

WHAT'S NEXT?



**FETTE
COMPACTING**

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Excellence United

FETTE COMPACTING MAGAZINE 2022/1



CONTINUOUS MANUFACTURING

Game changer: FE CPS world premiere

NEW i SERIES

The middle model F20i

DIGITALIZATION

Always available: alva learning app from OSDi

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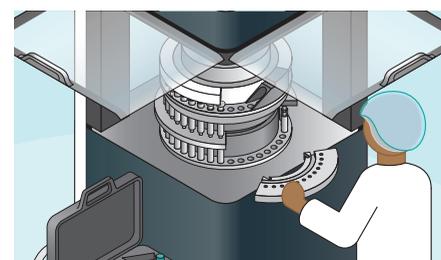


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DEAR READERS,

A new era has commenced in the area of Continuous Manufacturing. For years, Fette Compacting has relied on the lean and efficient direct compression process for continuous production. Building on this, we have now realized an entirely new technological leap to present you with a world premiere: clear the stage for the FE CPS!

In this issue of What's Next? you will discover what makes the new continuous tableting system so special. The FE CPS is as compact, efficient and simple unlike any other direct compression line before. It features dust-tight process units and fully-integrated process control. With these and other innovations, it takes Continuous Manufacturing to a new level.

But that's not all: we are also taking the next step with the i Series and are presenting the F20i tablet press, the middle model of the new series. And the OSDi business unit presents the alva learning app, which uses 3D graphics, animations and instructions to promote intuitive learning. You will also gain the latest insights into containment research, the handling of tableting tools, and Global Customer Support.

We hope you enjoy reading!
Your team at Fette Compacting

TECHNOLOGY stands for all offers in production technology – from tablet presses through process equipment to tableting tools.

SERVICE comprises all services relating to machines, plants and process equipment, e.g., provision of spare parts, plant modernization, and the technical field service.

COMPETENCE is the umbrella term for all process-based services. These include training offers, product tests, performance consulting, and engineering.

Imprint

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Picture credits

Cover, P. 4-21, 26-27, 30-31,35, Back Cover, Fette Compacting;
P. 22-23 Steffen Wirth, Dr. Martin Schöler; P. 25 Metagenics Europe;
P. 29 ZF Airbag; P. 32-33 Dr. Markus Krumme, Frank Eismann,
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GAME CHANGER

A new era has commenced in the area of Continuous Manufacturing: Instead of oversized and highly-complex plants, a technology is emerging that focuses on simplicity and efficiency. This game changer comes in the form of the FE CPS.

Continuous Manufacturing has been making its way into pharmaceutical and nutritional production for more than 15 years. It is associated with a wide range of advantages: Integrated processes increase efficiency and process reliability; process duration is shortened compared to batch processes, while the specific production output increases; formulation development can be done using far less API; market launches can be realized more quickly and production becomes more flexible overall.

In tableting, direct compression in particular is meeting with growing acceptance, as it enables a leaner plant design compared to granulation-based production. But that is not enough! Despite these advantages, many tablet manufacturers still have reservations. Concerns about potentially high costs and complexity continue to weigh too heavily.

Too large and too expensive?

A look at the typical pain points shows where the greatest development potential lies. For example, it can be observed that existing continuous plants require a large footprint and room height, which usually requires modifications to existing buildings or even entirely new builds. In addition, there are concerns about long lead times for equipment design and production, and investments tend to be high as systems need to be customized and require high facility investments. Many manufacturers are also put off by the complexity, as scientific personnel are required for set-up and specially trained operators. Interested parties also fear long downtimes during operation due to the time-consuming cleaning and product changeover processes. All in all, these reservations hint at high investment and operating costs.

However, solutions for economically viable Continuous Manufacturing can also be derived from such criticism. In essence, it is about a system that is less complex and easier to install and use thanks to a standardized, generic, compact and modular

