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Innovations for the **diagnostics of tomorrow**

Dr. Mike Mohns
Director Diagnostics,
OPTIMA pharma GmbH

Dear readers,

The diagnostics industry is evolving at a remarkable pace. Growing demands for flexibility, productivity, and supply security are accompanied by an increasing diversity of products, formats, and markets. For diagnostics manufacturers, this means that production processes must be both efficient and scalable.

The articles in this issue demonstrate the many ways these challenges are addressed in practice. They provide insights into successful customer applications, highlight the potential of digital twins for faster and more reliable equipment projects, and show how our global Technical Support Management strengthens production reliability and equipment availability around the world.

As a partner to the diagnostics industry, we look beyond individual machines and focus on the entire production solution. Whether through modular systems, digital technologies, or a globally connected service network, the key factor is always the tangible value delivered to our customers. Our goal is to help diagnostics manufacturers bring innovative products to market reliably and with confidence for the future.

I hope you enjoy reading this issue and look forward to continuing our exchange with you.

Dr. Mike Mohns

Director Diagnostics
OPTIMA pharma GmbH

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ImmuCoats at BioChek:
Performance meets flexible scalability

BioChek's production setup is designed for medium to large batch sizes. Its unique manufacturing strategy leverages both the flexibility of the ImmuCoat production system and the benefits of economies of scale. Years of successful production and service experience have proven the concept. Today, four base stations are used to manufacture and package 53 different diagnostic test types and variants.

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Interview with Dr. Mike Mohns

Dr. Mike Mohns, Director Diagnostics at Optima Pharma, brings extensive international experience from leading diagnostics companies. Since September 2025, he has been strengthening the team and driving the further development of the diagnostics business. In the interview, he shares his first impressions, discusses the role of Diagnostics, and highlights the importance of holistic turnkey solutions. His goal is to develop flexible, future-proof systems that support diagnostic manufacturers worldwide in ensuring a reliable supply of diagnostic tests.

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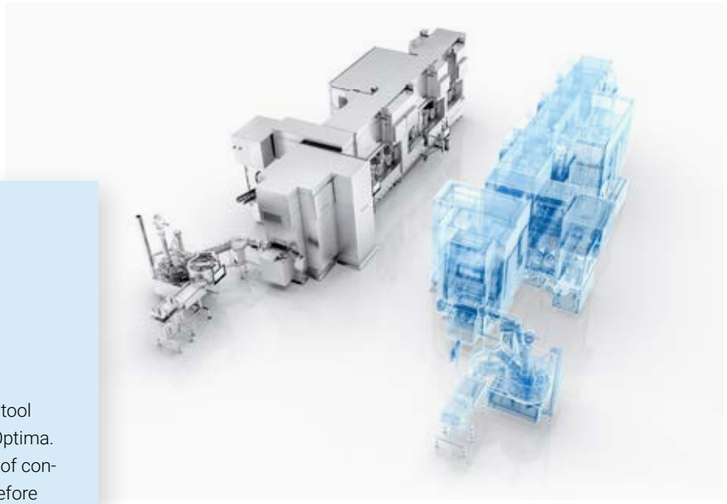
Technical support

Optima Pharma's Technical Support Management (TSM) is expanding globally, providing fast and expert support through local teams in North America, Asia, and Europe. Leveraging a global network, digital tools, and specialized expertise, many service cases can be resolved quickly and often remotely. Continuous investments in locations, know-how, and technologies further strengthen customer support worldwide and help reduce response times.



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Digital Twin

Digital twins are becoming an important tool for more flexible production projects at Optima. Already today, they enable virtual testing of control software, training, and simulations before a real machine is commissioned. This helps shorten commissioning times, reduce risks, and improve efficiency. The long-term vision is a comprehensive digital twin that accurately represents complex turnkey systems and enables real-time testing, optimization, and process simulation.

News

Closer to customers worldwide

To strengthen customer proximity and shorten project lead times, Optima further expanded its global network in 2025. Alongside growth activities in the United States and the expansion of engineering and production capabilities in India and China, new locations were established in Ireland, Italy, and Saudi Arabia. This local presence enables closer collaboration, faster response times, and stronger partnerships with customers. Further expansion is planned for 2026, with additional offices scheduled to open in Slovenia, Spain, and Denmark, reinforcing Optima's global footprint and customer support network.

Targeted expansion of facilities

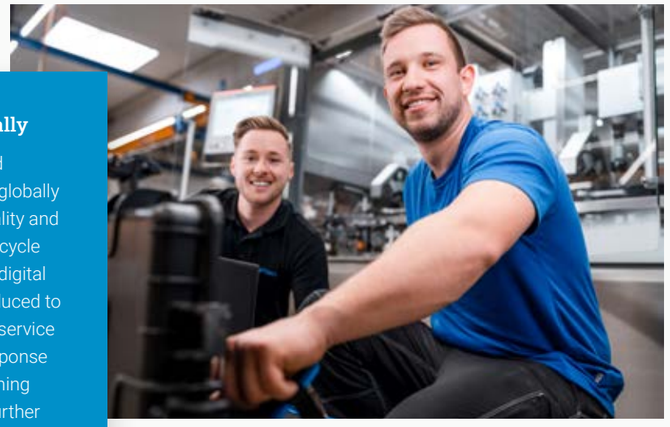
Optima Pharma expanded its capacities across several locations. In Radolfzell, a new 1,800 m² assembly hall for state-of-the-art isolators and more than 100 new office workplaces were added. In Schwäbisch Hall, an additional 4,800 m² facility was equipped to meet the specialized requirements of pharmaceutical machinery engineering. In Gladenbach-Mornshausen, assembly capacities for freeze-dryers were increased by 50% to address growing demand. These infrastructure investments are part of a comprehensive growth initiative that also includes team expansion across all sites, strengthening both future growth potential and in-house technological expertise.

Expansion of training center and training capabilities

The education and continuous development of employees and customers were a clear focus in 2025. With thousands of training days delivered worldwide, Optima made targeted investments in building professional expertise across its global organization. At the same time, the Optima Pharma Training Center in Schwäbisch Hall was expanded with a new two-story extension. Modern training facilities and state-of-the-art equipment now provide ideal conditions for hands-on qualification programs and effective knowledge transfer.

Fiscal Year 2025: OPTIMA continues to grow

In fiscal year 2025, Optima increased its revenue by six percent and created around 300 new jobs. The company also published its first Sustainability Report and was awarded the EcoVadis Platinum Medal for the second consecutive year. This recognition is reserved for companies that demonstrate outstanding performance in environmental management, social responsibility, and sustainable business practices. These achievements underline Optima's commitment to profitable growth while maintaining a strong focus on sustainability and corporate responsibility.



Service strengthened and expanded globally

Optima Pharma has continuously enhanced and expanded its service organization worldwide. A globally aligned service portfolio ensures consistent quality and clear points of contact throughout the entire lifecycle of customer equipment. At the same time, new digital solutions and service offerings have been introduced to address specific customer needs. International service hubs and additional resources enable faster response times and closer on-site support. Expanded training programs for both customers and employees further promote knowledge sharing, reinforcing service as a strategic partner in reliable and efficient production operations.

Follow the new channel and become part of the community.

