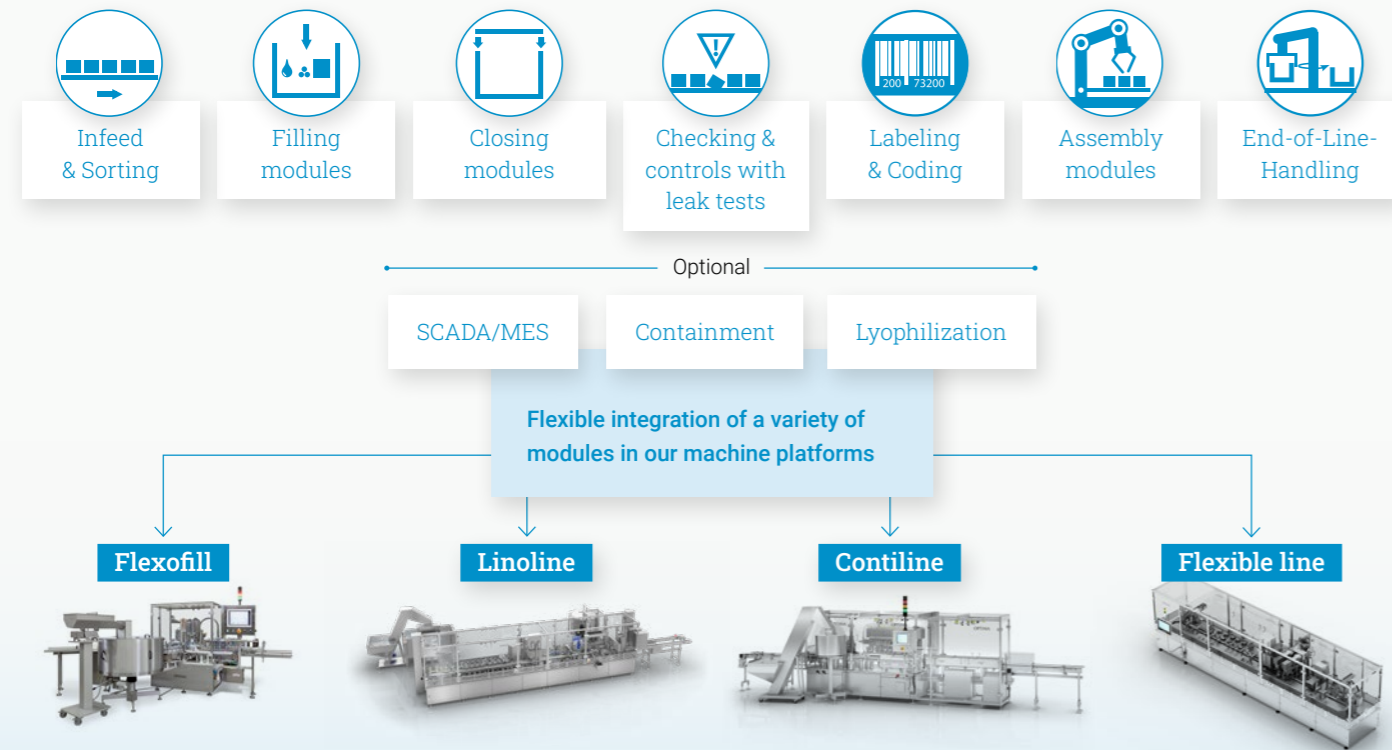
Diagnostics are also applied in criminology. In such cases, stringent hygiene measures are typically in place to prevent the introduction of foreign DNA into the tests. Enhanced hygiene standards are also essential in medical diagnostics, as seen in

blood platelet analysis, where the inclusion of any dust particles is strictly prohibited due to their potential to alter the test results..

How does Optima Pharma handle this wide range of tasks and technical diversity?

With a combination of in-house skill and collaboration with external partners as needed, Optima Pharma meets customer expectations and diverse technical requirements. What truly sets us apart is our process technology expertise. In other words, combining and integrating a wide variety of functions and process steps into a turnkey line, a practice we have been perfecting in the diagnostics field for several years. Our diagnostic customers benefit from the experience and expertise we have gained over many years of providing turnkey solutions to the pharmaceutical industry. This ensures a strong and well-established technical foundation for such tasks. Additionally, our close partnership with our customers is of utmost importance. We work hand-in-hand with our customers to develop system and customized solutions. This collaborative approach is a key factor in our success.

Diagnostic portfolio



Overall, would you see the turnkey offering as something unique on the market?

Absolutely. It is unique particularly because we are open to taking on new challenges. We are the partner for the new and unknown – always ready to explore new avenues. We offer the necessary flexibility to do so. Moreover, the definition of “turnkey” can vary in practice. The field of diagnostics turnkey, for us, means assuming overall technical and organizational responsibility for the project and serving as the primary contact for our customers, even when integrating system functions from third-party companies.

Systems should be created “as if from a single piece”. How is this actually approached in the project?

The turnkey approach begins with engineering. Here, we use simulations to harmonize various functions. Simulations test and optimize the entire system – or the combination of system components – before actual constructions begins. For example,

we simulate factors such as flow patterns over certain machine sections when a laminar flow is required. This also encompasses the evaluation of component strength, the establishment of the system's atmosphere, the additional suction for explosion protection, the potential for condensation, and more. Interface design also plays a crucial role in this process. By taking this step, we significantly reduce potential issues before building the system of stainless steel.

How does the implementation phase work? What are the benefits for the customer in a turnkey project?

One of the biggest advantages is that a turnkey diagnostic system is always fully assembled at our facility before it goes to the customer site. If third-party companies are involved, their equipment is also integrated into our assembly process. The entire system is harmonized during assembly at our facility. The turnkey approach allows us to identify and address critical points long before the installation at the customer site. The customer only gets here when

the system has already been extensively fine-tuned. This saves substantial time because these critical points are addressed much more efficiently during our assembly process than on site at the customer location. In the end, the customer benefits from a significantly reduced time-to-market and fewer disruptions at their site. Project management is centralized at our facility in Schwäbisch Hall, starting from the engineering phase, through assembly, and up to on-site installation. For international projects, for example in the USA or China, this is done in close cooperation with local Optima employees. In all cases, the customer has a single, central point of contact for their project.

What does your structure look like internally: Are you and your team part of Optima Pharma, but only deal with diagnostics projects?

That depends entirely on the specific activities. In the engineering department, we have a dedicated team that focuses entirely on diagnostics projects. The same applies to the assembly and qualification, where teams are specialized in diagnostic systems. Our sales team works across pharmaceutical and diagnostic projects, supported by experts who specialize exclusively in

diagnostics for all highly technical questions. The software department also works across the board, as does project management. It is crucial to have a strong network and close collaboration among all colleagues at Optima Pharma, whether they are working on diagnostics or pharmaceutical projects. We frequently work on projects with other Optima divisions and hold regular meetings to ensure effective communication and synergy between the teams and departments.

When you involve third-party companies in projects, are there certain structures and guidelines in the collaboration?

We have established proven partnerships with several companies – often those that are leaders in their respective fields, such as specific leak tests. In some cases, we also work with companies specifically requested by our customers based on their preferences and we are open to collaborating with them. In general, we conduct discussions with all external partners for software, electronics and, mechanics as needed. We also offer assistance when time is limited, as we ultimately bear responsibility for the project timeline.