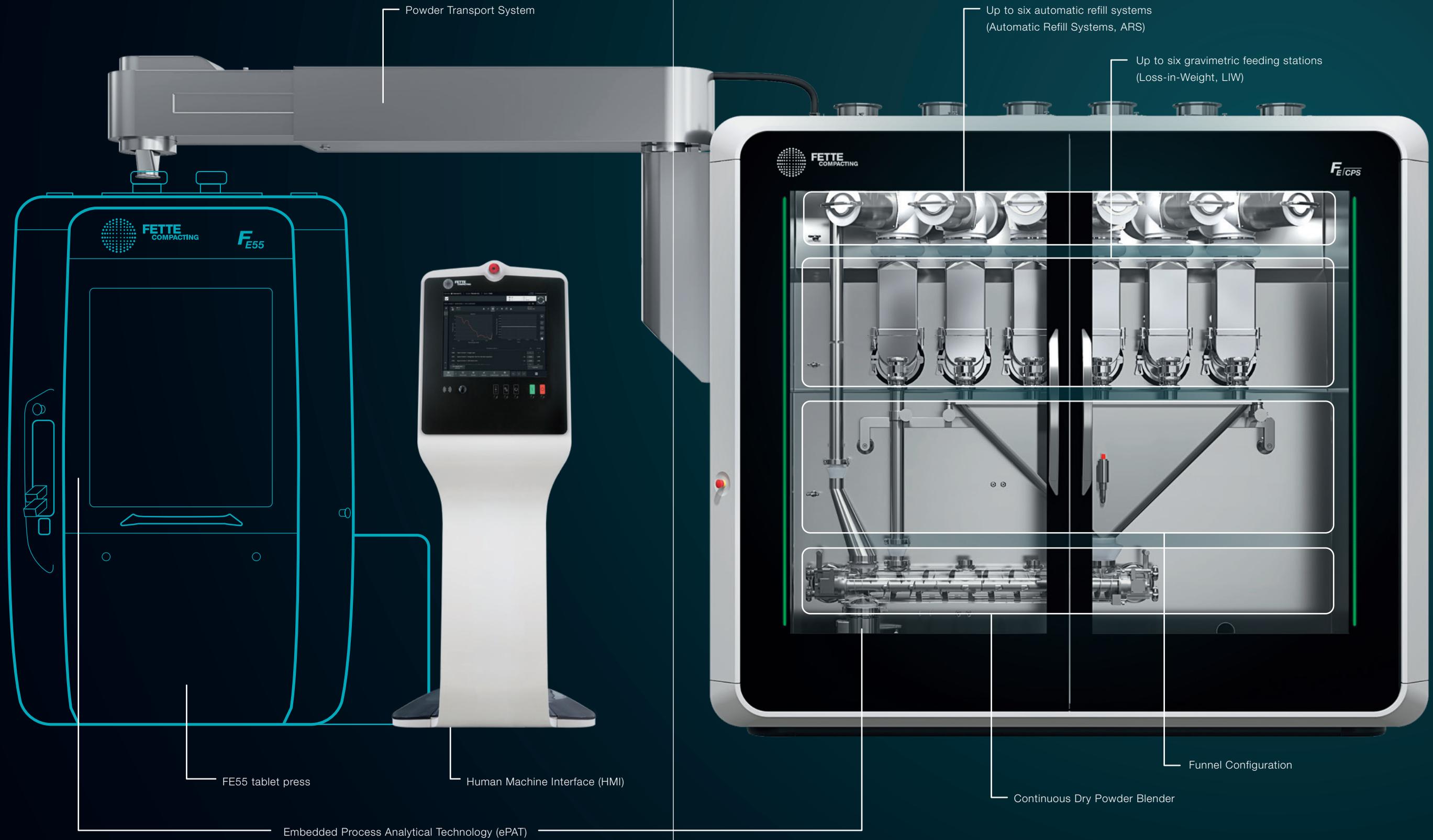
machine design. The direct compression process already creates optimal conditions for this, because upstream granulation processes are eliminated. The actual production process consists of only three or four steps and relies on less equipment. In addition the remaining unit operations should be re-designed and re-arranged in a fully integrated compact machine design. Direct compression also opens up more flexibility and faster product changes thanks to its lower degree of technological complexity.

On this basis, the task now is to significantly reduce complexity once again and dare to take a technological leap. Raise the curtain for a world premiere!



CONTINUOUS MANUFACTURING

reinvented



The next level of continuity

In the summer of 2022, Fette Compacting will present its Continuous Direct Compression tableting system. The modular system consists of the continuous dosing-blending-conveying system FE CPS, combined with an FE55 tablet press. The entire system can be integrated into existing production areas on just one level, so that building investments are reduced to an absolute minimum. The modular design allows flexible arrangement and installation of the process units on a maximum total area of 5 by 10 meters, including all free spaces for material handling. If space is limited, it is even possible to arrange the dosing/blending unit directly in the corner area of the tablet press, reducing the footprint to 5 by 6.5 meters. Alternatively, the classic two-tier concept can still be implemented, with dosing and mixing in the upper area and tableting below.

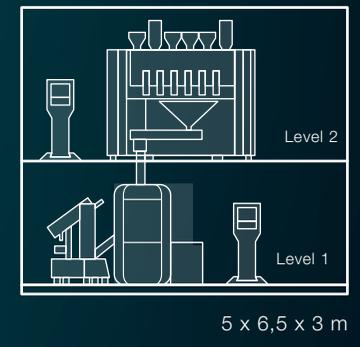
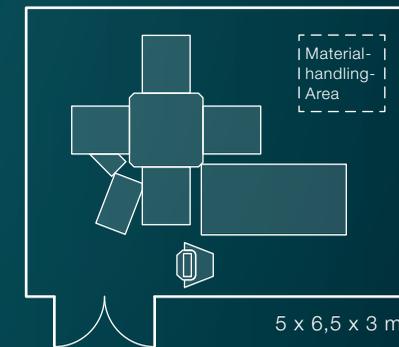
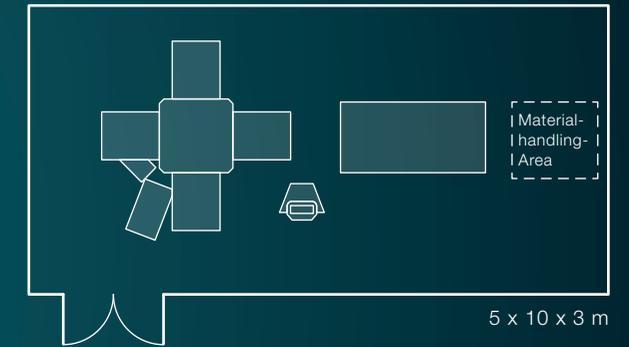
The FE CPS is capable of processing a wide range of formulations with throughput margins of about 5 to 200 kilograms per hour. It thus offers maximum process flexibility – from product development and smaller batches to large-volume production of medicines or food supplements. An FE55 is used for tableting as it can produce a particularly wide range of different tablet types and formats. The rotary press features three consecutive compression stations, as opposed to two on most tablet presses, which allows longer pressure dwell times at lower pressure levels, which is especially well suited for direct compression. This ensures gentler processing of raw materials as well as improving the flexibility of the tableting process. Such an overall design is also eminently suitable for a multiple-unit pellet system (MUPS), whose coarse-grain structure tends to segregate. With continuous production, such segregation processes can be effectively reduced in terms of process technology.

