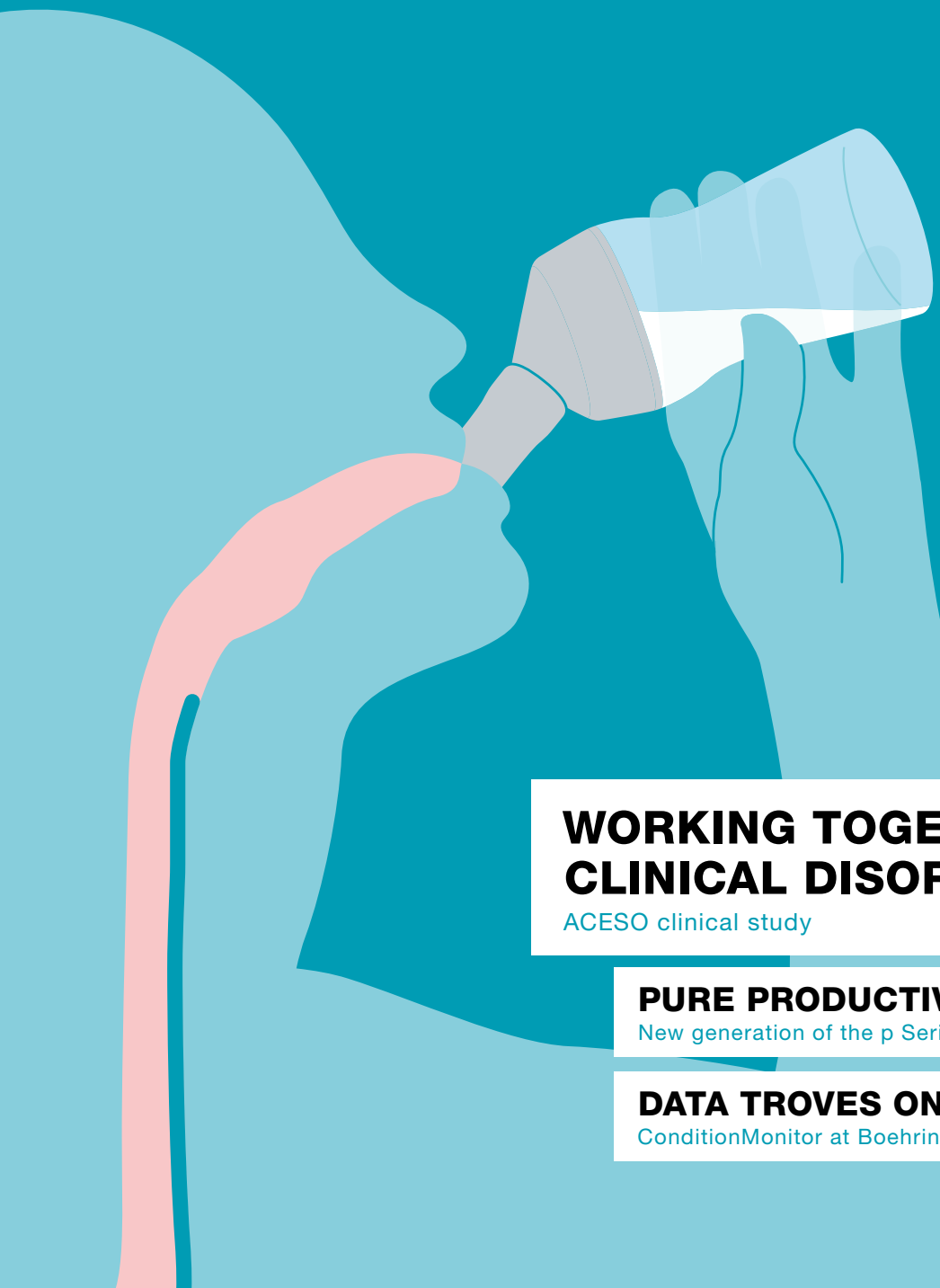
WHAT'S NEXT?

FETTE COMPACTING

FETTE COMPACTING MAGAZINE 2024/1



WORKING TOGETHER AGAINST CLINICAL DISORDERS

ACESO clinical study

PURE PRODUCTIVITY

New generation of the p Series

DATA TROVES ON THE RADAR

ConditionMonitor at Boehringer Ingelheim and Aenova

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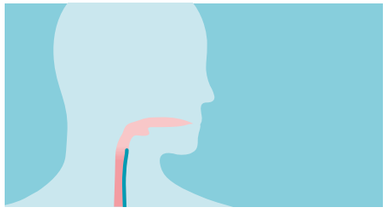

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Dear Readers,

Just in time for ACHEMA 2024 the new issue of What's Next? is here for you. As the leading trade fair for the process industry shows, OSD production is increasingly becoming a matter of cooperation between pharmaceutical producers and solution-oriented partners. To this end, we are pursuing innovative paths with our customers and partners, starting with an in-depth understanding of processes, through laboratory analysis of powder formulations, to continuous manufacturing.

My colleagues and I explain our comprehensive approach – from the laboratory to production – in this magazine. In our article on the ground-breaking ACESO clinical study, you can read about what such collaboration could look like in practice and what potential it holds for healthcare. This reflects our mission statement "Together – for Quality of Life," which is at the heart of everything we do.

There is also plenty going on in the area of tablet technologies and digital tools. Find out in this What's Next? how the new i Series has proven itself in field trials and why a prototype was taken straight into production. The p Series is also undergoing a generational change, enabling new leaps in performance for standard applications. In addition, the ConditionMonitor app has won over two well-known users, paving the way for data-supported process optimization and intelligent Predictive Maintenance.

We hope you enjoy reading!