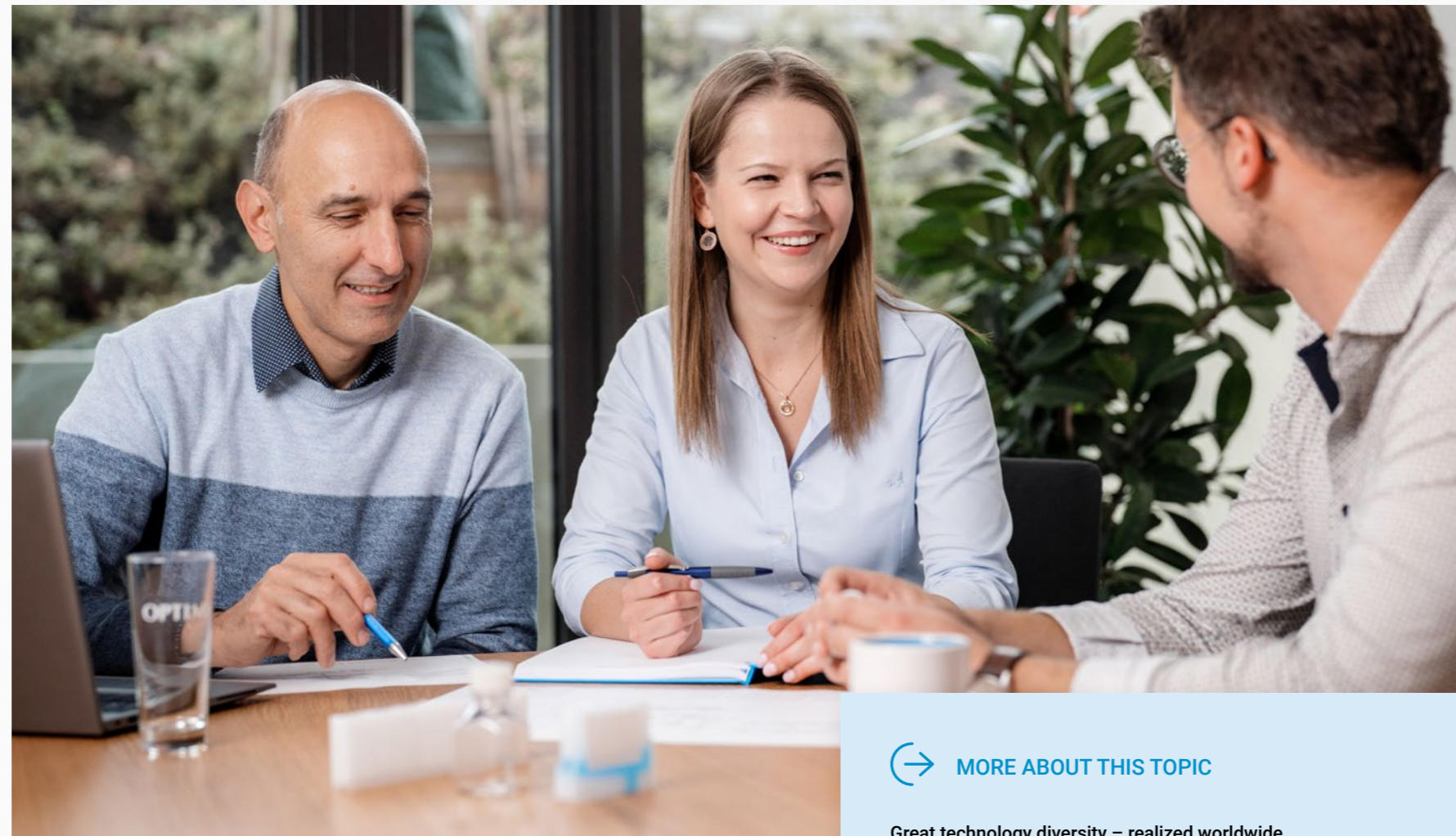


You mentioned that a technology transfer is taking place within the Optima Group. How does this manifest itself in the diagnostics field?

Frequently, technologies originally developed for pharmaceutical applications are also used in diagnostics. For example, there might be a requirement to protect diagnostic liquid from oxygen exposure – which requires the headspace in the container to be placed under vacuum and the container closed. Here we use technologies developed for liquid pharmaceuticals. If necessary, we adapt these technologies to meet the specific needs of the diagnostics. Freeze-drying or laminar flow are other examples of this cross application of technology. Additionally, we have integrated technology from Optima Pharma, like format-free transport systems, into a diagnostic system called the OPTIMA Flexofill. We apply this technology for projects requiring particularly short set-up times as it involves exceptionally small batch sizes for a very large number of different products.

What about the technology transfer from other areas of the company? Are there any examples that highlight this?

Yes, we are currently working on a project with extremely small dosage quantities. These dosing heads come from Optima Life Science. The customer was familiar with them from a microtiter plate coating machine and, based on their positive experiences, would like to integrate them into a complex, large system. Given the extensive automation in the upstream and downstream processes, Optima Pharma will manage the project. For filling large volumes, which can sometimes be as much as three liters per container or more, we utilize the established filling technologies from Optima Consumer.



How satisfied are you with the response to the turnkey offer for diagnostic systems?

We are very satisfied with the results. Installing systems for globally positioned diagnostic companies has often led to subsequent projects for us. There is much demand currently and it continues to grow. For example, the trend of companies developing custom containers that require specific processing aligns well with our capabilities. This is actually a unique aspect that distinguishes us from the pharmaceutical sector. Additionally, there is a growing need in the diagnostics segment for fully automated lines, where our experience is in high demand. ☺

➔ MORE ABOUT THIS TOPIC

Great technology diversity – realized worldwide

The diagnostics market features a large number of start-up companies on one end of the spectrum and global industry leaders on the other. As a result, the equipment and technology demands vary significantly. The industry's major companies are showing increasing need for solutions that go far beyond the simple filling and closing of diagnostic liquids. This can include the assembly of diagnostic devices, the collection and final packaging, hygiene features, or completely application-specific cross-technology solutions. The range of technologies applicable to diagnostics projects is considerable. Optima Pharma develops complete comprehensive solutions and assumes overall responsibility up to and including the Site Acceptance Test (SAT). Optima Pharma has a proven history of successfully implementing extensive turnkey solutions of this nature in Asia, Europe and the USA. Projects of this scale and magnitude require excellent skills at the process level, especially when different functions need to be coordinated from project to project. In addition, a close and collaborative partnership with the customer it is essential to create tailor-made custom solutions for specific requirements.

→
By synchronizing service areas across locations, maintenance operations for the individual line components can be optimally planned and stay in step with each other. System availability continues to rise.



One team, one product, one point of contact

Optima Pharma's support service is undergoing reorganization to boost customer satisfaction even more. We have consolidated all of our service areas across all of our sites. Now customers worldwide have a central contact for all issues in the form of a Service Account Manager who coordinates the back-office teams. The individual Optima Pharma sites continue growing together as "OneTeam".

IMPORTANT FOR YOU

- OneTeam: new worldwide service organization at Optima Pharma
- Cross-location core teams for customer support, maintenance support, competence team, qualification & validation, and business development/processes
- Benefits to the customer include: a central contact with clear responsibility, higher satisfaction levels, unified services and quality standards, faster response times, and improved planning of spare part packages and external operations
- Benefits for Optima staff include: professional and personal growth coming from specialization and exchange of knowledge, standardized tools, and shared expertise, a stronger team spirit, and a reduced workload for specialist departments



Our customers will clearly have the sense that we are one team and are working hand in hand on a product.

Holger Burgermeister, Service Director at Optima Pharma



2022 was a highly successful year for Optima Pharma. The integrated turnkey process, CSPE (Comprehensive Scientific Process Engineering), cuts the time to production start-up for filling lines. It has had a very positive take-up in the marketplace. Worldwide, the number of machines in operation has continued to grow. The service presence has also grown, with the new service hub opening in Raleigh, North Carolina, as one example. Even more than before, Optima Pharma is perceived by customers as a strategic partner for total systems that include technologies for filling and closing, for isolators, and freeze-drying. Hence work has focused on the service portfolio over the last year. What came out of this was a thoughtfully designed, target-group-specific program called "Lifetime Production Readiness."

Core teams across sites and a single point of contact

Holger Burgermeister, Service Director at Optima Pharma, explains, "The next step in our overall strategy is the collective, coordinated ongoing development of the service areas." That is why throughout 2023, Optima Pharma is now creating core teams for the following service areas: Customer Care, Maintenance Support, Competence Team, Qualification and Validation, and Business Development/Processes. These teams work in close collaboration across locations and with foreign subsidiaries. Optima Pharma's filling and closing technologies are created at its headquarters in Schwäbisch Hall, decontamination technologies and isolators originate in Radolfzell, and freeze-drying technology comes from Gladenbach-Mornshausen. One central Service Account Manager is in place to coordinate the customer's



Harmonizing the service areas results in coordinated replacement and worn parts recommendations, standardized service descriptions, and offers from a dedicated contact.

requests on all line items with these teams. Burgermeister says, "This is a response to our customers' desire to have a leading point of contact and leads to increased satisfaction."