Dust-tight and easy to clean

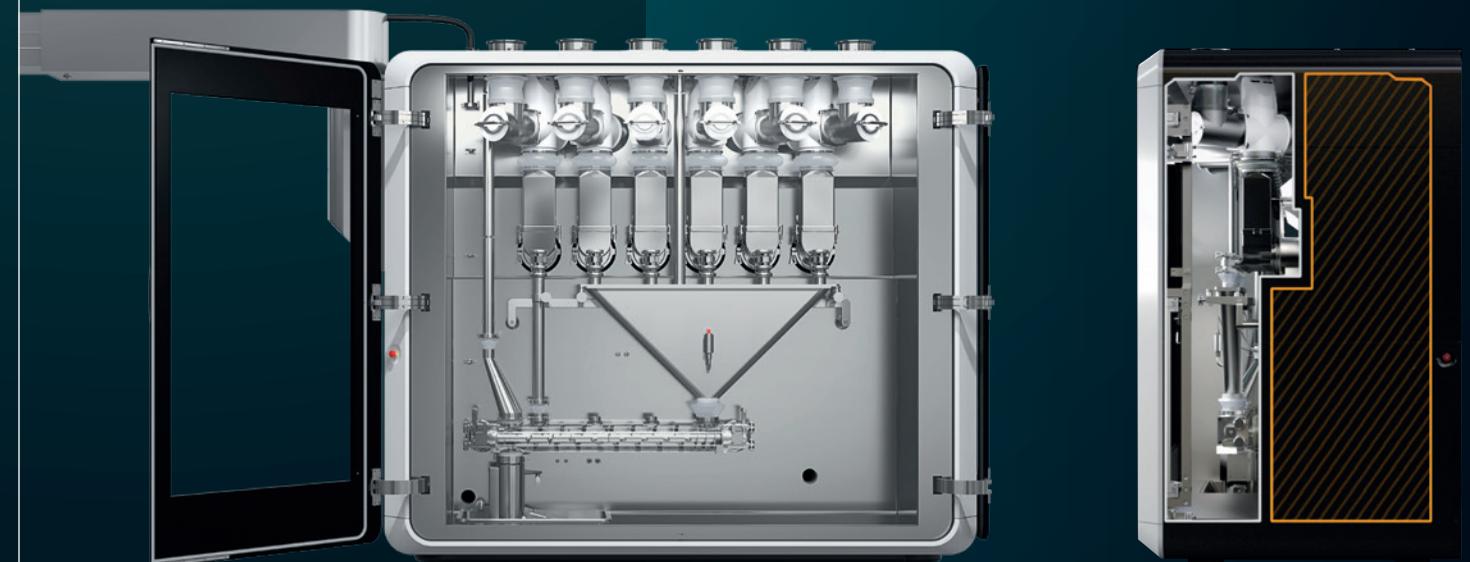
During the development of the FE CPS, the focus was on operator safety and fast product changeover. First of all, each unit operation has an inherently dust-tight design. Furthermore, the enclosed design of the unit with sealed front door panels acts as a second safety barrier. In addition, the process area of the FE CPS is kept under negative air pressure to keep airborne dust particles inside the machine.

The unit reveals its full potential during cleaning and changeover. It is precisely these work steps that often meet with reservations, since existing continuous lines usually consist of more than a hundred individual parts that have to be disassembled and cleaned at great expense of time at each product changeover. To facilitate this task, the developers have not only designed the FE CPS with fewer parts and interfaces, but also with separate process and technical areas. For this purpose, the FE CPS was divided in such a way that the

respective product contact parts of the ARS[®], LIW feeders and the blender are located in the isolated process area. The technical area, which is separated from the process area in a dust-tight manner, houses the drives, the electronics and the cabling, among other things. Both areas are easily accessible: the process area from the front of the machine through two large doors, while the technical area from the back via easily removable panels. All contaminated product contact parts can easily be removed from the process area for cleaning. This way, the process area can be completely emptied, making it very accessible and easy for an extremely fast cleaning.

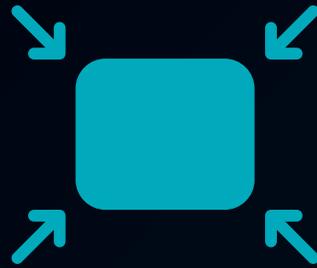


Exemplary arrangements of the process units on only one level (left and center) and vertical arrangement according to the classic two-tier concept (right).