Sincerely, Joachim Dittrich

CEO Fette Compacting

Imprint

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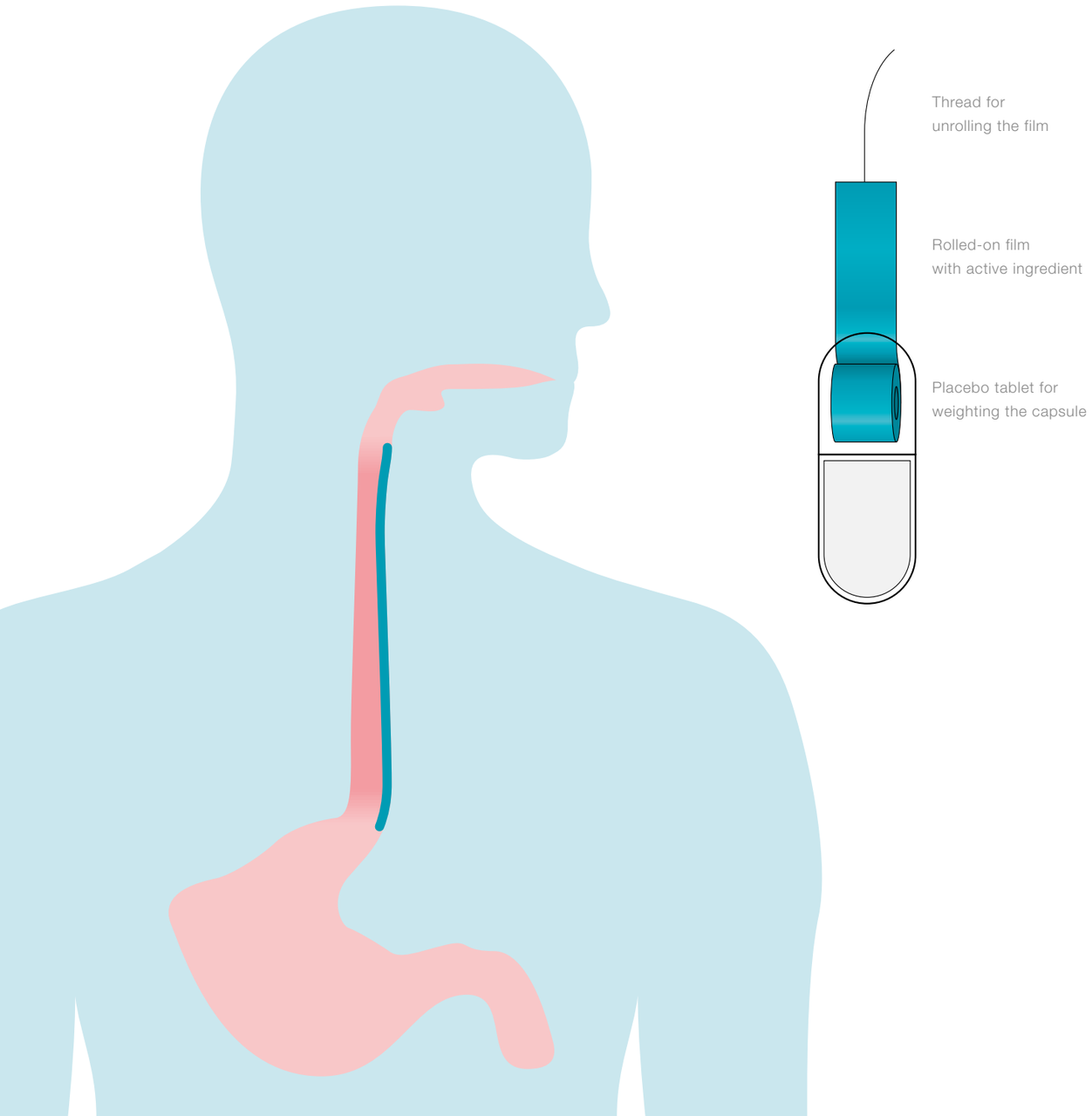
WORKING TOGETHER AGAINST ESOPHAGEAL DISORDERS



More than ever, sustainable health care requires cooperation between pharmaceutical research, medical technology, and specialist mechanical engineering. The project surrounding the ACESO study shows how this partnership leads to success right from the start. And even brings the targeted treatment of esophageal cancer within reach.

Around 370 million people worldwide suffer from diseases of the upper digestive tract: from eosinophilic esophagitis to reflux disease and Barrett's syndrome to dangerous esophageal cancer. * Such conditions pose a challenge in medicine, as local treatment has not been possible to date.

"The fundamental problem lies in the short transit times of only a few seconds from the mouth to the stomach, which make local treatment more difficult," explains Dr. Peter Stangier, Director Strategic Planning at the Swiss biotech company EsoCap. "Systemic treatment is in turn associated with toxic stress and possible restrictions in quality of life. Our vision, on the other hand, is to improve the lives of patients with severe esophageal diseases through targeted local and long-lasting treatments. And we have developed a unique form of administration for this purpose."

ACESO – the goddess of healing

The administration system is ingenious: It consists of a capsule holder and a hard gelatine capsule containing a thin film with an active pharmaceutical ingredient. When the capsule is drunk from a special drinking cup, the film unrolls and adheres to the mucous membrane of the esophagus, where it slowly dissolves and continuously releases the active ingredient. The technology offers maximum flexibility, as several relevant active ingredients can be integrated in the thin film, including biologicals and other innovative compounds.

Developed in collaboration with the University of Greifswald, the system has already proven itself in the first two phases of clinical development. Initially, tests were carried out on healthy volunteers and analyzed using magnetic resonance imaging. The images confirmed that the film unrolled well and adhered to the esophagus for at least 15 minutes. Swallowing the capsules on consecutive days was also accepted by the participants without any adverse effects. This was followed by a proof-of-concept Phase II study of patients suffering from eosinophilic esophagitis. The placebo-controlled study was named after Aceso, the Greek goddess of the healing process. It used the active ingredient mometasone furoate, which was administered to 43 patients in five countries using EsoCap technology. A statistically significant superiority of the drug over the placebo was confirmed. "The ACESO study confirms that our technology delivers medication to the mucous membrane of the esophagus, directly and effectively, which makes a noticeable difference in treatment," claims Stangier.

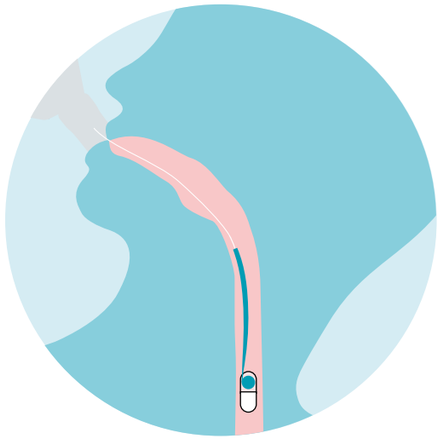
"OUR VISION IS TO IMPROVE THE LIVES OF PATIENTS WITH SEVERE ESOPHAGEAL DISEASES THROUGH TARGETED LOCAL AND LONG-LASTING TREATMENTS. AND WE HAVE DEVELOPED A UNIQUE FORM OF ADMINISTRATION FOR THIS PURPOSE."

Dr. Peter Stangier,
Director Strategic Planning at EsoCap

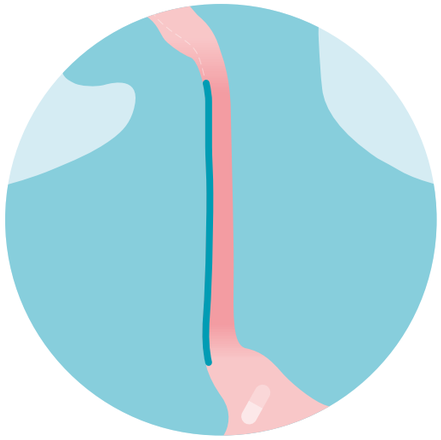
Placebos by weight

For the capsule to be easy to swallow, another crucial element was needed: a placebo tablet inside the capsule to provide the requisite weight and thus ensure that the capsule could be swallowed easily. EsoCap started looking for a reliable partner. Stangier remembers: “We were aware of Fette Compacting as a leading company in the area of tableting. So, we got in touch with the aim of working together to design a high-density placebo. It had to be made of heavy materials and make the best possible use of the limited space available inside the capsule. Together with the experts at Fette Compacting, we succeeded in making the delivery system easier for patients to swallow and it sinks easily into the gastric fluid once the active ingredient has been released.”