Diagnostics and pharma news: the new Optima Pharma LinkedIn channel

Since March 2026, Optima Pharma has been present on LinkedIn with its own dedicated channel. The goal is to provide more targeted diagnostic and pharmaceutical content and give customers direct access to relevant industry expertise. The channel offers insights into solutions, technologies, and innovations from the diagnostics and pharmaceutical sectors, tailored specifically to industry needs. It delivers valuable updates, expert perspectives, and inspiration while strengthening Optima Pharma's visibility within the market and creating an additional platform for direct engagement and exchange.

IMPORTANT FOR YOU

- BioChek uses Optima ImmuCoats with a dedicated production approach optimized for high output.
- Four ImmuCoat base stations produce and package a total of 53 diagnostic product types with high precision.
- Production capacity has recently been expanded with a new base station featuring highly flexible module configurations.
- Process simplifications and a new BioChek product line are under consideration. Extended drying units and dispensing stations can be integrated as modules at any time.
- Precision, reliability, and both remote and personal service have proven effective for years.

ImmuCoat systems at BioChek

Performance meets **flexible scalability**

BioChek develops and produces diagnostics for poultry and swine health. Their ELISA microtiter plates are manufactured on Optima ImmuCoat systems, with a distinctive production setup that maximizes both output and flexibility. This is demonstrated, among other things, by the recent expansion with a new ImmuCoat base station.

↑
Almost there: the Optima systems are arriving at BioChek's new, larger site in Bracknell.

Since 2018, BioChek has relied on Optima's ImmuCoat machine concept and it continues to offer several key features. Above all, functional modules can be added or modified within the process flow very easily – sometimes even without programming. BioChek primarily leverages the ImmuCoats for "economies of scale," while also taking advantage of their flexible configuration.
In an interview in April 2026, Harrison Williams, Technical Specialist at BioChek, explains the company's distinctive production structure. Here, ImmuCoats operate as stand-alone machines.
In the multi-stage coating process for ELISA microtiter plates, each ImmuCoat base station is dedicated to a single functional sequence per run within the complex coating process – for example, destacking, dispensing, and aspiration. Other diagnostics manufacturers, by contrast, typically build an inline process with the ImmuCoat system, in which functions follow one another continuously – step by step, including incubation – ultimately resulting in a fully processed and packaged product.

ImmuCoats deliver high output

Williams, on the other hand, describes the individual ImmuCoats at BioChek as "workhorses" that operate almost continuously each day. For example, a batch of a specific test may begin on Monday with destacking, de-ionizing, printing, coating and LVU fill-level checks in the wells. This is handled by one base station. Operators then take the processed, machine-stacked ELISA plates and transport them for overnight incubation. On Tuesdays, for example, the process begins with aspiration, followed by the dispensing of a blocking solution and then a further incubation phase. Aspiration is carried out again on Tuesday, after which the batch is left to dry overnight. On Wednesday, the fully processed and tested microtiter plates are packaged into pouches by the Optima system – meaning that a batch is ready in its primary packaging.
In this production setup, each base station is equipped with multiple functional modules. This allows one station, for example, not only to print, but also to dispense, extract, block and verify, etc., at any time. At BioChek, the intervening incubation and drying phases each take place in a separate room.

Williams can balance this production system very effectively. For instance, he knows that pouch packaging processes are relatively the most time-consuming. In the future, the pouch station from Optima will therefore be exclusively linked with modules for feeding in fully coated tests. Comparatively faster production and inspection steps related to coating ELISA plates are carried out on the other, larger ImmuCoat base stations at BioChek.
Recently installed Optima OPAL software automatically evaluates machine performance and generates batch reports, increasing transparency and helping meet regulatory requirements.

International markets increase production complexity

BioChek's current product portfolio includes 25 ELISA tests for poultry and 11 test types for swine virus infections, along with subgroups tailored to international markets with specific regulatory requirements.
Williams illustrates this using the example of the United States, where abbreviations for ingredients and infectious diseases are not permitted. As a result, labels and printed text are significantly larger than for tests intended for Europe and Asia.
Regional variations in viral infections are also reflected in production. To achieve precise test results, certain proteins (based on formulations) must be replaced with others to ensure accurate detection of local samples. This increases manufacturing complexity: In total, BioChek produces 53 different product types on Optima systems.

New ImmuCoat station, new process options

On the very day of the interview, another ImmuCoat base station arrives at BioChek. Three of the four ImmuCoats can accommodate up to 12 functional modules, while the station reserved for pouch packaging can hold a maximum of six. All base stations still have unused slots, allowing BioChek to increase output or functionality at any time.
With the new production setup, a capacity of up to 16,000 ELISA tests per week is achievable. At the current level of around 9,500 units per week, there is still room for growth.
BioChek typically plans batch sizes of at least 1,000 units for the ImmuCoats, benefiting from scaling effects. Often, batches even reach up to 3,000 tests. Smaller batches are handled using benchtop devices from another manufacturer.

Relocation, training, and qualification

The flexibility of ImmuCoats is further demonstrated by the company's upcoming move to a larger facility in Bracknell near London. There, BioChek plans to adapt its production process by modifying the modular configuration of the systems.
Two ImmuCoat base stations will receive new functional modules, including additional infeed units and inline process controls, complemented by existing modules. One base station will remain unchanged. BioChek could implement these changes itself at any time – "plug and play" is a perfect description.

↑
Not just during the move: fast and competent service is essential for BioChek.

↑
ImmuCoat base stations have empty slots: BioChek can flexibly increase capacity and add modules for new products.

Optima teams from Schwäbisch Hall and Norwich (OPTIMA machinery UK PLC) will support the conversion, training BioChek's growing operator team to broaden system knowledge across staff. They will also assist with dismantling and reassembling the equipment, installing the new process, and carrying out installation and operational qualifications (IQ and OQ). Following the PQ, regulatory audits will be carried out by, amongst others, the US Department of Agriculture (USDA).

Top priority: ELISA test quality

Despite all economies of scale, the quality of each individual test remains fundamental to BioChek's success. Test reliability and sensitivity depend significantly on the precision of dispensing into the 96 wells of a microtiter plate.
BioChek uses a two-stage control process: fill volume and variability. All three production ImmuCoat base stations are equipped with LVU (Level Verification Unit) modules, which use ultrasound technology to continuously monitor fill volumes in each well. Plates exceeding tolerance limits are automatically rejected. Additionally, manual checks of fill volumes per well are conducted at the start of each batch to assess variability. If variability is within the defined range, Williams knows that the LVU system will reliably monitor the process.
High precision is also ensured by gentle, parameterizable dispensing processes. All pumps feature bubble detection, contributing to consistent dosing. In practice, this prevents splashing or droplet formation outside the wells. Rare dispensing issues are usually due to intensive use and large batches and can typically be resolved through simple cleaning. Changes in formulations or flow properties can be compensated by adjusting dispensing parameters. Machine reliability is also impressive:
"The machines have been running daily for years, all day long – and we very, very rarely encounter problems," says Williams. Regular maintenance services play a key role in this reliability.

Flexibility: Ready for the future

Until now, there have been only minor changes to the production layout, mainly adding pouch packaging. However, the recent capacity expansion and modular enhancements clearly demonstrate the system's strengths. At the new site, production can be easily adapted.
Inline drying modules for antibodies/antigens are also under consideration, which could further simplify and accelerate processes. A new product line, recently discussed at BioChek, could also be implemented that would involve dispensing two different proteins at 50 microliters each. This would simply require installing an additional dispensing station, eliminating the need for a second processing cycle. Spare module slots are already available.
Another advantage is the system's response to occasional defects. Employees can remove a faulty module and continue production – possibly at reduced capacity – using an empty slot. Optima UK typically keeps key spare parts and modules in stock.