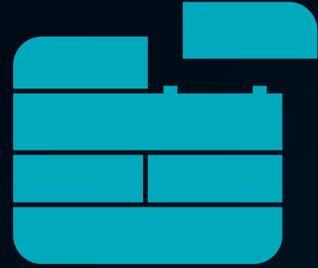
Strict separation of the process and technical area makes cleaning and product changeover of the dosing/blending unit much easier.

SEVEN REASONS FOR THE FE/CPS



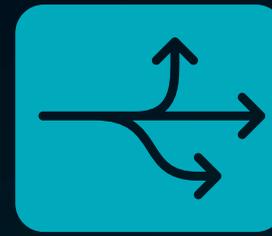
1. Compact

Setup on only one floor in existing buildings



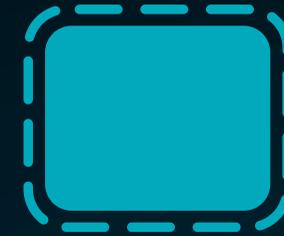
2. Modular

Flexible installation with separate dosing/blending unit



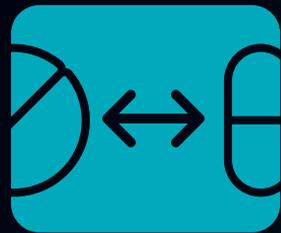
3. Generic

Universal process design for processing numerous formulations



4. Safe

Dust-tight units with separate process and technology areas



5. Fast

Reduced complexity for accelerated cleaning and changeover



6. Easy

TRI.EASY for facilitated operation: a single terminal for all processes



7. Controlled

Fully-integrated in-line process analysis technology (ePAT)

A single interface for all processes

The proven TRI.EASY design of the FE Series was transferred to the new system in an effort to simplify operation of the FE CPS. It consistently puts the user in the center and focuses equally on simplicity in the dimensions of operation, changeover and maintenance. At its heart is the Human Machine Interface (HMI), which provides operators with an overview of all parameters for dosing, mixing, tableting, and process analysis. From now on, a single terminal suffices to record the continuous process in full. This also includes recipe management, logging, events and diagnostics. Handling of the HMI is easy to learn, thereby drastically reducing the qualification threshold for continuous operation.

Integrated process analysis with ePAT

The stability of the continuous process largely depends on the material properties, as well as the machine and process design. The continuous tableting system sets new standards in this regard. To monitor the decisive quality attributes, it has a novel ePAT system (embedded Process Analytical Technology), where sophisticated sensors are integrated into the process units. They can be positioned at four points to continuously monitor relevant production parameters: at the outlet of the blender, at the inlet of the tablet press, at the Fill-O-Matic, and on the die table of the tablet press. For example, the sensor at the blender checks mixing homogeneity. Such in-line measurements, which are carried out directly in the production flow, allow a quick response in the event of quality deviations and direct control of the production process.

With data acquisition and analysis in real time, the FE CPS also sets new standards in terms of measurement and reaction speed. Near-infrared spectroscopy (NIRS) has proven to be particularly efficient in terms of measurement methods. Its advantage is that many active substances can be detected well in this spectral range. The infrared rays penetrate deep into the tablet without damaging it. NIRS enables ultra-fast quality checks on larger sample quantities, making it ideal for high-performance tablet presses such as the FE55 and the upstream FE CPS blender. Depending on requirements, Fette Compacting works with users to determine the appropriate PAT solution to exploit the full efficiency potential of the FE CPS.



The new user interface provides a quick overview of the parameters of the entire continuous process.



Jan Vogeleer,
Managing Director
at Fette Compacting Belgium

A deeper understanding

“The initial approach to Continuous Manufacturing of OSD was based too heavily on known principles in pharmaceutical processing and interconnecting existing unit operations. To take full advantage of the multiple benefits of Continuous Manufacturing it was necessary to re-think the entire process and equipment design concepts from scratch. That is what we did. But before we could do so, we had to set-up a multi-disciplinary expert team, who developed in-depth material behaviour know-how and Continuous Manufacturing process understanding. This extensive expertise was not only important to re-invent Continuous OSD Manufacturing, but also to be able to fully support our customers in every phase of their journey by introducing Continuous Manufacturing in their R&D and manufacturing operations.

Jan Vogeleer's team designed the FE CPS and developed it for market readiness.



Dr. Marten Klukkert,
Manager Technology Center,
Pharmacist
at Fette Compacting

Continuous Manufacturing reinvented

“In recent years, the maturity of continuous production technology has continued to grow. Along the way, we have worked closely with customers and partners to investigate material-specific process conditions and create an overall image of the attractiveness of the continuous production regime. In essence, we asked ourselves what machine design is required to create a positive business case with users. This is how we gradually arrived at the innovations of the FE CPS, with which we have virtually reinvented Continuous Manufacturing. As a result, we can now offer a technologically and economically highly-attractive overall solution that combines maximum production efficiency with minimum complexity.”

Dr. Marten Klukkert coordinated development of the FE CPS at the Schwarzenbek site in Germany.



Dr. Wouter Grymonpré,
Senior Process Scientist,
Pharmacist
at Fette Compacting Belgium

Development per Quality by Design

“Agility is a strong driver for customers to enter Continuous Manufacturing, both in R&D and production. When translated into requirements, the production equipment must guarantee high-quality robustness for a wide variety of ingredients at versatile throughput, meanwhile allowing fast changeovers and safe operation. In order to meet these requirements into our new technology, there was the need for using a Quality-By-Design (QbD) approach from the early phases of development onwards. Starting from an extensive knowledge on powders and process dynamics, an iterative development roadmap of design, scientific knowledge, process understanding and control ultimately led to the FE CPS. We are confident that this solution will facilitate agile production in both existing facilities and the ones of the future.”