A special drinking cup makes it easier to swallow the capsule.



When swallowed, the film with the active ingredient unrolls from the capsule, while the thread quickly dissolves in the mouth.



The film adheres to the mucous membrane of the esophagus and continuously releases the active ingredient there.

IT IS NOT ALWAYS EASY FOR A START-UP TO GAIN THE SUPPORT OF RENOWNED COMPANIES IN RESEARCH AND DEVELOPMENT. AGAINST THIS BACKDROP, OUR COLLABORATION WITH FETTE COMPACTING HAS BEEN AN EXTREMELY POSITIVE EXPERIENCE FOR US.

Dr. Peter Stangier,
Director Strategic Planning
at EsoCap

WITH OUR SUPPORT, ESOCAP HAS NOT JUST DESIGNED A TABLET, BUT ACTUALLY IMPROVED THE SWALLOWABILITY OF THE CAPSULE TO ENSURE EASY AND RELIABLE USE.

Dr. Anna Novikova,
Head of Process Consultancy
at Fette Compacting

“We took on the order with great passion because we saw a huge potential to improve patients’ quality of life,” reports Dr. Anna Novikova, Head of Process Consultancy at Fette Compacting. “The challenge was to optimize the placebo developed by EsoCap in such a way that it imitated the outlines of the capsule. In order to fill all the free spaces, it also had to have certain curves. At the same time, the material had to be pressed under maximum pressure in order to achieve the highest possible density. This resulted in special requirements for the process and the design, as well as the ensuing load limit of the tableting tools.”

LAB TO PRODUCTION

Pharmaceutical engineering has traditionally focused on commercial production. However, changing product portfolios, shorter market launch times and high pressure on costs are demanding ever earlier and more intensive collaboration during the product life cycle. Fette Compacting therefore supports users as early as the research and development stage. Insights into this extended partnership are provided by the management team: Joachim Dittrich, Chief Executive Officer (CEO), Anke Fischer, Chief Financial Officer (CFO), Dr. Marten Klukkert, Vice President Customer Development Center, and Dr. Martin Schöler, Vice President Technology.

What strategy do you pursue in the area of research and development?

Joachim Dittrich: We have embarked on a journey to become a process partner for powder formulation and tableting for our customers. We support our customers in all processes from research and development to production. We are evolving as a close partner in process development, powder formulation and tableting, particularly in the area of continuous direct compression. The focus is always on the customer, whom we support from the optimal formulation and selection of the right process technology through to production and services. For us, this means a lively technology partnership.

Our corporate philosophy “Together – for Quality of Life” is indicative of the values at the heart of our actions during this journey: Our aim is to work together to make a key contribution toward improving the health and quality of life of people all over the world. This applies to our employees as well as in our collaboration with our customers. We want to inspire our customers and develop processes with them. More than ever, this involves early collaboration with combined expertise in order to define an optimal powder flow and to provide the most suitable production technology.

Anke Fischer: I would like to pick up on the idea of common ground, which runs like a common thread through our daily activities worldwide. Whether at our headquarters in Schwarzenbek, at our second technology and production site in Nanjing (China), or at our other development site in Mechelen (Belgium), or at our many subsidiaries worldwide: our shared values form the foundation of our corporate culture and bind us together in the Fette Compacting family. This is something we take into account when looking for new talent. In this way, we ensure that we can continue to bring our philosophy to life in the future.

Joachim Dittrich and Anke Fischer,
CEO and CFO at Fette Compacting

Why has this early and comprehensive collaboration become so important? What has changed?

Marten Klukkert: There are several factors to be mentioned here. Firstly, manufacturers’ product portfolios have changed significantly due to new product launches and expiring patents. In order to give customers a competitive edge, we need to work with them to shorten time-to-market, reduce the amount of powder used in product testing, and accelerate technology transfers. Secondly, pharmaceutical developments are increasingly moving toward large-scale serial production, but also toward highly-specific, customized therapies with smaller batches. This means that users need targeted and flexible technologies for a wide range of applications. Thirdly, austerity programs in many countries are increasing the pressure on drug prices. This, in turn, increases the need for highly-efficient machines and comprehensive process consulting.

Martin Schöler: In terms of technology, we aim to deliver the ideal process and the most efficient machine configuration for specific products. This covers the entire product life cycle and includes all processes, continuous manufacturing, and batch-to-batch. Our experience in both technologies allows us to compare them directly and identify the best way forward for our customers. We have compiled this knowledge in the new process database QED (Qualified Expert Database), which we are constantly adding to with new insights.

What technologies are decisive for the development phase?

Martin Schöler: In addition to the machine and tool portfolio, the focus is increasingly on integrated metrological solutions, such as near-infrared spectroscopy as a reliable, robust and ultra-fast method for 100% analysis. In this way, we are moving beyond the boundaries of the production machine to support customers in their development process with a seamless system landscape.

Marten Klukkert: The technological offering starts with the production-related emulation of processes and the development of formulations in the laboratory. The Lab Solutions division provides users with state-of-the-art powder compaction analysis units, scales, micrometers, and breaking strength testers. As an analysis system, these modules provide a comprehensive image of the properties of the formulation and tablet. Once the optimum parameters have been determined in this way, we define a control strategy with the customer. Together, we emulate production processes and use embedded process analytical technology (ePAT) to ensure that powder blends and tablets are of a consistently high quality. Continuous direct compression in particular offers solutions for continuously monitoring processes in real time and reliably processing all kinds of products – from big pharma to smaller manufacturers.

What is the status of Continuous Manufacturing and what are the advantages for development?

Joachim Dittrich: By further developing continuous direct compression, we have made continuous manufacturing simple, flexible, controllable and economically attractive for pharmaceutical producers and manufacturers of food supplements. This makes it much easier for our customers to enter the market using this technology. Thanks to the continuous process, it is also possible to establish production capability for new products more quickly. To put it briefly: it has never been so easy to get started with continuous production.

Marten Klukkert: With the FE CPS (Continuous Processing System), we have moved even further in the direction of process development. Via a flexible process arrangement and a variable throughput range of five to over 200 kilograms per hour, we support our customers in their wide variety of development and production scenarios. The FE CPS can be easily integrated into existing production areas, works in a resource-saving manner, is highly digitized and easy to operate at the same time. As a result, it also forms a bridge for smaller manufacturers without their own development department who require a standard system for low-volume production.