Team spirit: Harrison Williams (left, Technical Specialist at BioChek) and Optima staff from Norwich and Schwäbisch Hall. →

Once delivered, the BioChek team installs them independently, and the system resumes normal operation quickly.
Fast format and product changeovers are also part of the flexible system design. Williams estimates a turnaround time of 15 to 20 minutes between products. During changeovers, dispensing and aspiration units are cleaned in place, while another operator prepares the next coating solution.

Remote and on-site service

Finally, Williams praises the service. Remote connectivity allows Optima experts to access the systems directly if needed. At the same time, he values personal interaction with engineers to resolve issues independently. Production typically resumes the same day. On-site service technicians are also seen as a "bonus," willingly sharing their expertise.
The conclusion is clear: Check! Optima's systems meet BioChek's high and extensive expectations.

→ Two ImmuCoat base stations receive a new, expanded module configuration. Thanks to "plug-and-play flexibility," this is achieved with almost no programming required.

← BioChek's production structure strategically leverages economies of scale. Four ImmuCoat base stations will produce and package 53 diagnostic test types and variants.

> The quality of every single test remains the foundation of BioChek's long-term success.
>
> Harrison Williams, Technical Specialist at BioChek

Interview

with Dr. Mike Mohns

Dr. Mike Mohns joined our team as Director Diagnostics on September 1, 2025. In this interview, he shares his first impressions of Optima Pharma.

Tell us a bit about yourself. What should we know about you professionally and personally?

I've spent about 20 years living and working abroad – in France, England, Switzerland, Taiwan, and Singapore. That experience really shaped how I see people, cultures, and collaboration at work.
I studied biology in Darmstadt and Bordeaux, and later earned my PhD at University College London with support from Cancer Research UK. After that, I worked at a biotech company in France while also completing an MBA in International Marketing & E-Business.
Things really took off for me at Roche Diagnostics in Switzerland. As a product manager for Elecsys reagents, I worked closely with physicians to introduce new biomarkers. During that time, I also had the opportunity to take on international assignments in Taiwan and Singapore, where I led marketing and consulting teams and managed lab automation projects across Asia and even New Zealand.
After returning to Switzerland, I partnered with Hamilton to develop my first machine for Roche: the cobas prime – a pre-analytical platform for molecular diagnostics that's now used worldwide. I'm still very proud of that.
When I moved back to Germany, I worked at Abbott in lab automation before getting the opportunity at Optima to grow and lead the diagnostics division.

What were your first impressions of the company?

My first thought was: "Wow, Optima is incredibly well positioned!" The stainless steel machines still look brand-new, even after decades in use – that says a lot about quality. A great example is the Inova H3 filling and closing machine in the entrance area at Optima Pharma.
But what impressed me even more are the people. Many employees have been with the company for 20, 30, even 40 years. That kind of deep, long-term expertise is a huge asset and makes Optima a very special place. I really appreciate that.

Your background is in diagnostics. What drew you to this new role at Optima?

At Roche, I had the chance to show customers the filling line in Penzberg. It was fascinating – not just for me, but for my lab customers as well. The scale, the level of automation, and the speed at which the system processed containers and filled reagents were truly impressive.

That experience completely changed how we thought about reagent cassettes. Engineers had done something remarkable, making it possible to produce diagnostic tests for patients at scale. It felt like science fiction, but it was real.

> This expertise, built up over decades, is a valuable asset and a key differentiator for Optima.
>
> Dr. Mike Mohns, Director Diagnostics

So, when I got a call last year asking if I could see myself leading a team that builds these kinds of systems for the entire diagnostics industry, I couldn't believe it. This role allows me to significantly expand my impact: bringing in new customers and helping design machines that improve access to diagnostic testing worldwide. I didn't have to think twice. Who wouldn't jump at that opportunity?

How have your experiences in Taiwan and Singapore shaped your perspective on global diagnostics markets?

Business practices, expectations, and cultural dynamics can vary quite a bit – and that's exactly what makes it interesting. I've learned not to think in terms of "good" or "bad," but rather to recognize differences and adapt to them.
At the same time, there's one thing that's universal: Every lab, whether highly automated or mostly manual, depends on a reliable supply of reagents, controls, and calibrators. On-time delivery and consistency are critical everywhere.
That insight translates directly into what we do. Automation levels and packaging formats may differ, but in the end, what matters most is system reliability and confidence in the results.

What does the current claim "Turnkey solutions for diagnostics" mean?

In diagnostics, we use "turnkey solutions" a bit differently than in pharma. For us, it means fully automated systems – from infeed all the way through final processing, like palletizing – combined with full process control. If needed, that also includes assembling more complex reagent cassettes.
At the end of the day, the claim reflects Optima's approach to delivering end-to-end solutions for diagnostic production. We take full responsibility, both technically and organizationally, and serve as the single point of contact from the initial concept all the way to the finished system and beyond.

How do our diagnostics customers benefit from synergies with Pharma?

Optima Diagnostics is a focused unit within a larger, very strong pharma organization. About 70 colleagues work almost exclusively on diagnostics projects.
Where we've already established expertise, we operate independently. In areas where we need additional support, we tap into the deep knowledge of the pharma team – both technically and organizationally. That combination makes us extremely capable.

Where do you see growing demand in the future, and how do you plan to address it?

The diagnostics industry has been under significant cost pressure for years. Large players are competing aggressively with new business models, while Chinese companies are steadily gaining market share.
For us, that means our machines need to be faster to deliver, more flexible, and designed for long-term upgrades.

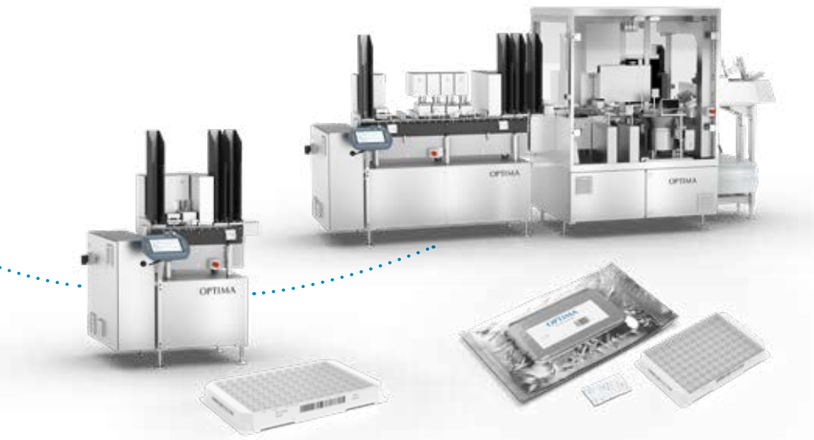
> We take full technical and project responsibility, from the initial concept to the finished production system.
>
> Dr. Mike Mohns, Director Diagnostics