Wouter Grymonpré is an expert in CM technology and leads the process development of the FE CPS.



Dr. Anna Novikova,
Manager Application Center,
Pharmacist
at Fette Compacting

Process control made efficient

“To date, process analysis technology has not yet become widely accepted in tablet production. In some cases, equipment is still used that only experienced PAT specialists can handle safely and efficiently. These techniques often come from third-party suppliers and are integrated into the production line via additional software, which greatly increases the complexity of the systems. With the FE CPS, we have taken an entirely new approach to process control: toward a more robust, easy-to-use and fully-integrated PAT. All relevant parameters are permanently recorded at the measuring points, and the use of real-time quality control systems ensures efficiency and product quality. This provides users with an all-round quality-assuring and economical solution for process control.”

Dr. Anna Novikova is a PAT specialist and played a central role in the development of the new ePAT system.

Curious?

If you would like to learn more about the FE CPS, please feel free to contact us at tablet@fette-compacting.com. Our experts will give you further insights, answer your detailed questions, and advise you on your individual Continuous Manufacturing project if you are interested. To experience the new technology live, you can make appointments at our locations in Schwarzenbek (Germany) and Mechelen (Belgium). Let's write the next chapter in the history of Continuous Manufacturing together!

THE MIDDLE MODEL

In the form of the F20i tablet press, Fette Compacting is expanding the trend-setting range of the new i Series. This powerful all-rounder is system-compatible, dust-tight and networkable. It also comes with numerous innovations: an innovative tablet chute, an optimized turret change system, and smart energy management.

In autumn 2022, Fette Compacting will launch the F20i, the next tablet press in the new i Series. As the youngest member of the new i Series, it closes the gap between the flexible single rotary F10i and the high-volume double rotary press F30i.

Producing up to 475,000 tablets per hour, the F20i is the true all-rounder in this trio. Optimized for quick turret changes, it is suitable for a wide range of products and batch sizes, enabling maximum flexibility in production. "For the new i Series, we have developed tablet presses that comprehensively meet modern solids production," says Senior Product Manager Jörg Gierds. "The F20i represents a highly-efficient extension to this pioneering project."



Jörg Gierds, Senior Product Manager at Fette Compacting



Maximum flexibility and efficiency: the new i Series is supplemented by the F20i, a powerful all-rounder.

F10i **F20i** F30i



The new i Series: cross-generational system compatibility

Comprehensive compatibility

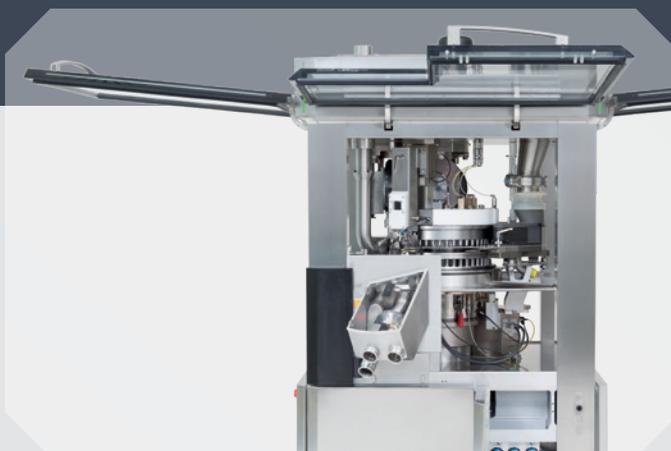
Like the other machines in the new i Series, the F20i displays cross-generation system compatibility. All process-based assemblies are identical or similar to those of the classic i Series. This means that die and segment turrets can be adopted with minor modifications from the tablet presses of the previous machine generation. Practical experience shows that this compatibility reduces the time and effort required for validation and qualification of a new tablet press from weeks to mere days.



Permanently safe: from dust-tight to containment

Standardized operator protection

All of the tablet presses in the new i Series are dust-tight in the standard version – from the press room through to the connections between the machine and process equipment. Stable negative pressure in the interior prevents any dust from being released from the machine. This protects operators from numerous types of exposure to active substances. If active or highly-active substances are to be processed on the F20i, it can also be upgraded with a suitable Containment Guard option.



Quick cleaning: fewer surfaces in need of cleaning

Optimized cleaning

The new design of the F20i is optimized for efficiency in all areas. Compared to its predecessor models, this machine has significantly reduced shrouding parts, which minimizes the area to be cleaned and thus also reduces the required cleaning time considerably. This saves costs and at the same time minimizes the exposure of operators to active substances during machine cleaning.



Smooth flow: innovative F20i tablet chute

Innovative tablet chute

For the new i Series, Fette Compacting has developed a high-performance multi-format tablet chute that is suitable for most common tablet formats. Thanks to the special shape of the track, the tablets automatically seek the path with the lowest frictional resistance, which actively prevents material jams. The new tablet chute is designed according to the so-called Poka-Yoke principle, which means that it can be disassembled and reassembled without tools.