Martin Schöler: We can report with great satisfaction that the FE CPS has already proven itself many times over since its launch. To date, we have received numerous inquiries, implemented a wide variety of product trials, and delivered several machines to the market. We have also received positive regulatory feedback for products that are to be continuously pressed. This shows that the FE CPS and ePAT will make it much easier to standardize processes.

From left: CEO Joachim Dittrich in conversation with Dr. Marten Klukkert, Vice President Customer Development Center, and Dr. Martin Schöler, Vice President Technology at Fette Compacting

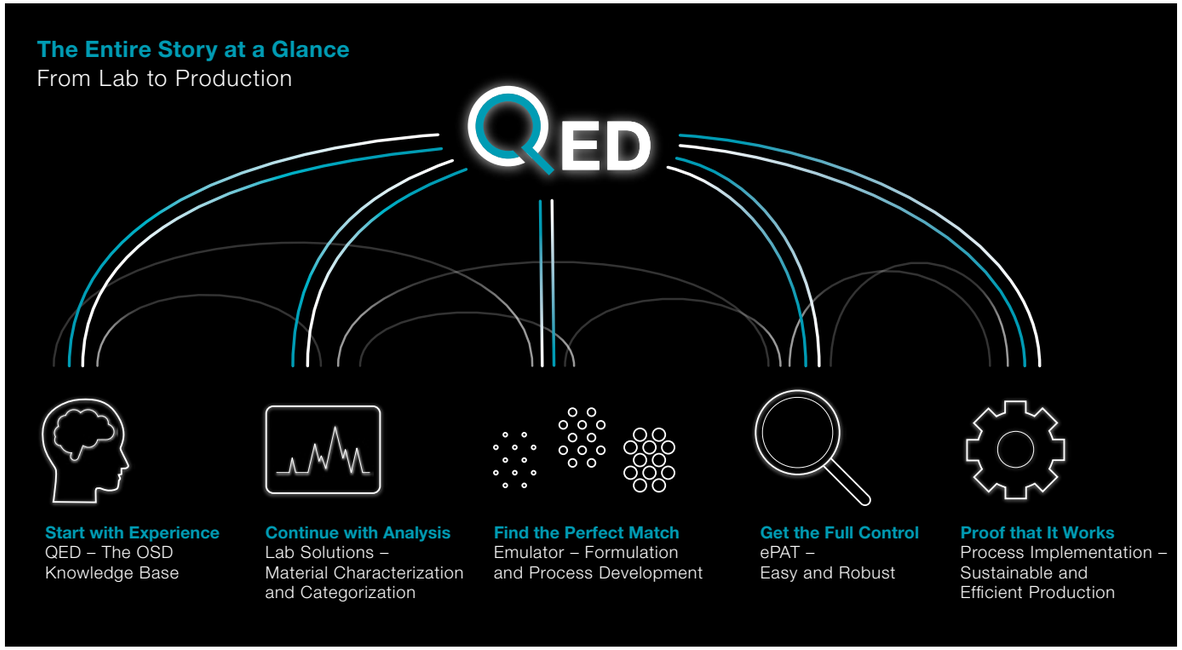
What are the next steps on this journey?

Marten Klukkert: Together with our customers, we are currently looking at how the entire set-up needs to be organized in order to be positioned in the best possible and most flexible way for process development. To this end, we are also expanding our consulting services, which start well before a product launch and range from individual new launches to holistic performance optimization via fleet management.

Martin Schöler: It is also important that we link data applications for machines and processes even further. This is an elementary component of our development considerations and real digitalization in tablet production. Accordingly, we are processing increasing amounts of data as well as materials. Based on this data, customer requirements can be defined much more specifically, enabling us to determine tailor-made solutions.

Joachim Dittrich: Overall, our aim is not just to deliver machines and tools “to the yard.” Instead, we want to provide customers with turnkey solutions that enable them to bring their development projects into production more quickly while reacting more flexibly to changes.

Anke Fischer: In an effort to achieve all of this, we work closely at the international level. The FE CPS milestone is already the result of intensive collaboration between various teams, such as our developers in Belgium, our headquarters in Germany, and our sales specialists around the world, who are now presenting Continuous Manufacturing to all interested parties. This inspiring exchange and passionate cooperation demonstrates our team’s enthusiasm for the future while also revealing our greatest potential: our employees, who represent the main pillars of the company. To this end, we will continue to create a motivating working environment with exciting and challenging tasks, for which we will continuously develop the specific expertise of our employees.



DOUBLY CONVINCING

The traditional family-owned company Dr. Willmar Schwabe is known for high-quality plant-based medications. After a field test with the F20i from the new i Series, the specialists were certain that this prototype should be used immediately in production.

The fact that we rapidly got the press up and running at twice our normal production speed, yet with higher quality, impressed us from the start" reports Sebastian Kopf, Group Manager Maintenance at Dr. Willmar Schwabe. The field test made it possible to double capacity within a short period of time. "We are now producing 4.5 million tablets a day of our blockbuster Tebonin® with a special ginkgo extract – that's two batches instead of just one," according to Kopf. The new i Series also displays numerous other convincing features. This led the company to take the unusual step of retaining the actual F20i prototype, which had been used on a trial basis, in-house.

Efficient, innovative and user-friendly

The i series from Fette Compacting has stood for ultra-efficient and flexible tablet production for decades. The new i Series offers even more possibilities on the basis of a technology platform. One innovation, for example, is a multi-format tablet outlet that is suitable for the majority of common tablet formats. Its special switch shape ensures that the tablets automatically find the path with the lowest frictional resistance, thus reducing the likelihood of material jams.

"We also save cleaning time, have reduced product loss, and consume less power," Kopf adds to the list of benefits. And the F20i has significantly fewer surfaces to clean. In addition to the reduced effort, this also lowers the potential exposure to active ingredients. Further time savings are provided by an optimized rotor change system, which reduces removal to just a few minutes with the help of an integrated removal carrier.

Quick training with intuitive operation

"I was also pleasantly surprised by the short training period," adds Kopf. "Due to the new user interface, some of my colleagues were understandably very cautious. After all, you don't want to make any mistakes with a new machine. However, these concerns were quickly dispelled, as operation is intuitive. The F20i scores points here with helpful graphic solutions that make our work easier. In addition, many machine parameters have been stored for troubleshooting, which saves an enormous amount of time. Thanks to the integrated help texts, we have even learned a few new things during our work."