From entry-level solutions to full integration

OPTIMA diagnostics portfolio

Coating and packaging

ImmuCoat und ImmuPouch

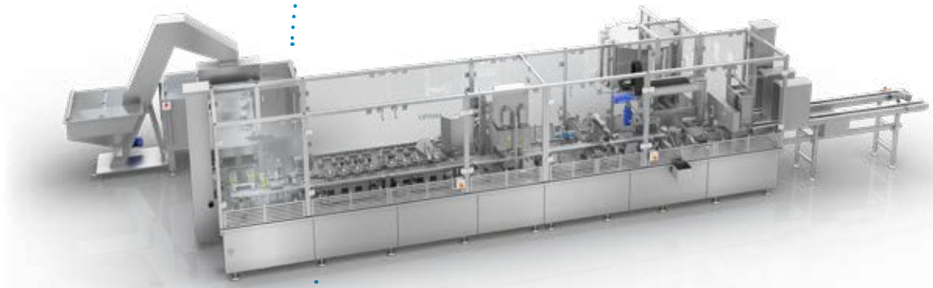


Our standard systems, ImmuCoat and ImmuPouch, deliver robust solutions for producing diagnostic test kits based on microtiter plates. **ImmuCoat** supports all key steps, including coating, incubation, and drying, and is designed for modular expansion into a fully integrated production line. **ImmuPouch** ensures secure packaging and sealing of microtiter plates in three-side-seal pouches. Both systems guarantee reproducible quality, complete traceability, and provide comprehensive process and batch documentation through SCADA/MES connectivity.

Filling and closing

ImmuFill und Flexofill

ImmuFill and Flexofill are compact, modular filling platforms for reagents in multiple formats. Both systems process various containers with precision while saving space. **ImmuFill** impresses with minimal format parts and easy handling – ideal for laboratories. **Flexofill** offers additional features such as explosion protection for maximum process safety, along with high-throughput options.



Maximum productivity

Linoline

Sorting

Filling with 100 % IPC

Closing

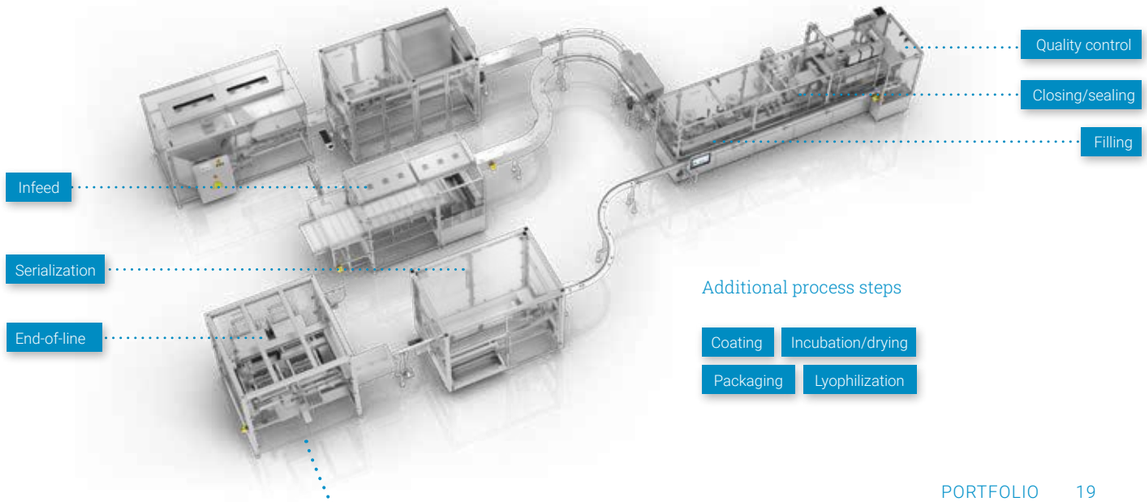
Coding

Our Linoline is a high-performance platform for processing a wide range of diagnostic formats. It fills and closes different kinds of products, e.g., liquids, powder, and more, in large production volumes. Thanks to a broad variety of pumping systems, Linoline covers an extensive filling range flexibly and enables rapid format changes. Integrated functions generally include 100% in-process control (IPC), a closing station, torque monitoring, and cap tilt detection. Laser marking and MES/SCADA connectivity make transparency and traceability an integral part of your production.

Fully integrated systems

Turnkey-Linien

We contribute our expertise across the entire value chain. Together we develop the optimal solution for your production, tailored to your requirements, needs and packaging materials. The graphic below provides an overview of the available process steps.

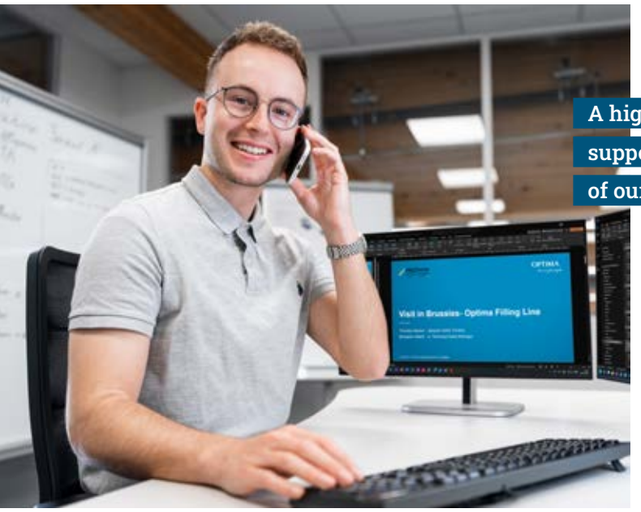


Technical support expands internationally – **enabling fast on-site assistance**

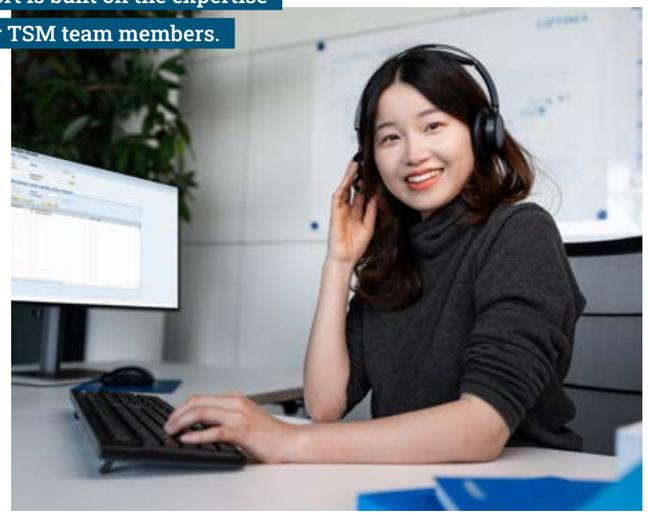
Robust processes form the backbone of modern pharmaceutical production. However, technical or human errors in fill-and-finish operations, including isolator technology and lyophilization, can lead to production interruptions that are difficult to predict. To ensure customers receive fast, expert assistance, Optima Pharma established Technical Support Management (TSM – see box). Local TSM locations in North America, Asia, and Europe, together with centralized TSM expertise, form an efficient network.

IMPORTANT FOR YOU

- Technical Support Management provides rapid, expert assistance whenever system technology does not perform as intended.
- Local TSM sites and hubs in North America, Asia, and Europe form a cohesive, globally integrated TSM network.
- International TSM hubs deliver immediate support for the vast majority of service cases from within the same or closely aligned time zone.
- Three competence centers for filling and closing, isolator technology, and lyophilization provide additional support from Germany whenever required.
- Continuous investment in employee expertise, expanding regional presence, and advanced TSM tools ensure sustained service quality.