Fully digital: optimized for future production

Comprehensive networkability

The F20i has all the technical prerequisites for networked use in a modern production environment. Among other things, the complete process equipment can be integrated effortlessly according to the plug-and-play principle. The open interfaces comply with the usual automation standards, which means that the machine can be integrated into a Manufacturing Execution System (MES) and the Internet of Things (IoT). With the SmartInterface app, production can be monitored in real time via mobile devices.



Everything under control: Human Machine Interface

Easy operation

Thanks to modern software, even less experienced users can operate the F20i effortlessly. A Human Machine Interface (HMI) provides solutions for intuitive control and documentation of the machine and process equipment. A Workflow Operation Wizard guides the user step-by-step and in an easy-to-understand manner through all standard procedures. The wizard can be used to save work steps, define process sequences, and call up checklists.



Time-saving: integrated mechanics for turret change

Faster turret change

The engineers at Fette Compacting have equipped the F20i with an optimized turret change system. The turret can be removed for product changes in only a few minutes – much faster than with conventional tablet presses. After the operator has moved the compression stations into the parking position, they can simply change the turret with the aid of a support carrier. This not only saves time, but also reduces minimizes physical exertion.



Record consumption: intelligent monitoring for sustainable operation

Smart energy monitoring

Like the other tablet presses in the new i Series, the F20i features a modern energy monitoring system. This means that power consumption can be recorded in real time and stored together with the other production data in the batch log. Users can thus determine the number of kilowatt hours required for each product batch and use these figures to derive detailed forecasts of future energy consumption. Energy monitoring plays an important role today, among other things in cost analysis and planned sustainability measures.

ALWAYS AVAILABLE



The new learning app **alva** from OSDi makes knowledge available around the clock. Using 3D graphics, animations and illustrated instructions, it promotes intuitive learning.

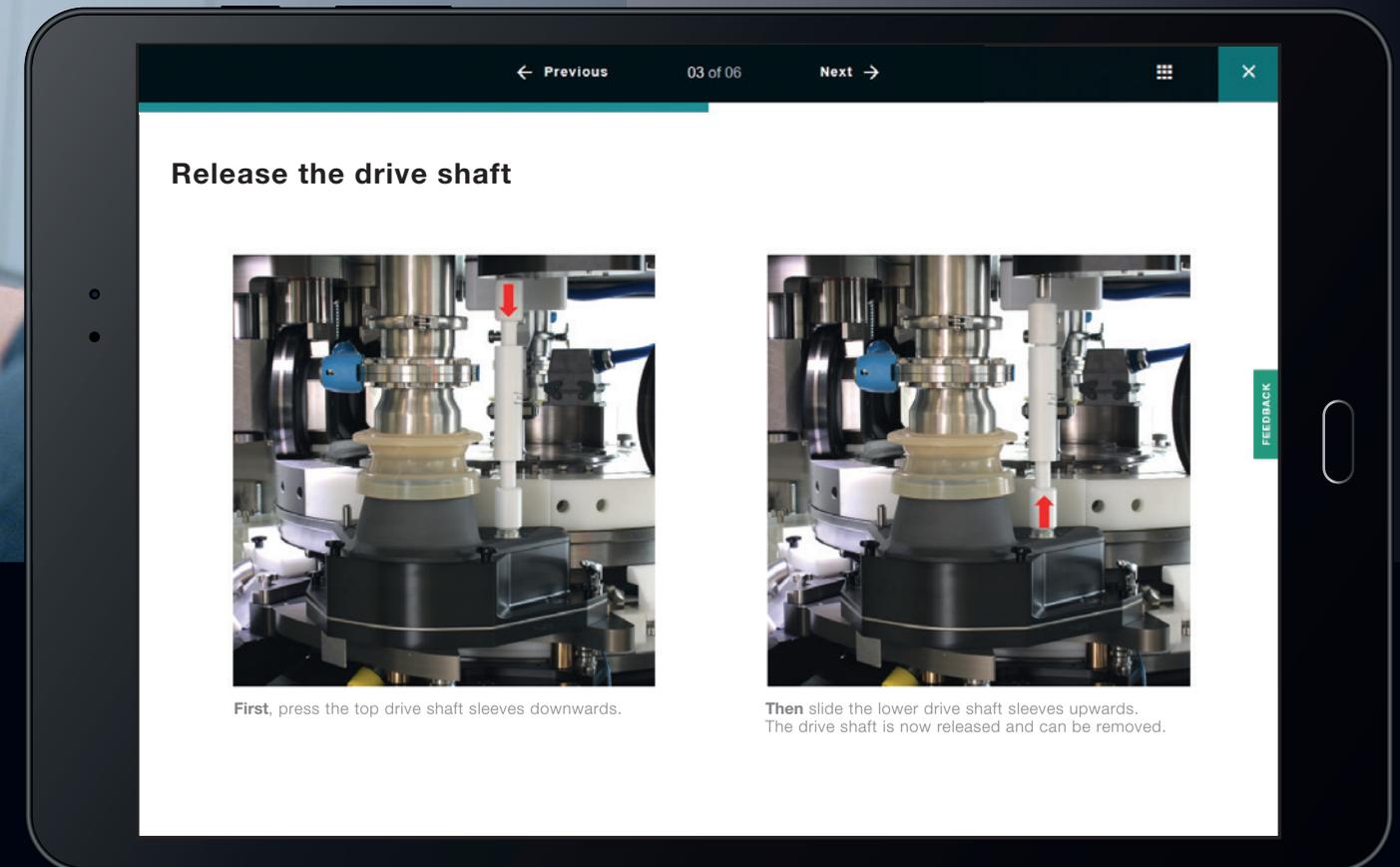
Fette Compacting's business unit OSDi develops digital solutions to make solida production easier, safer and more efficient. Its name combines Oral Solid Dosage with digitalization. Among other things, the team is working on apps that support training and troubleshooting, manage performance, cleaning and maintenance based on data, and enable mobile access to all machine data.