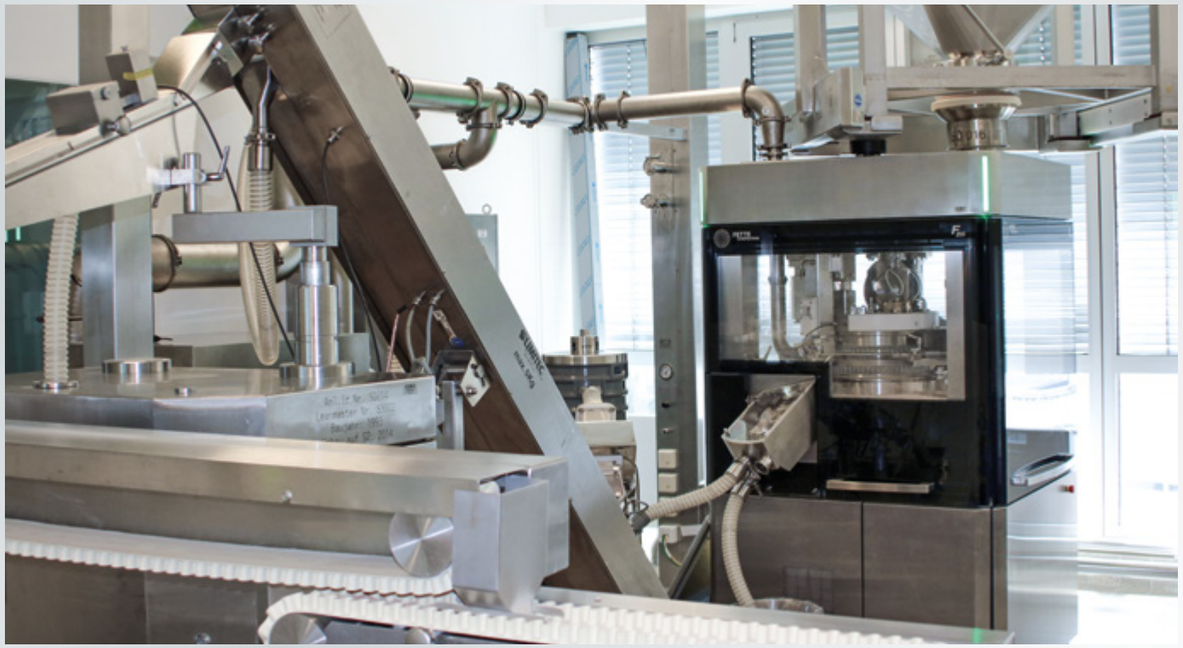
All-rounder for high demands

With an output of up to 475,000 tablets per hour and Pmax® technology, the F20i is the all-rounder of the new i Series. It is suitable for a wide range of products and batch sizes, allowing maximum flexibility in production. A decisive advantage of the entire series: Components from existing systems can continue to be used, as the new i Series is system-compatible across all generations. In fact, all process-based assemblies are identical or similar to those of the classic i-series. The models also have all of the technical requirements for a modern production environment such as the Internet of Things (IoT) and can be monitored via an app from any location.

For Dr. Willmar Schwabe, two aspects in particular ultimately tipped the scales in favor of the F20i: "Plant extracts are usually more demanding to process than chemically synthesized medicinal substances. The F20i enables us to achieve an optimum for both target variables: high output with consistently superior quality. We are therefore also considering further increasing production with another F20i," concludes Kopf.

"THE F20i ENABLES US TO ACHIEVE AN OPTIMUM FOR BOTH TARGETS: HIGH OUTPUT WITH CONSISTENTLY SUPERIOR QUALITY."

Sebastian Kopf,
Group Manager Maintenance at Dr. Willmar Schwabe



The prototype of the F20i was retained by Dr. Willmar Schwabe immediately after the field test.

A multi-flexible tablet outlet reduces the risk of material jams.

The rotor of the F20i can be changed in just a few minutes using an integrated removal carrier.

The intuitive controls facilitate training and daily operation.

PURE PRODUCTIVITY

Productive, universal, robust, efficient – in short, PURE. This is what the new p Series stands for, which for the first time is based on a technology platform for all standard applications. It combines high-performance tableting with maximum flexibility and a modern operating concept.

Good news for all users of the p Series or those who want to become one: Each of the three models is being modernized and launched as the new p Series. This means that extremely efficient tablet presses based on an innovative platform will be available in the near future for high productivity requirements in standard applications. The PURE concept not only provides numerous performance, quality and operating advantages, but also ensures simple (re-)validation of formulations given its full compatibility with the proven p Series.

Continuation of a 20-year success story

The success story of the p Series began in 2004 with the P2020 tablet press, in which Fette Compacting combines cost-conscious production with high precision, quality and safety. Since then, over 1,000 machines have been manufactured at the Nanjing site in China and delivered to more than 45 countries. After a series of upgrades and face lifts, a renewal of the entire series began in 2022 with the F10p, F20p and F30p models. The latter has now been available since May 2024 as the first model of the next generation. This generation change is accompanied by a high level of system compatibility: All relevant electronic and mechanical components of the new models are based on a universal Fette Compacting platform, ensuring a high level of vertical and horizontal compatibility with the existing series.

PURE as an overarching concept

With this concept, the new p Series is aimed at the increased requirements of companies looking for a powerful and economical solution for standard applications in tablet production. This has resulted in the following key performance attributes: productive, universal, robust and efficient. The platform therefore enables particularly high performance in standard applications (productive). The new development focused on achieving an optimum balance between innovation and compatibility (universal). The machine design is geared toward intensive and long-term use in challenging production environments (robust). And these basic features are complemented by modern technologies for energy-saving operation, smooth integration of process equipment and even greater cost-effectiveness (efficient).

“The platform principle brings even more flexibility, performance and ease of operation for users. With the new models, we are taking the basic idea of the p Series to the ultimate level, i.e. the optimum combination of efficiency and quality,” says Rory Wang, Product Manager at Fette Compacting China.

PURE tableting

Technology platform as a basis:
The F30p kicks off the launch of the new p Series.

High standardization and performance
The new concept ensures the requisite consistency in the core parameters, for example a consistently high tablet quality thanks to precise control of weight, density and hardness. In this context, the new p Series offers simple, standardized processes for validation, making it easier to comply with regulatory requirements. Added to this are fast changeovers between products or tablet shapes and increased output, which can be further increased by using the proven Fette Compacting segment technology. An efficient torque drive ensures improved device performance, a long service life and unrivaled energy efficiency. All of these leaps in performance can be achieved with a reduced footprint – thanks to a compact design with integrated components such as the dust-tight control cabinet and space-saving window flaps.

The high level of standardization of all operating modes minimizes potential process deviations and operator errors. Handling and maintenance of the tablet presses have been simplified even further. In addition to the robust structure, the main focus of the machine design was on a safe production environment. This includes reduced dust exposure, for example through the integration of an innovative dust-tight tablet chute. Furthermore, a broad integration of process equipment and improved data management are possible, ensuring a high level of future readiness and investment security.

Next-generation operation
Operators can look forward to an all-round intuitive concept with the new p Series. The revised Human Machine Interface (HMI) offers simple operation and monitoring of all production processes, based on a state-of-the-art graphic user interface. In addition, all models use the widespread NGCC central controller with a CAN-Bus based internal communication system. This means the machines are equipped for the future and “digitally ready” for state-of-the-art connections, including IoT, digital management systems, and Industry 4.0 applications.