The cross-location service strategy provides the turnkey concept with an even broader scope. The new service strategy accompanies increased internationalization. Burgermeister points out, "This is a significant advantage for our customers. Optima Pharma mainly has its own personnel in the markets." This means that service staff often work directly on site on the customer's premises or out of an Optima Service Hub and are in close contact with customers. Holger Burgermeister is responsible for the cross-location area of "Business Development/Processes" and supports the development of the global service structure.

Five Service Areas, five Managers

Customer support is centralized through Manuel Müller, Group Leader of Customer Support at Optima Pharma. His area covers project management, project planning, and worldwide customer support. "The reorganization aims to provide customers with a target-group oriented, coordinated service portfolio for filling machines, isolators and freeze-dryers, one that meets their high expectations of lifetime production readiness," says Manuel Müller regarding the restructuring of the service areas. "In the future, customer requests will be projected and processed in line with defined standards for the entire turnkey line. For quotations and order processing, we work as OneTeam, aiming to deliver real added value to our customers," says Müller.



↑ Now qualification documents for pharmaceutical lines come from a single source.

Our customer service is now being structured worldwide in line with this philosophy so that both the needs of local one-off projects and global turnkey projects are met.

"Our leading points of contact are operating globally, so they are usually in the same time zone, making them much more available to our clients," says Müller. "Our staff's greater availability ensures that our customer's requirements can be coordinated more quickly and locally, but without sacrificing the link to the technical departments based in Germany." To this end, service employees receive unified training via cross-location qualification programs, ensuring the same standard of training worldwide.

Matthias Staus, Group Leader of Service at Optima Pharma, heads up Maintenance Support. This service area schedules preventive and status-based maintenance work at customers' sites. When asked about the benefits of the new service strategy, the answer

is clear: "We are able to offer our customers proactive spare part and maintenance strategies across multiple sites," says Matthias Staus. This standardization results in coordinated recommendations for replacement and worn parts for the entire plant, uniform performance descriptions, and a single quotation from a single point of contact. Service calls for the different line components can be better coordinated. "Our team is coming even closer together, and colleagues can benefit from the expertise and experience of their team members," says Staus confidently.

Ronny Wiske, Group Leader of Life Cycle Services at Optima Pharma, will be responsible in the future for the Competence Team area across all locations. This department focuses on support services for the systems and troubleshooting. "In the event of malfunctions at the entire plant, customers can expect that troubleshooting will be easy, documented, and coordinated.

Our team is positioned to analyze and resolve complex, cross-product incidents jointly. To this end, unified procedures are followed, both in the choice of remote tools and methodology. The reorganization has enabled us to successfully use synergies and lessons learned for further installations in the field and in our new projects," says Wiske. "By standardizing our tools and processes in Germany, with the organization in place overseas, and by having experts on the ground, we are learning together and becoming even more effective in handling all of our customer's needs," Wiske adds.



We are able to offer our customers proactive spare part and maintenance strategies.

Matthias Staus, Group Leader of Service at Optima Pharma

Andreas Milich, the Radolfzell-based Service Director, is responsible for qualification and validation across all sites. The same principle holds true in his area: One team, one approach, one quali-

fied system for the customer. "When it comes to qualification and validation, we are continuing to embrace the CSPE 2.0 approach and are bringing the expertise of all our sites together even more effectively," Milich explains. All the qualification documents come from a single source, and in-depth internal coordination means that extensive parts of the qualification process can be handled seamlessly during continuous plant operation. Also, customers benefit from this coordinated approach using resources like calibration materials. "This makes the CSPE 2.0 an all-around trouble-free package in terms of qualification and validation, too," says Milich. Employees receive intensive training to prepare them for the new organization. ©



← With our service account managers working all around the world, they have particularly close relationships with customers, and it's clear that service response times can be significantly shorter.

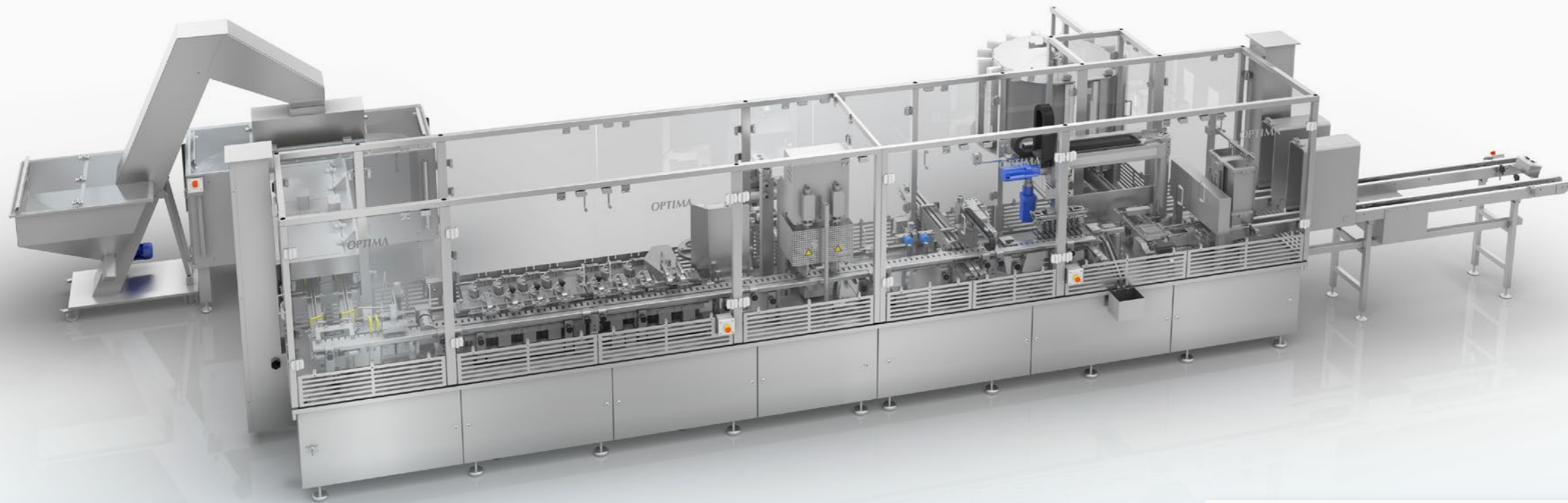
MEDICAL REPORT

Micro-dosing and maximum performance combined

In addition to personal protective measures, it was diagnostics that mitigated the spread of the Covid-19 virus. During this phase, Promega decided to increase their production of Maxwell cartridges significantly and set a target to be delivered within 12 months. Therefore, they selected Optima as the supplier for their new machine once again. Micro-dosing and high performance are two central features of the new system – and Promega already had a “role model”.

IMPORTANT FOR YOU

- Fast delivery within 12 months during the pandemic
- Copy of an existing custom line for Maxwell cartridges
- High flexibility to process many different containers and formats
- High-precision micro-dosing up to min. 180 µl with feedback control and high output (3,600 objects/h)
- Ensuring the homogeneous consistency of a suspension with Micro Beads
- Trays are loaded 100% without gaps and inspected cartridges



For Promega, these are effective systems with high throughput.

Sarah Melsen, Project Manager at Promega in Madison, USA

An implementation time of 12 months is quite “optimistic” for a complex, customized diagnostic system – not even the fact that Promega already had a “role model” made it less challenging: Their existing equipment, an OPTIMA Linline, had to be essentially duplicated. During a pandemic, the additional need for reagents has to be met as quickly as possible.