The learning app, **alva**, was recently launched on the market. With up-to-date knowledge from experienced full-time trainers from Fette Compacting, it helps to qualify employees to work on tablet presses. "Users can expect vivid 3D graphics, animations and easy-to-understand explanatory texts in an app that is intuitive to use," explains Britta von Selchow, Head of Digital Product Innovation at Fette Compacting. "And the best thing is that as browser-based software, **alva** is always available on stationary PCs, as well as on mobile devices. This means that users can access expert knowledge directly in the machine room, for example - always with the comforting feeling that they are doing the right thing on the machine. To express this flexible availability, the name of the app is derived by the phrase **always available**."

Assemblies and functions at a glance

alva is divided into knowledge modules, each of which presents an assembly group. The app shows how the individual components work together and what their central functions are. Once users have completed a module, they can check their knowledge in a test and document their understanding of the content.

"Intuitive usability and conveying the most relevant detailed knowledge played a key role in the development," says von Selchow. "The learning content aims to offer thematic depth and accompany the user through clear and easy-to-understand features. Accordingly, **alva** is taking a new approach, as conventional learning apps are often not detailed enough, yet overloaded with numerous functions. With OSDi's tool, users can now concentrate on the essentials. In addition, the software ensures that users always receive up-to-date, first-hand information. This also prevents outdated information from being passed on."



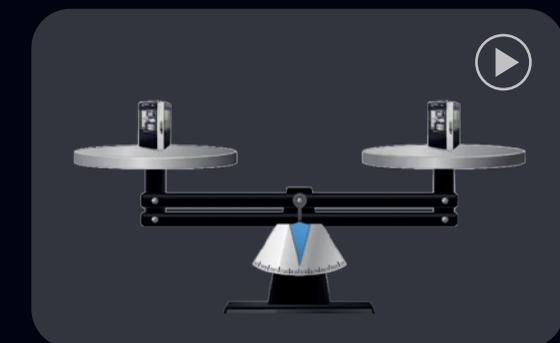
First, press the top drive shaft sleeves downwards.

Then slide the lower drive shaft sleeves upwards. The drive shaft is now released and can be removed.

Professional photos illustrate components and functions. With the aid of the descriptions, even new employees know how to proceed when dismantling individual parts.



In three-dimensional graphics, **alva** describes the structure of essential components, for example the Fill-O-Matic.



Animations also promote understanding of the complex production process. In addition, **alva** provides catchy rules of thumb, such as this one pre compression force.