Optimal alignment to individual application scenarios
Similar to the previous series, the three models in the new p Series are designed for specific production requirements and capacities. The F30p, which is now the first available on the market, is ideal for large batches and also for the production of double-layer tablets. “The new generation brings together innovation and proven quality in tablet press technology. And, with the PURE concept, it provides the necessary efficiency, productivity and flexibility for all standard applications,” says Wang, summarizing the leap in performance of the new p Series. “For our worldwide users of the p Series, this represents a huge technological advancement,” adds Dr. Andreas Risch, Managing Director of Fette Compacting China.

Compact design: In addition to the integrated switch cabinet, space-saving window flaps ensure minimized space requirements with 360° accessibility and largest in class compression chamber.

Intuitive operation thanks to an ultra-modern graphic user interface

WITH THE NEW MODELS, WE ARE TAKING THE BASIC IDEA OF THE P SERIES TO THE ULTIMATE LEVEL, I.E. THE OPTIMUM COMBINATION OF EFFICIENCY AND QUALITY.

Rory Wang,
Product Manager at Fette Compacting China

Universal
+ Well-balance between compatibility and innovation
+ Minimized re-validation effort
+ Ease of use: managing and operating formulations

Productive
+ High output in standard operations
+ Boosting tableting production capacity and driving operational excellence

Robust
+ Optimized design for intensive utilization and high yields
+ Outstanding lifetime in standard tablet productions

Efficient
+ Upgraded energy saving technology – up to 40 %
+ Optimized integration of process equipment and improved intuitive user experience
+ Enhanced cost efficiency

DATA TROVES ON THE RADAR

Data-supported process optimization can often unlock inconceivable potential in tablet production. Digital tools help to monitor machine fleets, detect process deviations, optimize maintenance strategies, and predict wear using AI. Two pilot projects at pharmaceutical manufacturers show how Fette Compacting's ConditionMonitor contributes to this.

During the tableting process, numerous and sometimes complex machine data are generated, which manufacturers can use to comprehensively optimize their processes. However, digital treasures often remain untapped due to a lack of applications that process data in a simple and user-friendly way. Fette Compacting has developed the ConditionMonitor exactly for this scenario. The web-based application gathers information from the tablet presses and compiles the most important parameters on a dashboard. Basic machine data, production progress, and derived key figures such as Overall Equipment Efficiency (OEE) are displayed for the current batch.

The ConditionMonitor also identifies valuable detailed information such as figures for good and bad production. Operators not only have an overview of the real-time status of the individual machines, but also receive early indications of potentially undesirable deviations. A notification center brings together the warnings and error messages from all connected machines in one central location. With this data basis, application specialists can look even deeper into the data and uncover potential. Fette Compacting has also been working with data science service provider Point 8 for years to achieve this.

Achieving ideal production via DeepDive

The software offers clear advantages: The dashboard makes it easier to identify common errors and analyze their causes. In addition, users can compare historical and current real-time data, for example, in the detailed view – the so-called DeepDive – in order to identify deviations. The Golden Batch function allows production managers to select parameters for ideal batch production, which are then visualized by the app. Batches can also be saved and compared with each other. ConditionMonitor can therefore not only define benchmarks for ideal production, but also prepare them visually.

The process optimization solution is already in the starting blocks: Together with various customers, Fette Compacting is testing the ConditionMonitor in field trials; with success, as the following two projects show.

The ConditionMonitor gathers all of the information from the production machines and compiles the most important parameters on a dashboard.

Put to the test in the SO[u]L Factory

In Boehringer Ingelheim's SO[u]L Factory, many things are already running automatically: In order to produce new drug launches efficiently, the smart factory has networked machines and self-controlling systems. At the same time, new methods of production optimization are being tested in the factory. The company was therefore looking for an application that would clearly display and evaluate the machine data already collected. Boehringer Ingelheim opted for the ConditionMonitor to get one step closer to its goal of predictive maintenance.

"We approached Fette Compacting because we wanted to move from preventive to condition-based maintenance," reports Martin Döhms, Process Specialist in the Engineering division at Boehringer Ingelheim. "The machine data were already available, so it was a logical step, therefore, to test the ConditionMonitor for processing." But the test phase was not without its challenges. A typical hurdle for web-based applications is the connection to a cloud, which raises questions about data protection. "This was a decisive criterion for us, which is why we made some arrangements before the test," says Döhms. "Together with Fette Compacting, we swiftly found solutions that met our data protection requirements."

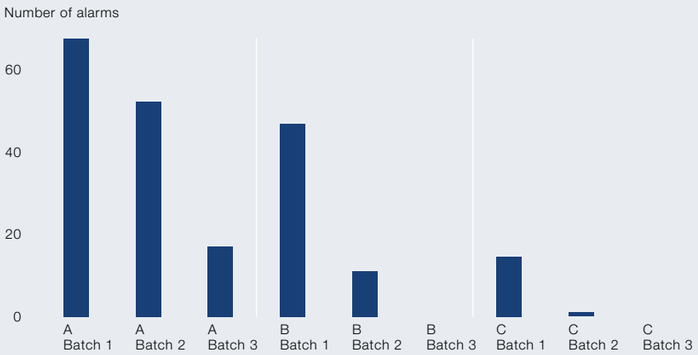
Focus on batch production and performance

The ConditionMonitor was previously used primarily to compare batches and optimize supply chains. To do this, the ConditionMonitor analyzed the diagnostic messages from the tablet presses, which were displayed during production and in the batch report. "The comparison of different products and individual batches directly revealed optimization potential," adds Döhms. "For example, we noticed that there were increasing problems with individual products in the area of tablet verification with the Checkmaster. Something we were able to rectify immediately."

An „alarm analysis" tested the performance of the tablet press. This involved investigating which punch pairs and punch positions were increasingly leading to rejects. This revealed that hardware components of the press performed differently, which can now be investigated further. In addition, individual punch pairs were identified that increasingly led to poor production. The punches identified could then be examined more closely and replaced in a targeted manner.

"We were impressed by the analysis options, which is why we will continue to use the ConditionMonitor," says Döhms, confirming the success of the pilot phase. "The collaboration and services in the field of digitalization are also unparalleled in the world of pharmaceutical processes."

In operation at Boehringer Ingelheim:
On the basis of the data analysis, the alarms in the individual batches declined sharply during measurements.



Optimized production at Aenova

The German contract manufacturer Aenova, which produces pharmaceuticals and food supplements and offers research and development services, has come to similar conclusions. Even before the ConditionMonitor was used, it was clear that a certain high-runner product had an increased production shortfall. However, it was not yet possible to evaluate the data in such a way that the production process could be optimized during the campaign. This is where Fette Compacting and Point 8 came into play.