Fast track: it's urgent

Promega offers various diagnostic products under the Maxwell brand name. Biological samples, like samples for genetic identity or for research purposes, are analyzed. The Maxwell cartridges, with up to eight cavities, are not stable containers. This requires solutions for automated handling. Extremely small filling quantities,

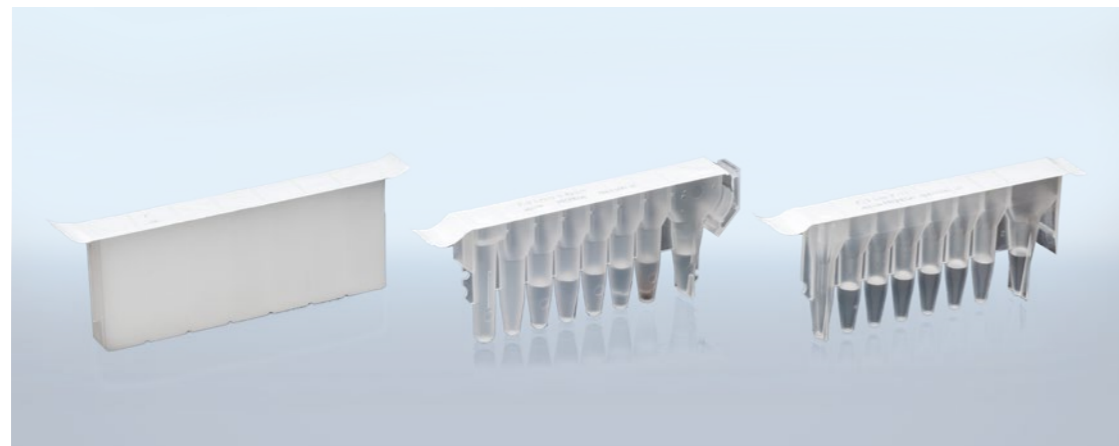
ranging as low as a couple hundred microliters, also creates a challenge. In addition, some of the liquids contain alcohol, which could affect the foil seal.

Last but not least, a special reagent with microbeads is dosed with the OPTIMA Linline. A dosing unit has to ensure that the original composition of liquid and solid components remains consistently homogeneous within the system. Optima met all of these requirements in a first project based on an OPTIMA Linline 120. The implementation of the new project, although an almost identical version of the “first edition”, was challenging in terms of time. However, let's first discuss the system technology ...

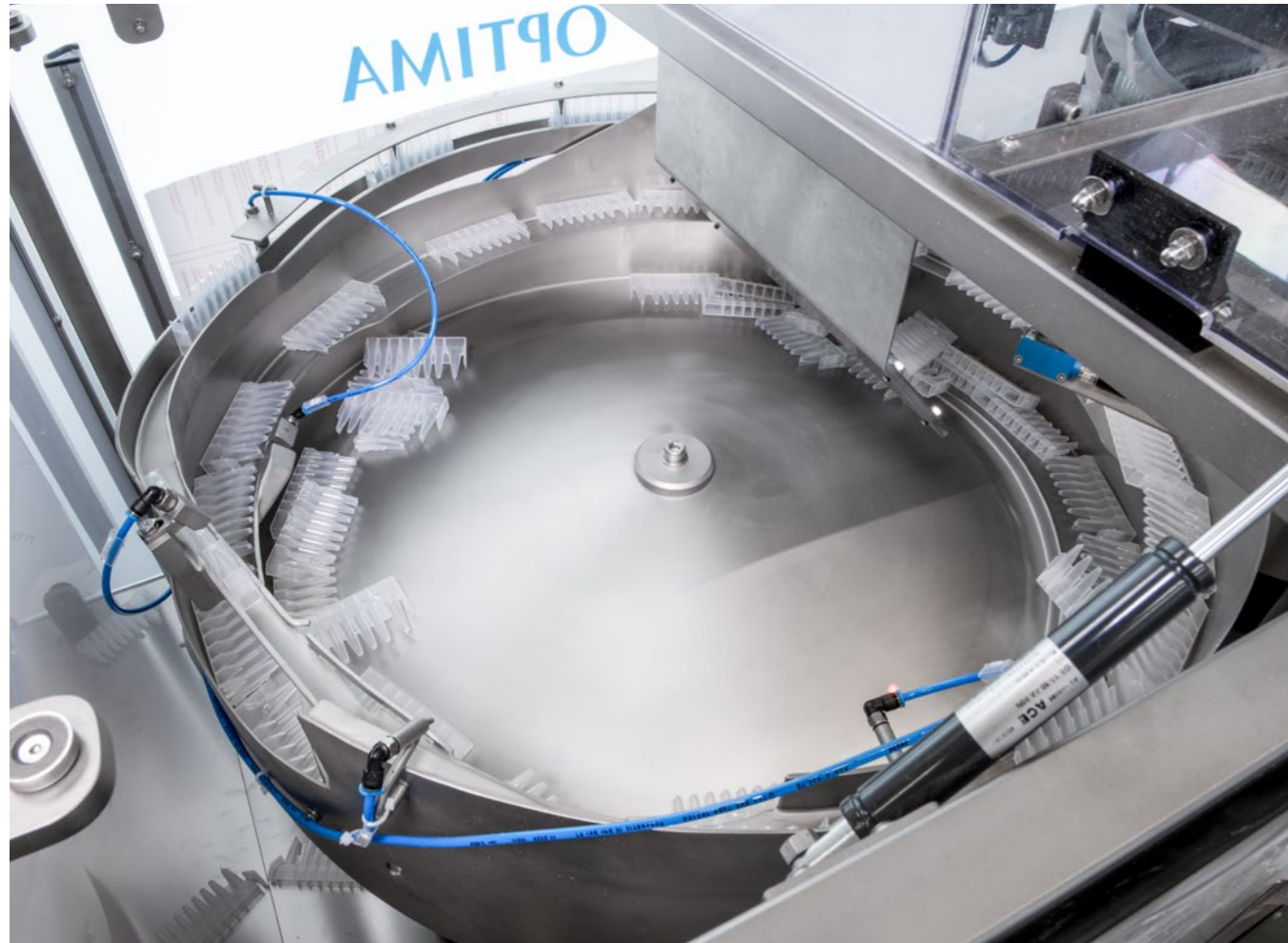
Safely transported through the machine

Correct orientation of the asymmetric Maxwell cartridges is important; these must arrive with the cartridge inverted in the transport system. In the infeed section, after the storage bunker and sorting bowls, the cartridges are guided onto a two-track infeed belt. A combined camera/turning unit recognizes the position of the cartridges and turns them at full line speed to achieve the desired alignment, if necessary.

A blowout station follows the transport rake of the OPTIMA Linline. At the next station, the cartridges are turned right side up. In this position, the containers are no longer stable, but ready to be filled. In order to



↑ Promega is currently processing three formats from the Maxwell series on the OPTIMA Linline.

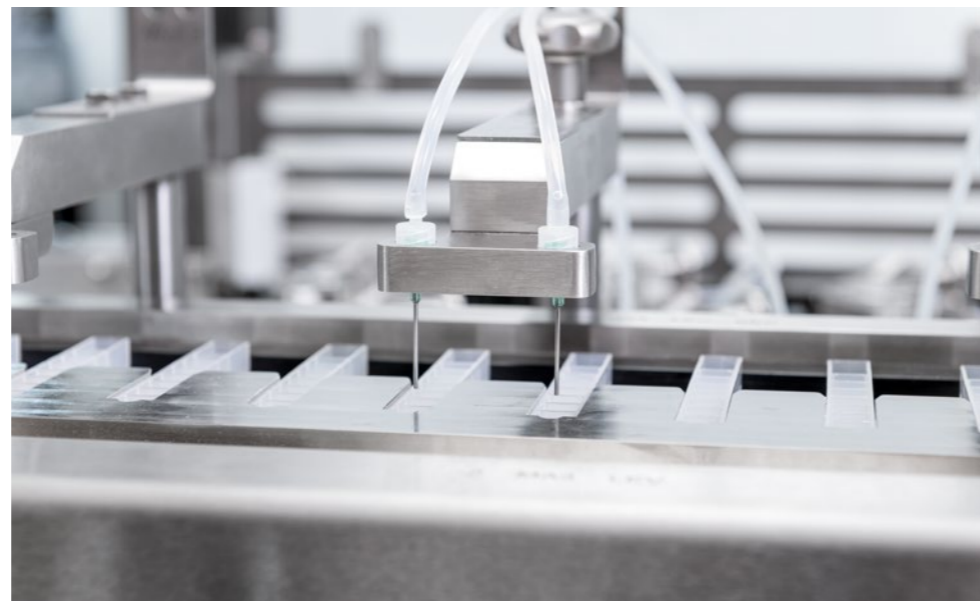


↑ One of two sorting bowls: The cartridges are placed in an upright position and directed onto a belt.