A high standard of customer support is built on the expertise of our TSM team members.



System processes can come to a standstill for a wide range of reasons. In addition to technical or operating errors, new pharmaceuticals or modified drug formulations can also present challenges. Especially in the event of production interruptions, it is essential that first-level support is immediately accessible. This requires a dedicated, highly specialized organization – at Optima, this is Technical Support Management (TSM). Within this structure, Technical Support documents each incident and works proactively with customers to resolve issues swiftly and effectively. Internationally established locations are in place across North America, Asia, and Europe. These sites are staffed by generalists and specialists in process engineering, software, electrical systems, and mechanics. This structure allows Optima to eliminate the critical factor of time-zone differences in most cases. However, the demands of complex turnkey systems cannot always be resolved entirely at the local level. Therefore, all TSM resources are integrated into our global network. The remaining cases that require coordination across time zones are also handled as quickly and professionally as possible within the organization – as the following insights illustrate.

TSM locations in the USA and Asia

In the United States, Optima established its TSM team in 2024 in Knightdale near Raleigh, North Carolina – directly adjacent to the "Research Triangle" known for its concentration of leading pharmaceutical and diagnostics companies. Support is available not only remotely; technicians can also be dispatched quickly to customer sites when needed. The experts handle topics ranging from weighing technology to the lyophilization process, reports team leader Friedemann Brinzing. The team is expected to continue growing later this year.

The central TSM hub for Asia is located in Seoul, South Korea. Established in May 2025, it is led by Sascha Siegle, who brings extensive industry experience and in-depth knowledge of the Asian market. To provide the best possible support across the Asia-Pacific region, the organization is structured in a more decentralized way. Additional local TSM locations have been established not only in South Korea but also in Pune and Bangalore (India) and in Shanghai (China), with a site in Kyoto (Japan) to follow soon. The representative E2joy in Taiwan is also integrated into the TSM network. Sascha Siegle describes his role as an interface function: Setting the right course, he notes, is a key success factor. A central database supports this work by storing information on which issues occurred where and how they were resolved.

Internationally well connected

Three German TSM teams are the central competence centers for filling and closing, containment, and lyophilization. They are located in Schwäbisch Hall, Radolfzell, and Mornshausen. Each site brings together process and software experts, as well as specialists in mechanics and electronics. In addition, the TSM teams collaborate with engineering developers when particularly complex issues arise. Specific members of these specialist departments are permanently assigned as dedicated contacts for TSM. From Germany, the teams support European systems while also assisting North America and Asia. Additional locations are situated in France, Italy, and England. Together, they form a complete global structure.
The international network creates an efficient combination of clear responsibilities, rapid response times, concentrated expertise, and a high degree of flexibility. This structure has proven effective even across borders and time zones. A 24/7 service can also be booked worldwide for complete systems or for individual components. In this case, experts are available around the clock.

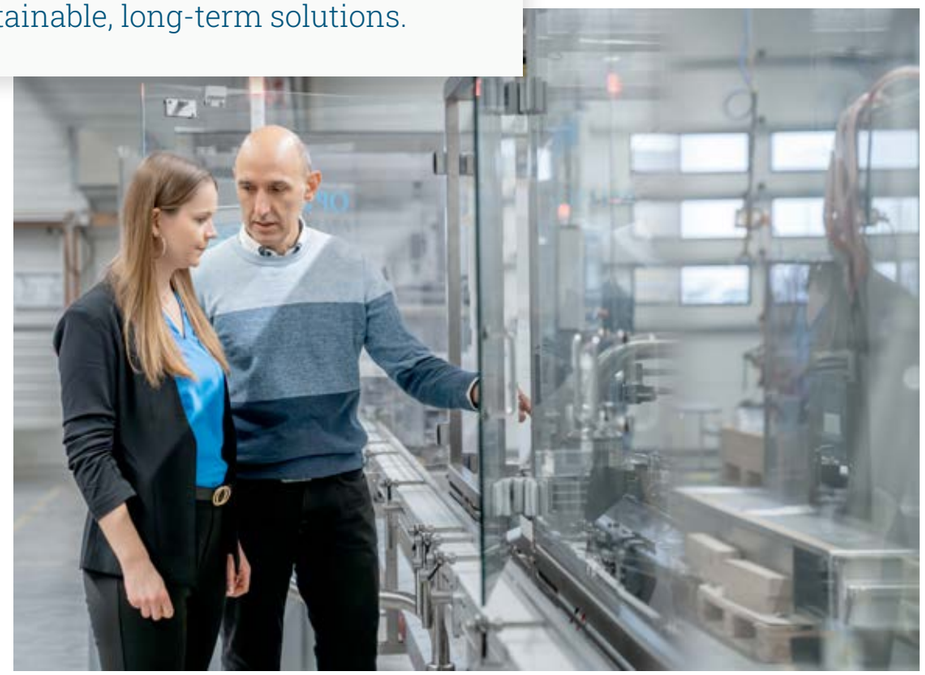
Around-the-clock availability

At the first point of contact with TSM, a support checklist is completed to describe and narrow down the incident. For root-cause analysis, key framework data is collected: format values, recent changes to packaging materials or products, previous troubleshooting attempts, and more. Photos and videos stored in the system also support this process.
A TSM service ticket is then created. This gives colleagues from different departments straightforward access to all information related to a service case. It also helps ensure continuity during substitutions, for example in cases of illness or vacation. Within the international TSM network, it offers fast and systematic exchange across time zones.

Remote support with TSM tools

Ideally, the experts resolve issues remotely. This shortens production downtime and eliminates both travel time and the need for on-site personnel. Depending on the functional unit or machine type, TSM experts report that up to 60% of cases can be traced back to process or software-related questions. In these cases, the chances are good that no on-site intervention will be required. However, an immediate solution is not always guaranteed.
If changes to the program code are necessary, GMP requires a change-control process, which typically takes several days.
The TSM teams have a range of tools at their disposal to ensure the shortest possible response times and lasting solutions in every case. The isolator specialists, for example, work with their own software test environment. The recently installed test isolator, reserved exclusively for R&D and service tasks, is also highly valuable. In Mornshausen, the control systems for lyophilization processes can be simulated using digital models. Subsequent hands-on tests on real equipment in the production hall then lead efficiently to the final result.

TSM teams have access to tools that enable rapid response times and support the delivery of sustainable, long-term solutions.



TSM at Optima offers a 24/7 service option. This service can be booked either for complete turnkey systems or separately for individual system components.

Global presence for greater customer proximity – Optima locations around the world

+100 %
growth of the global TSM network
within 24 months

60 %
of inquiries can be resolved remotely

The **global** **TSM** network

1 global knowledge base

available **24/7**

Keeping expertise up to date

A high standard of customer support relies on the expertise of the TSM employees. Optima therefore invests purposefully in developing individual competencies and ensuring that TSM staff remain updated in their training and expertise. In the United States, for example, each employee follows a dedicated training matrix, Brinzing explains.
The locations also maintain regular communication. Siegle is in daily contact with the specialist departments in Germany. The same applies to Brinzing and his team: Every two weeks, scheduled meetings are held with the team leaders in Germany to address ongoing topics and cover new technical developments. Another factor contributing to technically sound customer support is the early involvement of the responsible mechanics during the FAT of a system, Siegle notes.