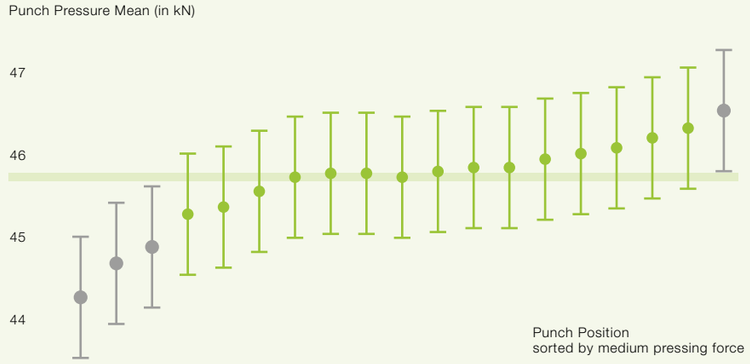
High potential for tableting tools

An analysis of the machine data by the ConditionMonitor revealed several conditions warranting further investigation. It turned out that the main reason for the product losses was due to the set pressing force limits being reached. It was also possible to identify the punch pairs that were responsible for this. In further investigations, these pairs were exchanged for replacement pairs or the pairing of individual punches was changed.

"During the test phase, the machine data, in this case diagnostic messages and individual compression forces, were sent to us via the ConditionMonitor data pipeline," explains Julian von der Ecken, Senior Data Scientist at Point 8. "In the future, further analyses and visualizations are to be integrated in the ConditionMonitor and the next-generation user interface in such a way that the production managers can independently make adjustments."

After the data evaluations and subsequent optimizations during the campaign, the first successes were immediately visible. "We already noticed during production that the tablet press was running more stably," adds Tobias Schmid, Head of Continuous Improvement at Aenova at the Regensburg site. "And the results of the analyses also make things quite clear. This more than halved the production shortfall, which also significantly reduced the number of process warnings. In addition, the occurrence of short downtimes has been reduced to a minimum, which has also significantly reduced staff interventions."

In operation at Aenova:
The ConditionMonitor data basis was used to identify the punch positions that were outside the optimum compression force range. Simple adjustments to the tableting tools more than halved the production shortfall and avoided a large number of stoppages.



Potentials of data-driven production

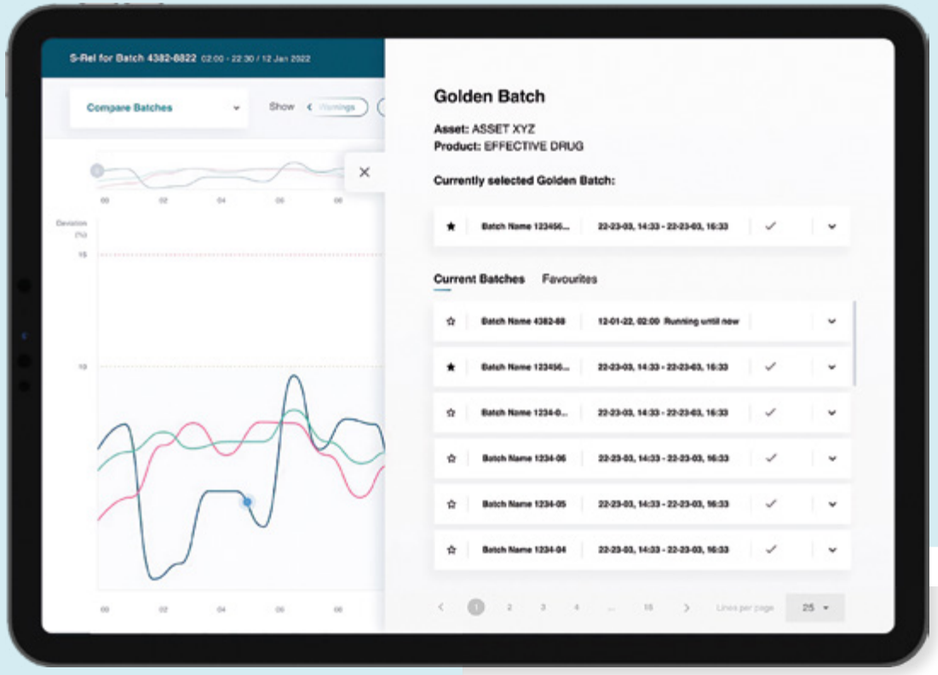
The pilot projects have shown that ConditionMonitor can improve processes via various levers. By evaluating the machine data, it not only identifies anomalies, but also quickly eliminates sources of error. In the future, the implementation of self-learning artificial intelligence will further pave the way for predictive maintenance. And maintenance work will no longer be carried out at fixed intervals, which are often too early and sometimes too late. Instead, the digital tool will determine the ideal time for maintenance work based on usage and wear data and thus define a more efficient and individual maintenance strategy. ConditionMonitor is the tried-and-tested basis for this next step.

THE COMPARISON OF DIFFERENT PRODUCTS AND INDIVIDUAL BATCHES DIRECTLY REVEALED OPTIMIZATION POTENTIAL.

Martin Döhms,
Specialist Process in the Engineering division at Boehringer Ingelheim

WE ALREADY NOTICED DURING PRODUCTION THAT THE TABLET PRESS WAS RUNNING MORE STABLY.

Tobias Schmid,
Head of Continuous Improvement at Aenova at the Regensburg site



The path to the Golden Batch

By visualizing a typical batch production, parameters can be saved and compared. This gives users the opportunity to set benchmarks for their production based on a solid data basis.

ConditionMonitor
Empowering your data

FROM THE WORLD OF FETTE COMPACTING

ACHEMA 2024
Together to the next

June 10 – 14, 2024
Hall 3.0, Booth F3

In June, ACHEMA in Frankfurt am Main invites you to “Inspiring Sustainable Connections.” This leading trade fair for the process industry offers space for more than 3,000 exhibitors who are expecting visitors from all over the world. On board again: Fette Compacting.

Process technology is more than just a question of collaboration. Visitors to the Fette Compacting stand will be able to experience how pharmaceutical production and mechanical engineering can work together to shape the future of OSD production – for a high quality of life for patients. The opportunities for cooperation range from a deeper understanding of the process and development of the perfect powder formulation to continuous production that is safe, robust and simple thanks to embedded process control. To this end, the team of experts from Fette Compacting will be presenting a new knowledge database, digitally supported analytical instruments from the laboratory, a continuous direct compression line, the tablet presses of the new i Series and comprehensive system solutions for tableting tools.

Trade fair dates

We will once again be represented at numerous trade fairs around the world in the second half of 2024. Here is an overview:

BIO Asia-Taiwan July 25 – 28 in Taipeh, Taiwan
FARMAFORUM September 25 – 26 in Madrid, Spain
AllPack Indonesia October 9 – 12 in Jakarta, Indonesia
Pack Expo International November 3 – 6 in Chicago, USA
PMEC November 26 – 28 in Delhi, India

PMEC India
All series in a single place

In Delhi, the Pharmaceutical Machinery and Equipment Convention (PMEC) in November 2023 provided a stage for the latest pharmaceutical production solutions.