transport the cartridges to the filling and sealing station, they are stabilized in their resting position. For all additional processes the cartridges are guided laterally with a specific transport rake system and set down at the weighing positions over format parts

Microbeads and microliters

The OPTIMA Linoline achieves exact dosing quantities per cavity with 100% in-process control, which directly regulates the control of the integrated peristaltic pumps. A total of 16 peristaltic pumps and 18 load cells are installed for double-lane processing. The empty cartridge is weighed in the first weighing position. After the first fill and the subsequent weighing, the net filling quantity of the first cavity is calculated. This procedure is continued at the other filling positions. Deviations from the target weight of each individual



↑ The system fills smallest volumes up to micro-dosing. The filling weight of each individual cavity is exactly determined. Possible deviations from the target weight are recognized and corrected if necessary.

cavity are recognized by the control and, if necessary, immediately corrected, which results in a very high filling accuracy per cavity.

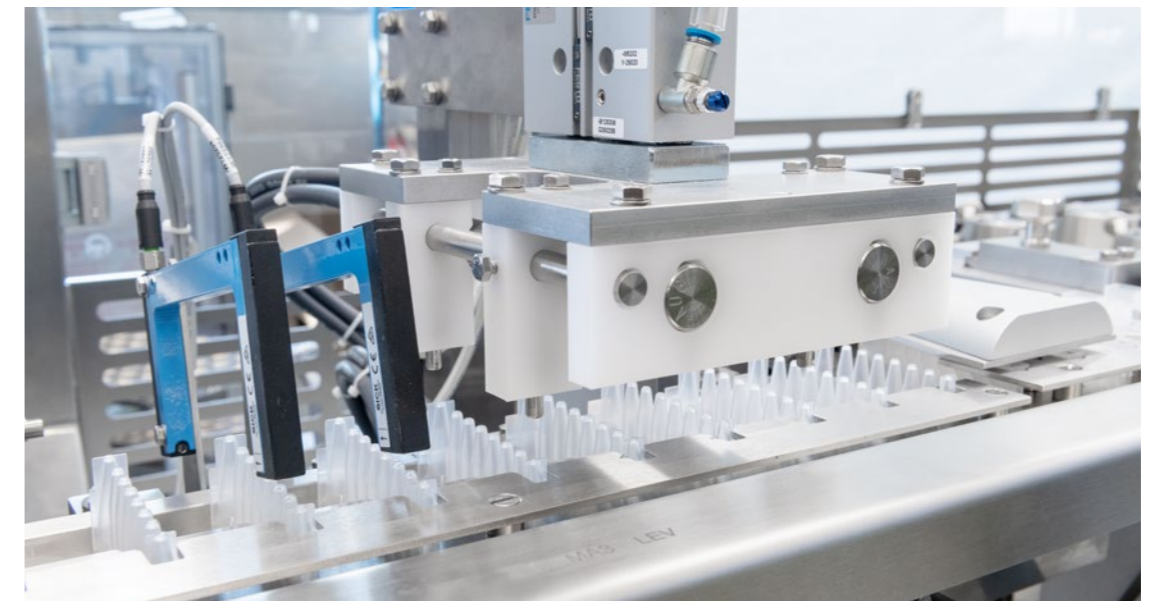
The last cavity in particular, where filling quantities as low as 180 µl are filled with peristaltic pumps, stands out. For comparison: A drop of blood corresponds to approximately 15 to 20 µl. On one hand, the weighing technology is required to measure these low weights precisely in a very short time. On the other hand, the peristaltic pumps must be able to implement the smallest filling quantity corrections of the weighing control.

Always on the move

Dosing the last cavity presents one of the biggest challenges, because the expensive product consists of a liquid and special microbeads mixture. It is essential to maintain the homogeneity of the solid and liquid

parts. This challenge was solved in close cooperation with Promega by developing a special recirculation device. The amount of liquid that has not been filled returns to the tank through a hose, connected to the filling needle. In conjunction with a stirring device in the product tank, the original consistency remains unchanged. With this dosing system, Promega benefits from minimized product loss, fewer rejects, and assured product quality.

During the subsequent closure, the film is placed over the entire length of the cartridge and then precisely sealed. It is crucial that all edges of each cavity are completely sealed to prevent the liquids from cross-contamination (for example during transport). These sealing edges also withstand alcohol-based liquids. After sealing, a print is applied to the side of the container and verified by two cameras. An additional print is applied to the foil on top of the container.



↑ Still upside down, the cartridges are blown out from below.

Checked and without gaps in the tray

Now the cartridges are placed into the trays. However, there may be empty spaces in the transport rake caused by deviations during the inline quality control when cartridges were rejected. Quality samples requested through the HMI during production also can cause gaps. To ensure that every tray is complete, Optima has integrated another sophisticated system: An intermediate shuttle that can be moved to the transport rake. If there are any empty spaces, the intermediate shuttle is aligned accordingly so that there are no gaps after the cartridges have been pushed over. As soon as eight cartridges are lined up, the formation is taken over by a pick & place conveyor and precisely inserted into a tray.

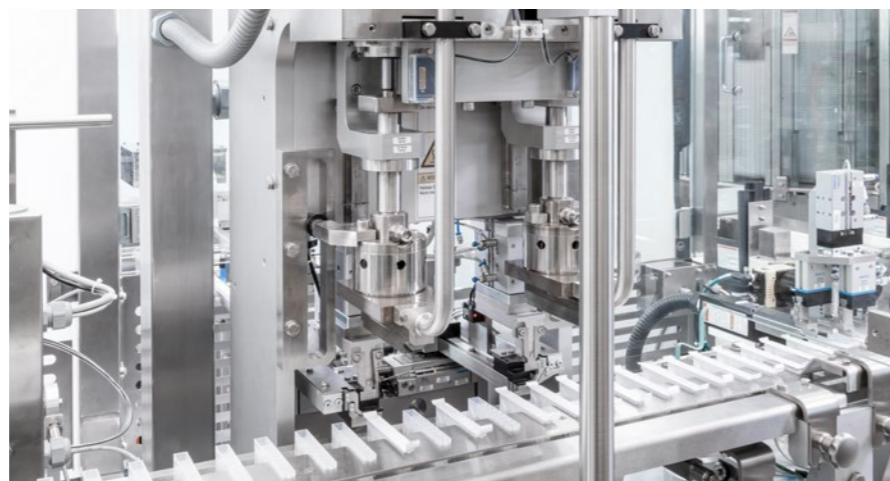
Precision timing

The line processes up to 3,600 cartridges per hour. The system is equipped with a laminar flow from the infeed to the discharge conveyors. In addition to the controlled airflow above the containers, this creates a slight overpressure in the system, which keeps particles out. The OPTIMA Linoline is currently designed for three formats. Optima met the customer's requested timeline of 12 months, including the installation at the Promega location near Madison (WI) – another result of the successful cooperation between the two companies. ☺



↑ The large tray magazine has space for different tray formats.

→ Precision is required for two-lane sealing to seal all cavities evenly – all around. At the same time, the quality of the sealing seams has to prevent potential delamination caused by the diagnostics, some of which contain alcohol.



← Cameras check the print applied vertically to the cartridges.



→ MORE ABOUT THIS TOPIC


And the customer perspective? Promega about the project and partnership

"Because of the pandemic, we quickly needed additional capacity to accommodate demand for our Maxwell line," says Promega project manager Sarah Melsen, explaining the background for the third joint project. "Optima guaranteed us a timeline of 12 months from project order to delivery for a 'copy' of our first Optima line. Based on the proven partnership, we decided to award the contract to Optima without a proposal request."