Working across borders

Cultural backgrounds also play a significant role in international collaboration. In both the United States and Asia, expectations for rapid technical support and strong service performance are very high, as the local TSM managers report. Understanding differences in communication styles is therefore essential. Polite, indirect phrasing – common in the United States – should not obscure the fact that an urgent issue is being raised, notes Friedemann Brinzing.

Sascha Siegle emphasizes the even greater cultural diversity in Asia compared with Europe. This diversity stems from a wide range of religious influences, as well as the ideological and political perspectives present across individual countries. The cultural dimension plays "a very, very substantial role" in daily work, another key component of TSM's success.

Customer feedback is already highly positive, particularly regarding the comparatively young TSM units in the United States and Asia. "Customers clearly recognize the improved support," says Brinzing. "The fast response times, in particular, stand out." Siegle reports similar observations from the Asian market, where customers likewise notice the significantly reduced reaction times.

Mission Accomplished?

Technical Support Management continues to expand steadily at Optima. The international integration of the TSM units, the structured yet highly flexible organizational set-up, the strong culture of collaboration, and the company's ongoing investment in technical expertise collectively generate clear value for customers: Rapid response times paired with strong problem-solving capability. With these elements in place, key milestones have already been achieved, and further development is being actively advanced.

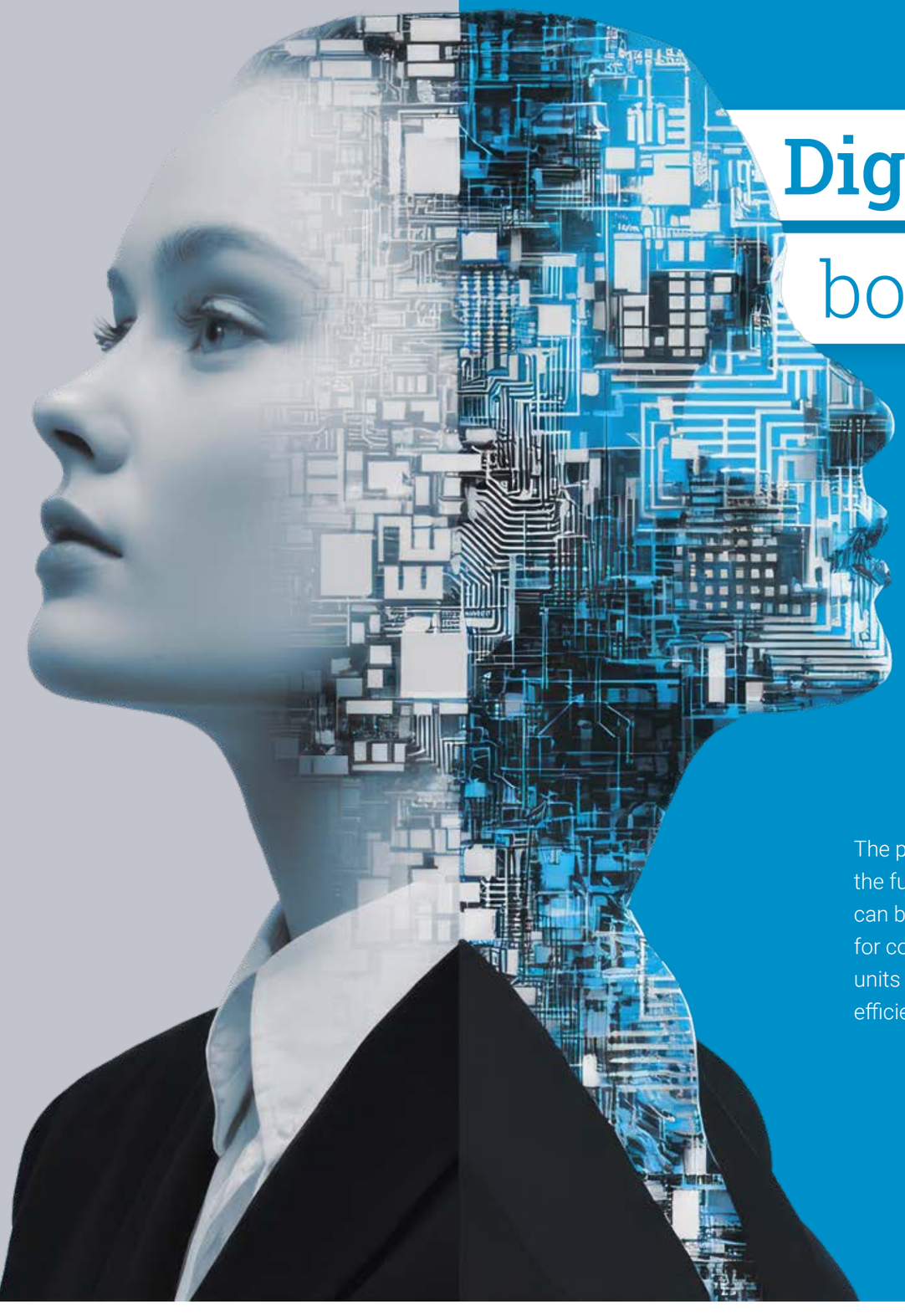
↑ Quick on-site support whenever needed: Technical Support Management (TSM) is responsible for technical malfunctions. Most issues today can be resolved remotely.

TSM: Fast and competent when it matters

Technical Support Management assumes responsibility for system support once the SAT has been successfully completed. Equipment malfunctions – technical troubleshooting – form the core of TSM's remit. Scheduled maintenance and routine service activities, however, do not fall within its scope. System modifications are likewise outside the TSM mandate, as these tasks are handled by dedicated specialists within the organization.

IMPORTANT FOR YOU

- Optima offers digital twins, also for diagnostic systems.
- A key milestone is the programming and testing PLC code on the digital twin at an early stage.
- Additional applications include training and firmware updates, and functional system upgrades.
- Significant efficiency and time savings are already being realized.
- The vision: A centralized, detailed digital twin encompassing all simulations and tests.



Digital twins boost efficiency

The potential is clear. If digital twins can fully replicate the functionality of turnkey systems, project timelines can be significantly shortened. Specialized digital twins for complex fill-and-finish systems, including lyophilization units are already available. This article explores the efficiency boost these digital tools provide.

CAD data produces a 3D model, but only by integrating digitized mechanics, kinetics, sensors, servo motors, and software does a digital twin emerge that accurately represents the processing workflow.

Preliminary testing of control software on the digital twin offers substantial time savings and efficiency improvements – capabilities now included in Optima's portfolio.

The concept of the digital twin has been widely known for years, but what it truly entails is interpreted differently due to the diverse fields in which digital twins are applied. Today, they are already being used in logistics, personalized medicine, and even marketing.
Even within mechanical and systems engineering, there are numerous "types" of digital twins. The complexity of the system to be digitized plays a key role in determining how easily it can be digitally mapped. In addition, the potential application scenarios for a digital twin are equally diverse. Whether these varied tasks can ultimately be fulfilled depends largely on the level of detail the digital twin is able to achieve.