Fette Compacting presented all of its machine series up close: from a standard tablet press of the p Series to a containment model of the new i Series and a high-performance rotary press of the FE Series. The F Lab 10, a powder compaction analysis unit (PVA unit), which is ideal for developing and analyzing formulations, was also on display. As a highlight, visitors were treated to a live video demonstration of continuous direct compression with the FE CPS.

CIPM China
F20i well-received

High visitor turnout in Xiamen: the China International Pharmaceutical Machinery Expo (CIPM) Autumn took place in the south-western Chinese city in November 2023.

At one of the largest trade fairs for pharmaceutical engineering, Fette Compacting presented its new products for the Asian market. The launch of the F20i tablet press went down particularly well. This German Design Award-winning machine from the new i Series impressed visitors as an all-rounder for practically any application scenario.

Further premieres followed in May 2024 at CIPM Spring in Qingdao: Fette Compacting presented the F30p, the first tablet press in the new p Series. Visitors to the trade fair were also able to see an F10i with extensive containment equipment.

IFPAC USA
Continuity in a 24-hour test

Companies presented their process innovations at the International Forum for Process Analysis & Control (IFPAC) in March 2024. At the symposium in Maryland, USA, Fette Compacting presented their novel continuous direct compression line: the FE CPS dosing/mixing unit, in combination with the FE55 and embedded process analytical technology (ePAT), which finally makes continuous manufacturing economically attractive for both large scale and small scale manufacturers of pharmaceuticals and food supplements.

A use case on the line with a model drug of one customer over 24 hours non-stop running was presented, in which a control strategy build around the ePAT sensors proofed to be highly successful in continuously controlling the blend homogeneity and concentration of active ingredients in the final tablets. The result: the continuous process ran smoothly and reached state of control already in the first minutes after start-up, while using the tablet uniformity sensor (TU) as primary control during this 24h production was positively validated against an off-line reference method.

Silver medal from EcoVadis
Certified sustainable

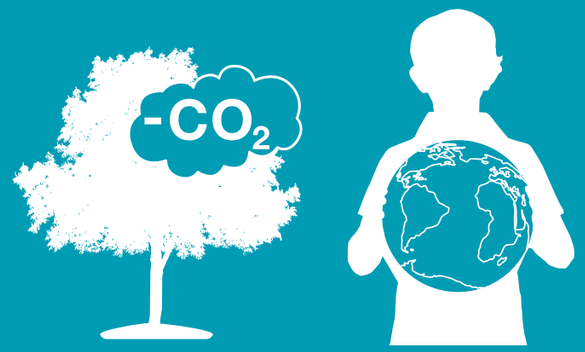
The renowned rating platform EcoVadis has raised its standards for sustainability performance. The new silver medal for Fette Compacting shows that the company is eminently prepared for the increasing requirements.

Fette Compacting was once again awarded the silver medal for its sustainability activities in 2023. Since the last assessment, its score has improved from 58 to 67. This puts the company in the top five percent in the “Manufacture of special machinery” category. With this improvement, the conditions have been created to clearly meet the assessment criteria, which have likewise increased.

New ranking benchmarks as of 2024

EcoVadis evaluates the topics of environmental protection, labor and human rights, ethics, and sustainable procurement in global supply chains. Increased regulatory requirements and growing pressure from stakeholders have led to sustainability standards rising in almost all sectors. For this reason, the rating platform has revised its threshold values for certifications and defined stricter benchmarks. For example, as of this year, a 25 percent higher percentage threshold applies to the silver medal level. This corresponds to a ranking among the top 15 percent of the companies assessed.

With this improved silver certification, Fette Compacting is confident of achieving the new benchmarks and continuing to become a driving force for more sustainable pharmaceutical production. To this end, the company has launched several strategic initiatives, including the establishment of a global reporting system and the continuous improvement of sustainability performance as a whole.



Find the right spare part quickly with eCAT

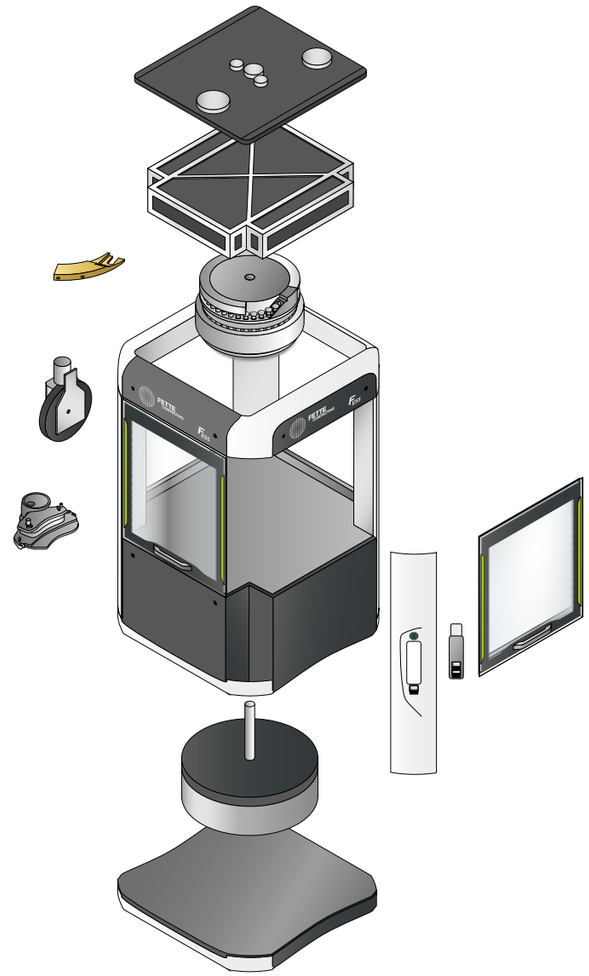
Smooth production is dependent on the right spare parts being available quickly. To ensure this, Fette Compacting operates a spare parts warehouse with more than 1,500 different parts that can be called up within a very short time. To further simplify the supply of these original parts, the service team is working on an electronic spare parts catalog (eCAT).

The eCAT enables users to clearly display their technical documentation for all tablet presses in the machine fleet. The assemblies and components are visualized in two dimensions for older machines and in 3D for newer tablet presses. These illustrations make it easier for manufacturers to identify the parts they need, recognize technical correlations, and access relevant information at a glance.

Assemblies and components in 3D

A click on the respective assembly or component provides detailed information. In the 3D view, it will also be possible to rotate and move selected assemblies and components, show and hide parts, and much more. These functions are based on computer-aided design (CAD). The program also features a search function to find a specific part in the tablet press.

The eCAT offers a convenient method for finding the appropriate spare part: After an individual login, the customer places the desired product in the shopping cart and requests a quote. Following internal processing, the customer is quickly sent a personal offer. And the entire process can be traced in a quotation history.



eCAT

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