Looking back, the project manager reports: "The first cartridge line gave us the confidence in Optima's quality and technical ability. The precision and detail given throughout the entire process, from filling to sealing, stands out. Over the course of both projects, the teams from both companies learned how to bridge the differences between countries, cultures and languages, which helped to deliver the second project on time. The same teams that worked on the previous project also completed the new line, resulting in a seamless process and expedited delivery."

With regard to the operation of the OPTIMA Linoline 120, Melsen names the advantages: "Throughput and the possibility of being able to process many different containers and formats by using size parts. Another benefit is the easy access to the various functional units for the operators due to the machine layout. In addition, we carry out In-Process Controls (IPC) at a very precise level, even with extremely small fill volumes. The user interface, having numerous menu levels, ensures excellent control over all functional units and keeps us informed on all activities."

Now that three Optima systems are installed at Promega, Melsen is certain that Optima is very competent in all its disciplines and has developed numerous creative solutions to many questions and topics. She says: "For Promega, these are effective systems with high throughput."



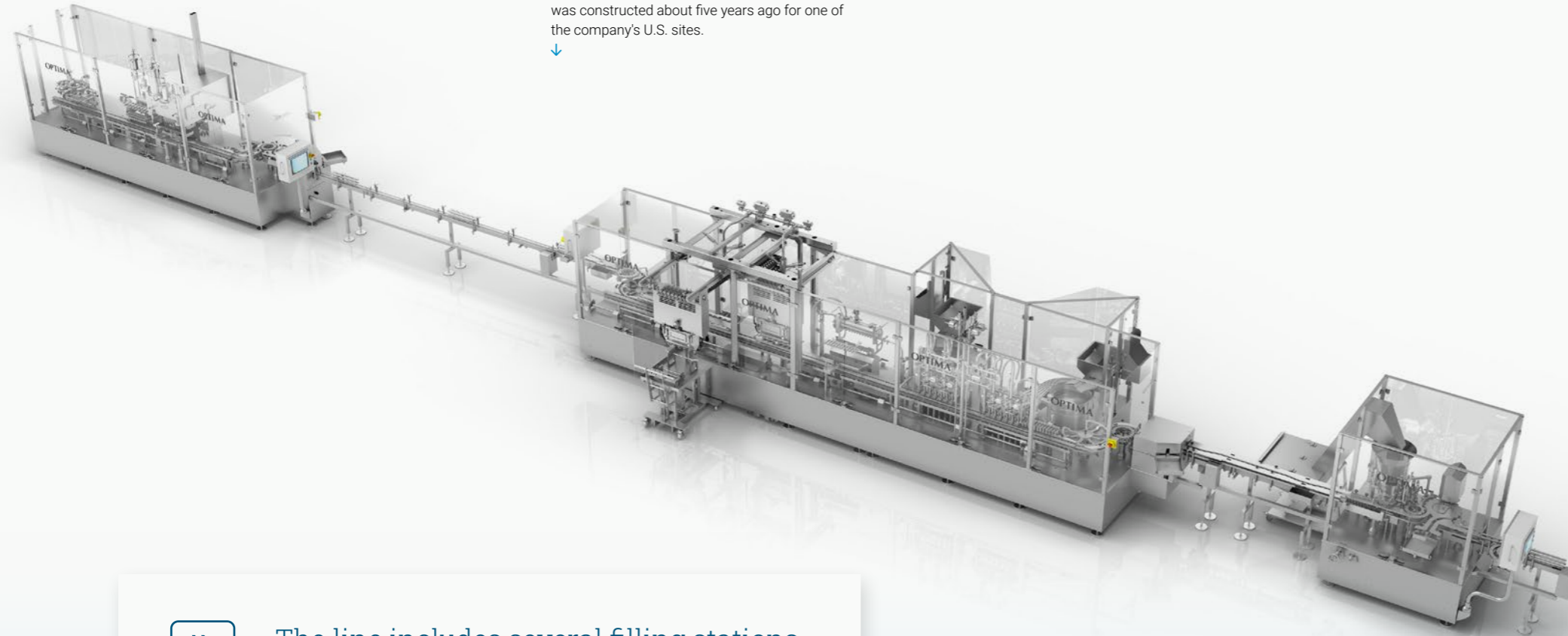
Technology transfer for diagnostics in China

IMPORTANT FOR YOU

- In the future, bioMérieux will produce a successful diagnostic product in China too
- The engineering process has been made easier and faster by duplicating a proven Optima system from the USA
- Dosing four different media requires a wide variety of dosing methods to be well mastered, synergy effects within the Optima Group are a driver for success
- The Chinese operating team familiarizes itself with the complex technology by using a semi-automatic laboratory pilot line

One vial, one filling material, one closure – done. But it is not always that simple. In fact, when diagnostic products from bioMérieux are filled, there are four very different media. In 2016, Optima Pharma has developed a specific production line for this. Because of the principle of “never changing a running system”, the company has decided to purchase a duplicate of this system for its Chinese production site in 2021. Operators there are able to familiarize themselves with the process in advance, using a laboratory pilot line from Optima Pharma to run the approval process.

bioMérieux's vial filling line for diagnostic media was constructed about five years ago for one of the company's U.S. sites.



By combining different processes, the line masters the dosing of four media with very different properties – from spray dosing of a liquid to the addition of the resin-like reagent.



The line includes several filling stations for very different media that are not easy to handle.

Claudio Schneider, Project Engineering Manager at Optima Pharma

Suzhou, with its many canals, is known as the Venice of the East. The city, with its numerous gardens and temples, attracts not just a large number of tourists. Numerous international companies such as Apple, Bosch and GlaxoSmithKline have settled in this booming metropolis situated about 100 km west of Shanghai. bioMérieux is a global leader in in-vitro diagnostics and also operates one of a total of six Chinese subsidiaries there. As part of new production facilities, a vial filling line for one of the manufacturer's best-selling products is to be built there. bioMérieux is already producing the diagnostic product in the USA using a special, complex process line that was set up by Optima over five years ago.

The great market success of the product made it vital to increase capacity, and at the same time to conquer the Asian market. Firstly, the U.S.-based project team and the company's French headquarter thoroughly reviewed the options with a variety of line types from different manufacturers before making a decision: They came to the conclusion, to replicate the technical solution used in the previous successful project is the best option. In addition, the decision was taken to set up a semi-automatic laboratory line that would accurately map the process. Alain Gourmelon, Senior Vice President Global Manufacturing Support & Industrialization at bioMérieux, explains what the aim was: "By doing this, we want to develop the relevant expertise at

our Chinese site ahead of time. The employees there can acquaint themselves with the technology they need right away. This will ensure the smooth ramp-up of the production line." In addition, the pilot line will support the product approval process for China ahead of time so that the filling line can go directly into production as soon as it is delivered. It is worth taking a look at the USA to understand the process. This is where the big brother of the future Chinese line is already located, with twice the capacity. In the USA, the different dosing and filling modules, as well as the capping machine, have a double design. There, the two lines intersect at a furnace where the partly filled vials are heated. At Suzhou, all of this is only needed once.



In addition to the fully automated production line, Optima Pharma supplied a laboratory pilot system for Chinese staff to get to know and train the process.

Sharing its experience worldwide is part of the bioMérieux DNA

Almost a 100 percent technology transfer – bioMérieux is extremely consistent in this respect. “Sharing experiences and practices worldwide is part of bioMérieux’s DNA as a way to learn and grow together. So we prefer to rely on the well-established technology of our proven solution,” says Will Darrigrand, VP Engineering Americas at bioMérieux. This makes it easier for the U.S. team, who are familiar with the line, to provide future support for the Chinese team.

The Project Engineering Managers, Claudio Schneider and Mark Seitz, who were entrusted with project planning for the new line in early 2019 at Optima Pharma, were able to build on existing technology. “The line includes several filling stations for very different media that are not easy to handle. This is due to the

high complexity of bioMérieux’ s product,” explains Schneider. Different filling techniques for very different media and quantities have to be combined. Additionally, there is a great difference in the requirements for filling accuracy.