Bringing the vision to life

In the medium term, Optima's digital twins will represent all relevant details of a comprehensive turnkey system. These models are fully functional and operate in real time. This single central model will integrate all process steps of a complete turnkey system, including fill-and-finish operations and, where applicable, lyophilization processes with automated loading and unloading. Consequently, this digital twin will digitally replicate the entire process undergone by liquid, solid, powder-based, and lyophilized diagnostic products within the production system, as well as all associated supporting processes.
Subsequently, the model can be used to perform simulations covering the entire system, including all moving machine components and operation under real-time conditions. Software testing, as well as other tests and simulations, can be conducted using this centralized digital model, even before the physical system is built. That's the vision and it is now almost within reach.
Every day, a dedicated team of experts at Optima is working to make digital twins suitable for both current applications and future requirements. These efforts are already yielding results. What began as a development initiative has evolved into a new service offering available to Optima's customers. The first pharmaceutical companies are already commissioning digital twins of their actual production systems, some of which are highly complex, large-scale installations. One key distinction from the long-term vision is that these digital twins are currently specialized for specific application areas rather than serving as centralized models of entire systems.

Practical application: Preliminary PLC testing using the digital twin

"Today, we already identify several areas where digital twins can be applied," says Nicholas Schloer-Müller, Team Leader Digital Twin at Optima. One of the key development goals is to use the digital twin to conduct virtual testing of a system's control software (PLC) in advance. "We see enormous potential for time savings here. If we can fully test the program code for an entire system in a virtual environment, rather than on the physical machine, it marks a significant milestone. "Our customers benefit from faster and much more efficient commissioning."

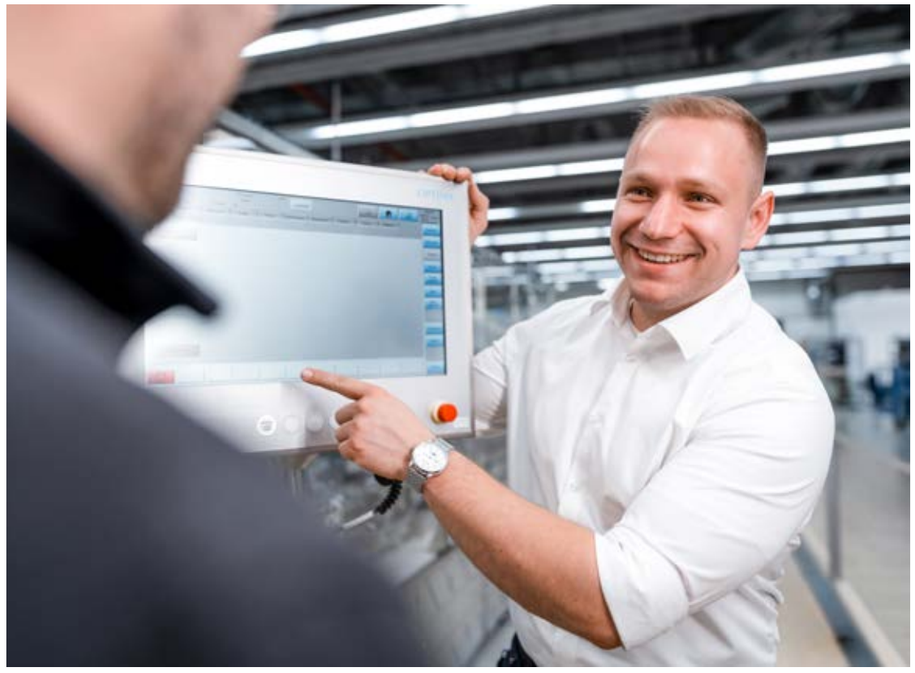
The digital twin team is close to achieving this – for even highly complex turnkey lines. The objective is to develop a model in which the PLC cannot distinguish whether it is operating a real system or its digital counterpart. Ideally, this would allow the program code developed on the digital twin to be transferred to the real system with little to no modification. As a result, time-consuming iteration loops on the physical system, which were previously almost unavoidable, could be eliminated.
Another key application for this type of digital twin is the testing of firmware updates from PLC and component manufacturers. Rather than deployment directly to the physical system, updates are first tested on the digital twin. Only after successful validation are they rolled out to the real system. Similarly, any functional changes or enhancements developed jointly by Optima and the customer can be virtually tested in advance. This approach eliminates the need for prolonged production downtime and significantly reduces the risk of errors, offering an additional layer of security.

> A key development objective is leveraging the digital twin for virtual testing of a system's control software (PLC) prior to physical commissioning.

From training to better visualization

Today, new functions or modules are typically tested on physical hardware – often using test setups. Any changes require redesign, rebuilding test rigs, and sometimes ordering new components. With a digital twin, potential improvements can be identified virtually – no need for physical modifications or additional parts. It also makes it much easier to understand highly complex processes within systems. Visualizing these processes on a screen, complete with moving components, improves clarity significantly.
Digital twins are also a major advantage for training. Operators in training are not allowed to work on live production systems, so machines must be reserved for training purposes – causing downtime or lost revenue.
With a digital twin, operators can train using a real HMI in a fully simulated environment. They can practice tasks like starting a system or performing format changes, while realistically observing how processes and system behavior respond.

Digital twins, operated through original HMIs, are already being successfully utilized for training purposes.



Physics and the digital twin

Despite the well-founded enthusiasm surrounding digital twins and their potential, considerable challenges remain. Schloer-Müller points out that, to date, there is no central tool for creating digital twins. Substantial manual effort is still necessary to develop a digital twin that meets system requirements. Similarly, the development tools themselves are still evolving. Optima has implemented one key advancement – a simulation interface compatible with both Rockwell and Siemens control software. However, support from component manufacturers continues to offer room for improvement.

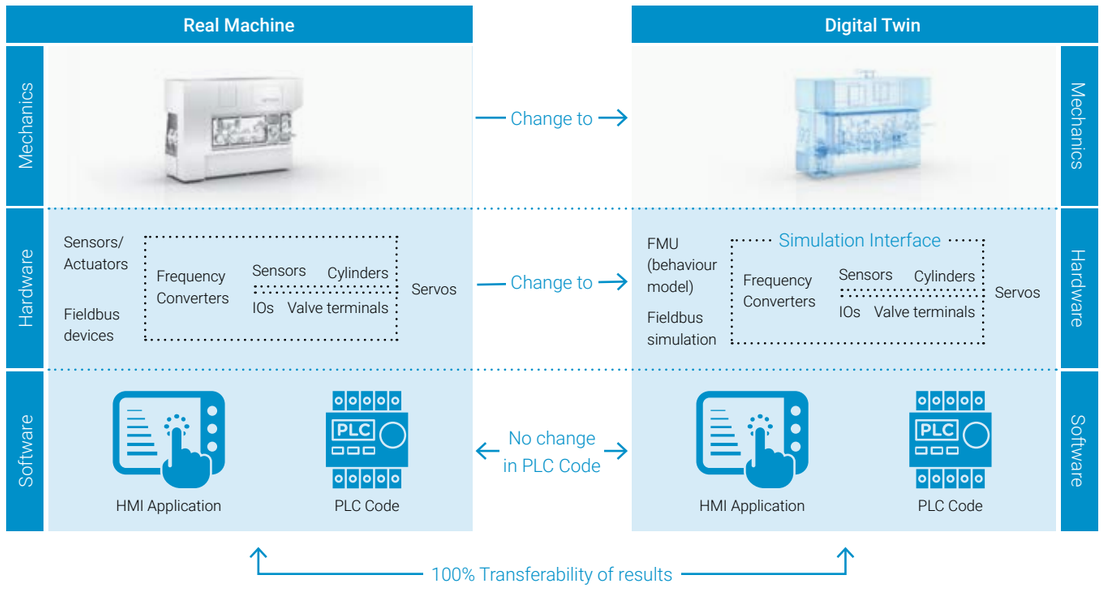
The level of detail is a key differentiator and ultimately a measure of quality for digital twins. Optima's ongoing development of its digital twin explicitly aims to represent processes as realistically as possible. This objective goes hand in hand with the increasing integration of physical phenomena into the models. Physics encompasses many effects, such as drive slippage or compensatory movements in motor mounts. In these cases, if a load is not applied precisely as introduced, the deviation may seem negligible in isolation, but the sum of such slight inaccuracies will be noticeable in the digital twin.