The line includes three dosing modules. After determining the exact tare, the vials reach the first station; here their inner walls are sprayed with the first medium by a micro-dosing device. Without any further intermediate weighing, the next station delivers a second liquid. After controlled weighing, the bottles pass through a tunnel oven where the added components are dried. This is followed by the second filling machine. Here a resin-like medium is introduced after a further weight check. Schneider explains that this stage, which is performed with the aid of an auger doser, as being particularly difficult: “The dosage of that component is highly dependent on its moisture



↑ The technology transfer makes it easier for the U.S. team, who are familiar with the line, to provide future support for the Chinese team.



↑ The project for bioMérieux shows that technology transfer pays off, for both sides.

content. In this respect, the experience gained in designing the U.S. line has been of great help.” After the correct dosage has been checked by the next in-process control load cell, twelve vials are simultaneously filled with another liquid medium. Finally, they are closed with a stopper and fitted with a cap, which is subsequently crimped.

Complex technology in the laboratory pilot line too

This technology is also used in the laboratory pilot line, although a variety of steps are carried out by hand. It had already been delivered and is ready to run, around few months before the production line. A few thousand vials will probably have been produced by then, which will be used, among other things, for team training and local know-how development.

In each case, the technical platform for dosing the key components is the OPTIMA VFVM filling machine, where a rake ensures the safe transport of bottles. There is a total of five in-process control points that ensure quality by verifying correct filling with the individual components of the diagnostic product. At the end of the line, there is the OPTIMA VVM2428 closing machine, which also carefully transports the products. The line was successfully delivered to China. Both the manufacturer and the users were able to draw on the tried-and-tested processes of the preceding system. Technology transfer pays off. “In this way we will benefit once again from Optima’s experience and the reliability of its technology,” expects Foster Zhang, Senior Director of Manufacturing at bioMérieux China. ☺



It's all happening here:

PCR tests during
corona pandemic

i IMPORTANT FOR YOU

- A new system for PCR diagnostics and the upgrade of an identical existing machine in 10 months during the peak of the pandemic
- Drives and safety technology were updated and various technical improvements implemented
- Minimized introduction and installation phase (new system) and conversion phase (existing system) with minimized interruptions to production
- Crucial to the success of the project was a very close coordination at all levels with the customer and Optima internally

Most countries have largely recovered from the Covid-19 pandemic. In 2020, things were different. During a filling project for PCR diagnostics, time was of the essence – to complete the project faster than originally planned. Two rotary machines, one new and one existing machine, which was upgraded to state-of-the-art standards, were to go into operation on time.

The motto of the project was, “the sooner, the better”. However, even under time constraints, machine quality remained the most critical criterion. After all, the well-being of many people depends on proper production processes. The project was based on an existing custom-designed system for filling diagnostic liquid into cartridges and closing with a film. Now, the customer wanted the exact same system, processes, and functions as the system built in 2008, while adhering to the latest technical and safety standards. Simultaneously, they sought to update their existing system to the same standards.

PCR tests in the pandemic

It can be safely assumed that the customer, a renowned company for active pharmaceutical ingredients, as well as diagnostic tests and ingredients, was satisfied with the first edition of the machine, if it is to serve as a template for the second, new system, 12 years later. At the same time, 12 years of daily operation inevitably led to insights how to improve the system. Feedback from the customer and the Optima service department, which maintained the existing system over the years, was directly incorporated into the new design.



Two-stage filling of 50% of the total volume leads to an increase in performance.



← Part of the updates to the first machine version was a new container magazine. This means the systems can now be operated without interruption.

The improvements included, in particular the drive, the conversion to current safety standards and technologies, as well as various additional material upgrades. The new installation and modifications to the existing system would unavoidably interrupt ongoing production. Consequently, the project team had to make this project phase as short as possible. The intended timeframe for the entire project: 10 months – instead of the minimum 12 months Optima had originally calculated.

Fast track for the project

Reducing the time line by two months requires intensive cooperation from everyone – internally and externally. A strategic and trusting partnership, like the one that has been established with this customer for years, is very beneficial. Pushing the limits regarding the project timeline also means that many, but not all, customer requests can be implemented within the required time frame.



↑ Pre-sealing at four points and then final heat sealing. No waste: 100 Percent of the film is used.



↑ After pre-closing, there is enough time to complete the final heat-sealing with a high output.

Rational and quick decision-making by management, speedy design reviews and the contribution of everyone working with the machines on a daily basis, characterized the close cooperation with the customer.

Meanwhile, Optima service technicians provided valuable input on how to improve the machine's durability and precision.



← As part of the updates to improve format changes for the five different container sizes, updates were installed.

At Optima, particularly close coordination was required between the design and technical purchasing departments – to clarify which parts would be available and when, or whether there was a useful alternative. At this point, the supply chains were already under significant strain and demand on pharmaceutical suppliers high.

Technology upgrade: Increased performance

Five different, custom-designed cartridge formats are processed on the system. A revolving magazine serves as container storage, into which entire container "towers" can be inserted manually. From this enlarged magazine, the containers are stacked into a transport

Saving two months of time requires intensive cooperation between all those involved – internally and externally. This requires a strategic and trusting partnership with the customer.



star wheel. In the updated machine versions, the revolving magazine and the entire system are equipped with a servo drive, which allows more time for stacking into the transport star wheel leading to an overall increase in performance. In addition, operators can now add containers during operation, which greatly increases system efficiency.

The rotary machine has two filling stations with rotary piston pumps, each filling 50 Percent of the diagnostic liquid. Dividing the filling process into two stations provides a higher performance than filling 100 Percent of the product at a single station. The filling station is followed by the first closing station, where aluminum film is fed from the roll and decontaminated inline using UV radiation. Its width corresponds exactly to the container dimensions therefore, 100 Percent of the film is used without creating any waste. The punched-out film is placed on the container by pick-and-place and fixed at four points. With the fixed film on the cartridges, they are then transported to the second closing station, to heat seal the film. A laminar airflow covers the revolving magazine, filling and closing station completely.

Fully in control

All (repeatedly) inspected cartridges are now transferred to an inkjet printer with a linear transport system. The film is imprinted and checked for accuracy by

a camera system. A continuous scale checks the cartridges for their final gross weight. Once these inspection points are passed, the products from the two diagnostic machines are combined on a newly installed conveyor and transported to the automated secondary packaging equipment.

Material improvements were made to the star wheel and shafts. Parts previously made partially of aluminum are now designed in stainless steel. These format parts are not only more durable, but offer greater long-term precision, for example during heat sealing.

A good plan saves time

Finally, in the midst of the pandemic, the installation phase of the new system took place, including the rebuild of the existing system with the new format parts. Exact timing was the key. To reduce machine downtime as much as possible, Optima once again closely coordinated with all departments. Optima sent two teams of specialists to the customer site. Setting up a new system and converting an existing system on site are two different things, each having their own individual challenges. The intensive planning, and carefully examination of the conditions on site, paid

off. Both the installation and conversion time windows were met – as well as the entire project timeline of 10 months. Both systems operate according to the customer's requirements. The maximum output of both systems is identical: 1,500 objects per hour.

After completing this project, the customer placed another order for a diagnostic machine with Optima – positive customer feedback! This time it is a significantly larger system and another custom designed machine to meet specific customer requirements. ☺

Interview

with Dr. Stefan König



Dr. Stefan König has been a member of the Optima Group management board since the beginning of 2021.

“OPTIMA has evolved from machine manufacturer to solution provider”

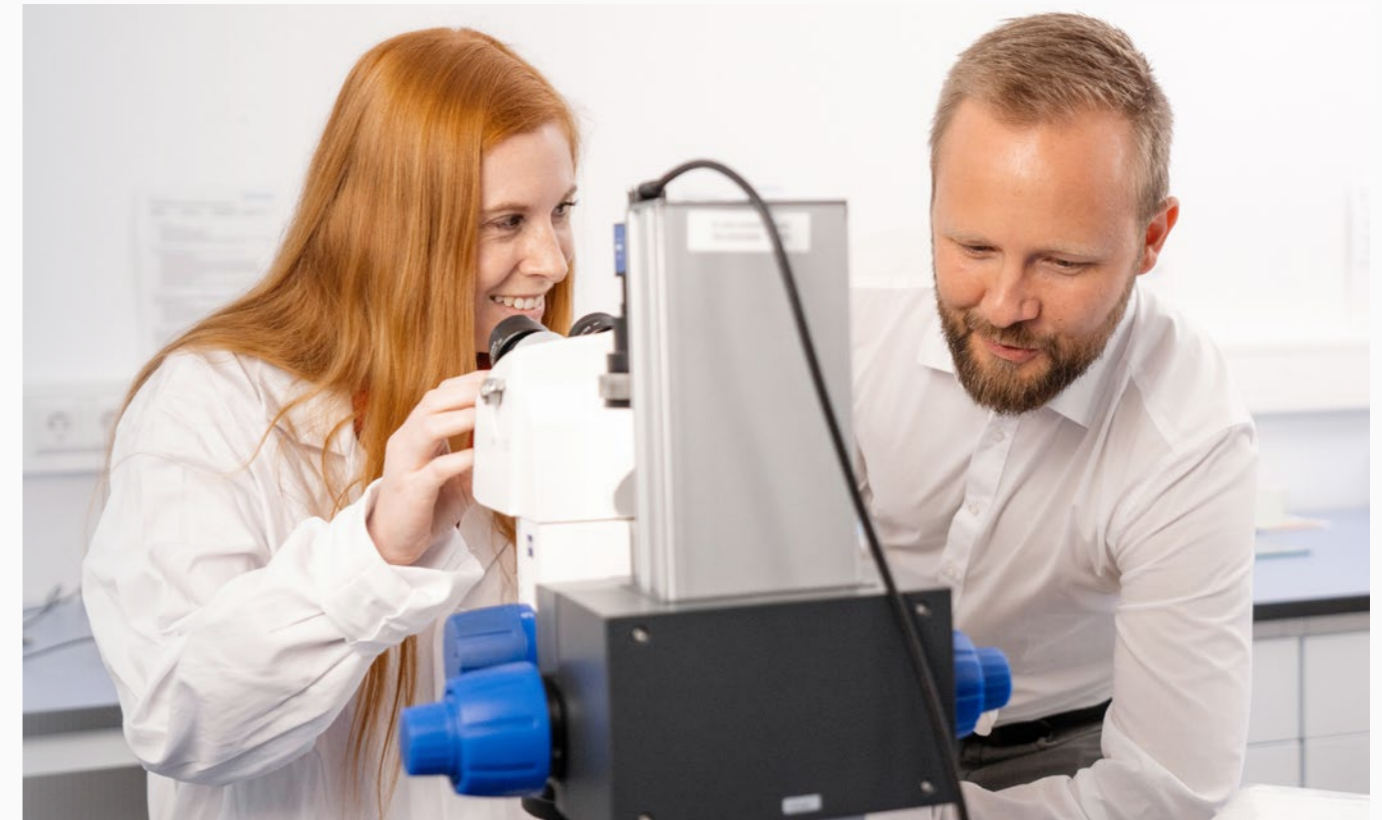
What does sustainability mean for Optima?

We understand sustainability as long-term, partnership-based and resource-conserving management. Our goal is to safeguard the world for future generations. Sustainable production, filling and packaging along the entire value chain – this is what our core sustainability strategy “We care for tomorrow” stands for. That’s how we wish to excel across the board in the areas of the environment, social affairs and corporate governance. Our strategy is based on three pillars.

- **Circular packaging:**
In cooperation with our customers, we develop straightforward packaging solutions that enable a functioning circular economy.
- **Corporate sustainability:**
Optima is committed to ecological, fair, and successful long-term business practices.
- **Sustainable technology:**
We design machines and systems to operate as resource-efficiently as possible while taking the entire life cycle into account.

How have the demands of the market changed in recent years?

In the past, product packaging usually consisted of a non-recyclable material mix with the focus on cost minimization. Sustainability aspects were not considered. The task of machine manufacturers was clearly defined: Please design a packaging system for this product with this packaging.



↑ Working together with customers and partners, Optima is developing sustainable packaging solutions – from the initial idea through to production.

Today, we use many new products, including concentrates and dry products. These require new packaging with a holistic sustainable design, and often portion packaging. New alternative materials are being used, which require other sealing processes, for example. Optima has evolved from machine manufacturer to solution provider. Today, the requirement is: This is my product, please assist me in developing sustainable packaging and transferring the concept to a fully automatic high-performance packaging machine (engineering-to-order). We accompany and guide our customers from the initial idea to successful production. This includes, for example, consultation on packaging. The focus is on aspects such as the style and type of packaging, the materials used for packaging, the product protection and the legislation applicable in the country. In addition, our service portfolio includes the manufacture of samples (simple mock-ups or samples for test markets). We also conduct barrier tests and shelf life tests together with our partners. Small semi-automatic systems are then scaled to fully automatic turnkey systems.

How long have you noticed a growing interest in sustainability topics?

For around four years now, we have noticed a greater demand for sustainable packaging solutions. Our customers have been inquiring about sustainable packaging solutions for around two years now. The demand today is for an overall sustainable concept tailored to the company (at Optima: Corporate Sustainability) and product (at Optima: Circular Packaging and Sustainable Technology).

Which specific wishes and demands does Optima receive?

Alongside the changing market requirements already described, the systems need to be as flexible as possible when it comes to packaging materials. The currently changing legislation in Europe (packaging directive) is a game changer. Here, we expect to see new packaging requirements. This is why our customers want to change their systems over to alternative materials very quickly.

Which trends are you seeing in Germany and other countries in this context?

In addition to the required flexibility in terms of packaging materials, using paper as a packaging material is a very clear trend. Two reasons are apparent: The recycling possibilities for paper are the most well developed in the world, and end consumers consider it the most sustainable packaging material. If you compare Germany with the rest of the world, we are one to two years ahead when it comes to plastics recycling.

How will packaging machines, filling and production systems continue to change with regard to sustainability aspects?

For us, it is particularly important to meet the demand for maximum flexibility in terms of packaging material. Machines will have to be checked for alternatives in the future in terms of the materials used. Manufacturing processes must be weighed up against each other regarding sustainability aspects. Different technologies for performing specific functions need to be compared. This will ensure that we continue to reduce the product carbon footprint holistically in the manufacture and usage phase.

Which specific sustainability goals has Optima set?

By consistently using renewable energy sources, Optima has already been able to reduce greenhouse gas emissions by 40 percent. With an extensive package of measures, we will reduce our climate footprint by an additional 25 percent by 2030. The company is also systematically working on advancing emission reduction goals using the approach of the Science Based Targets Initiative (SBTi).

With regard to regulatory measures: how do you see the development here?

We welcome suitable regulatory measures that continue to drive forward the topic of sustainability in a positive way. This means that projects, which have not been implemented recently for cost reasons, could be realized with a positive effect for the environment.

With the new travel set "Trific" the cooperation partners Optima, Holmen Iggesund, Yangi® and FutureLab & Partners are revolutionizing the value chain for personal hygiene travel sets.



Optima offers a new sustainable can portfolio with different shapes and closure solutions. The highlights include aluminum-free barrier solutions and a completely fiber-based lid with hinge function.

Taking into account the entire packaging industry as well as the consumer goods industry: Do you get the impression that everyone involved is pulling together or are there areas making compliance with sustainability criteria difficult?

We are setting a good example here. For years now, we have relied very successfully on cooperations across the entire value chain, for example with three partner companies from Sweden, in order to develop the sustainable packaging concept "Trific". As a technology partner, Optima has supported the development of a sustainable travel set for daily personal hygiene from renewable, fiber-based raw materials. The project aims to motivate brands to switch to sustainable packaging. ☺

Global in-vitro diagnostics market

Outlook

2022 to 2032



85 bn € market size
in-vitro diagnostics
market in 2022



25% share
immunodiagnostics
of the total in-vitro
diagnostics market
in 2022



4% annual growth
(CAGR) of the in-vitro
diagnostics market
from 2022 to 2032



Over 5% annual growth
(CAGR) for molecular
diagnostics, forecasted
highest growth of all
segments until 2032



Distribution worldwide
diagnostics market
39% North America
23% Europe
29% Asia-Pacific
8% Latin Amerika