> Optima's ongoing development of its digital twin explicitly aims to represent processes as realistically as possible.

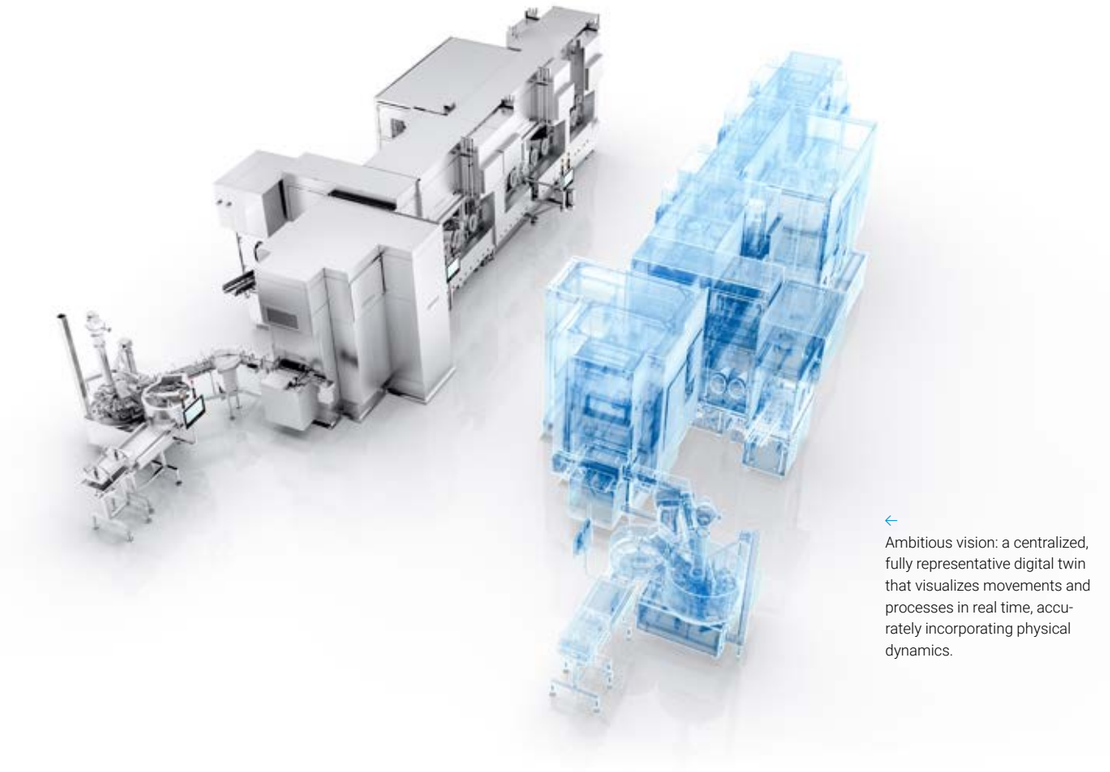
Digital support

Another aspect of digital twins involves developing and integrating behavioral models for the many hardware components, aiming for the highest possible level of differentiation. Schloer-Müller uses cylinders in systems as an example: Do they simply open and close digitally, or do they also simulate damping effects as in the real system? Optima is committed to achieving the most precise simulation possible and ensuring the control software can be transferred seamlessly from the digital twin to the physical system. Consequently, the digital model incorporates dampening effects in cylinders.

What remains on the developers' agenda is the integration of previously separate digital elements into a comprehensive, higher-level model. Current models, tools, and computational capabilities are not yet sufficient to fully support this. For example, the dispensing behavior of liquids and products across the full range of diagnostic packaging formats, from vials, bottles, microtubes, and microtiter plates to canisters, could also become part of a central model. While isolated simulations of this behavior are already feasible, representing it accurately as a component within an overall system model is still out of reach. This would require including factors such as laminar flow and, where applicable, simultaneous dosing and transport processes involving acceleration and deceleration.



How does Optima create a digital twin? One key element is the simulation interface, which digitally replicates the behavior of hardware components such as sensors and valves. Ultimately, the goal is for the PLC code developed and tested on the digital twin to be transferable to the physical machine with minimal effort.



Ambitious vision: a centralized, fully representative digital twin that visualizes movements and processes in real time, accurately incorporating physical dynamics.

First projects: comprehensive

Optima's initial digital twin deployments are already being delivered for complex pharma systems. One ongoing project involves creating a digital twin of an Optima turnkey system including the fill-and-finish line, isolators, and four freeze-dryers.

These large, complex pharmaceutical systems are hardly comparable to other "twin projects" in mechanical engineering. A pharmaceutical line, like the one currently being developed both physically and as a digital twin at Optima, can consist, for example of nine machines connected inline. In total, up to 150 servo motors, sensors, and other components operate together and are software controlled.

In addition, strict regulatory requirements make these digital twins even more demanding. Software changes must be traceable and validated. Access controls must ensure that only authorized users can make modifications.

These successes in pharma are paving the way for expanding digital twin applications into other areas – such as diagnostics.

Driving digital progress

Optima is making significant strides in the technological advancement of digital twins, which demands substantial investment. High-performance computing power and the latest graphics cards have been acquired to meet these requirements.

However, advanced development tools are only effective when paired with qualified personnel who have the expertise to utilize them properly.

Additionally, Optima's experts collaborate with specialists across company boundaries when necessary. "To accelerate development, we evaluate each situation individually to determine the most efficient and effective path to achieve our goals," says Schloer-Müller.

Turnkey advantage

Considering Optima's development objectives and the complexity of pharmaceutical systems, one point stands out: Optima's turnkey approach provides optimal conditions for creating digital twins. All relevant information integrated into a digital twin is directly accessible without company boundaries or restrictions. The greater the level of detail in the digital twin, the more effectively numerous functions can be digitally coordinated.

Additionally, having program code developed by a central provider for all plant components offers a distinct advantage. The ability to digitally test this program code for the entire system beforehand marks a significant step forward. At Optima, the digital twin has not only found its footing but is taking major steps toward a promising future. Its appeal lies not only in its development potential but also in the tangible benefits already delivered, which validate and encourage its deployment in customer projects.

Highlights of this edition

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ImmuCoat at BioChek – 53 test variants, four core platforms.

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Interview with Dr. Mike Mohns:
Rethinking diagnostics – flexibility, turnkey solutions, and global perspectives.

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Digital Twin:
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