alva

Expert knowledge
at your fingertips

Close to the needs of users

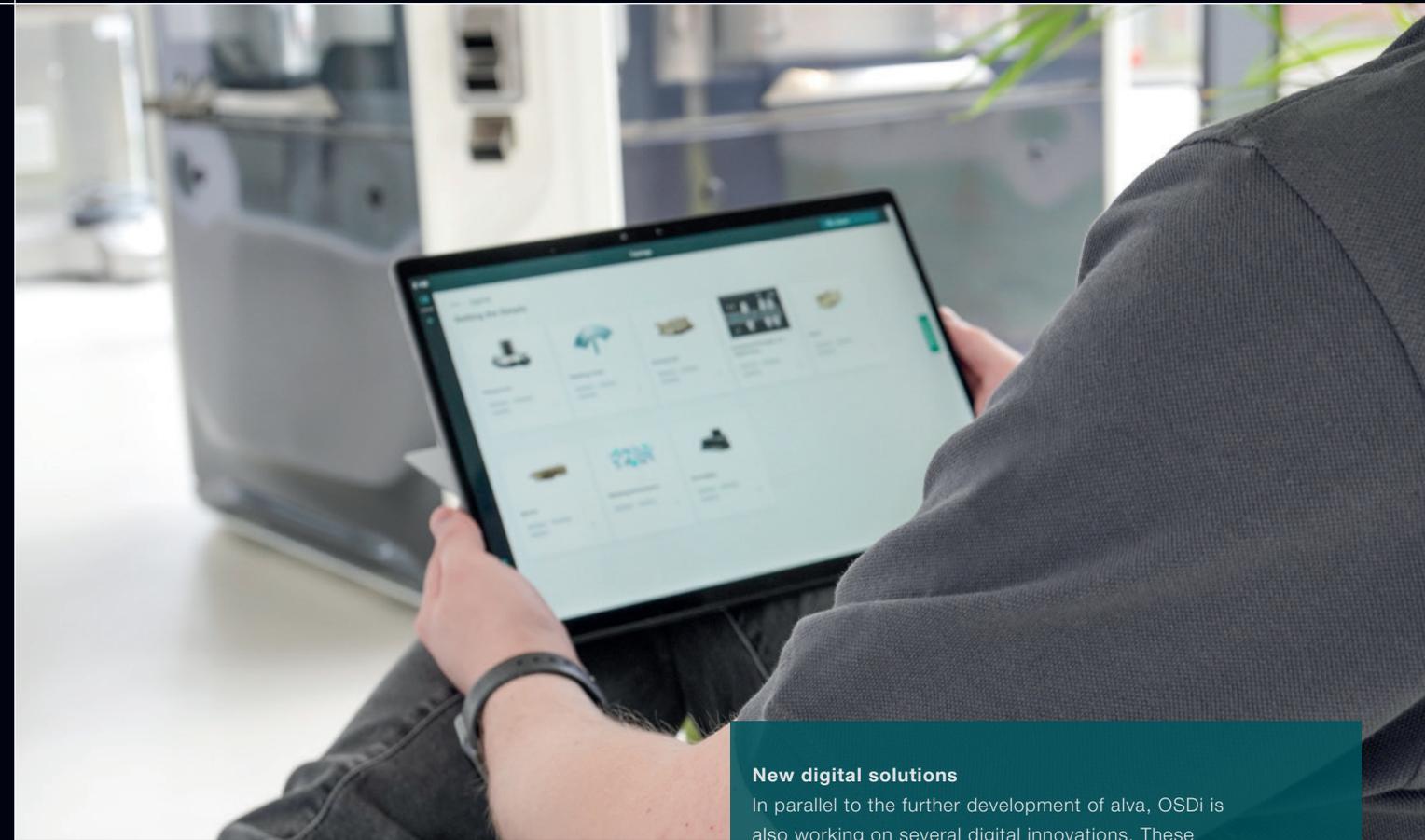
In order to make the learning tool practical, the OSDi team used the agile methods of design thinking and lean start-up in its development. Both approaches ensure that products are developed in close consultation with customers. In design thinking, software developers start with a real problem and move forward step by step. OSDi develops initial prototypes, asks customers about their impressions, and takes them into account in the subsequent development steps. With lean start-up, the team makes sure to learn something from each attempt for the following development step. In combination, these two methods ensure a high degree of customer benefit and a manageable risk, because users advance iteratively and are always oriented toward the actual customer needs.

Initially, alva has nine modules that can be used for all tablet presses. "In addition, the app will be continuously equipped with new knowledge, for example with content for specific machine series and different user groups," von Selchow promises.



»ALVA IS TAKING A NEW APPROACH, SINCE CONVENTIONAL LEARNING APPS ARE OFTEN NOT DETAILED ENOUGH, BUT ARE AT THE SAME TIME OVERLOADED WITH NUMEROUS FUNCTIONS. WITH THE OSDI TOOL, USERS CAN NOW CONCENTRATE ON THE ESSENTIALS.«

Britta von Selchow, Head of Digital Product Innovation at Fette Compacting



New digital solutions

In parallel to the further development of alva, OSDi is also working on several digital innovations. These include, for example, software that will help minimize unplanned machine downtimes through predictive cleaning, maintenance and inspection. This app is designed to combine a reliable database with comprehensive insights from the past to accurately measure the life cycle of wear parts. The tool can then calculate the optimal time to replace or maintain parts. Machine failures are thus significantly reduced and components remain in use longer. The app has already successfully completed several series of tests.



TWO CHAMBERS

For years, containment research has been trying to better understand the dust dispersion of pharmaceutical powders. However, results from exposure measurements can rarely be transferred to other facilities. A novel dual-chamber model developed by the University of Hamburg together with Fette Compacting hopes to change this.

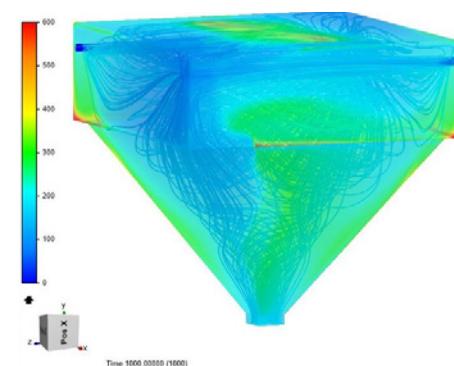
Highly-active substances such as cytostatics, hormones or steroids are being used more and more frequently in pharmaceutical production. Due to the broad growth of this market, the pharmaceutical industry is increasingly focusing on operator protection and quality assurance.

Fette Compacting has therefore set itself the task of stepping up systematic research into more efficient containment systems. With Containment Guard, the leading machine manufacturer for tablet presses has already developed a system for exposure measurements that reliably predicts the dust isolating performance of containment systems.

Beyond its own research, Fette Compacting also works closely with scientists who are advancing the state of knowledge on containment systems. One of the most recent projects of this kind was carried out in cooperation with the University of Hamburg, where pharmacist Steffen Wirth is developing a new type of device that can be used to examine the dust behavior of pharmaceutical powders more precisely. He is supported by Dr. Martin Schöler, Head of Engineering & Design at Fette Compacting, and his team.

Unlike previous devices, this dual-chamber model takes into account how air flows within the machine chamber influence dust dispersion. "A better understanding of dust behavior and mass transport mechanisms in containment would significantly improve both the development of manufacturing facilities and the assessment of exposure in existing systems," explains Wirth.

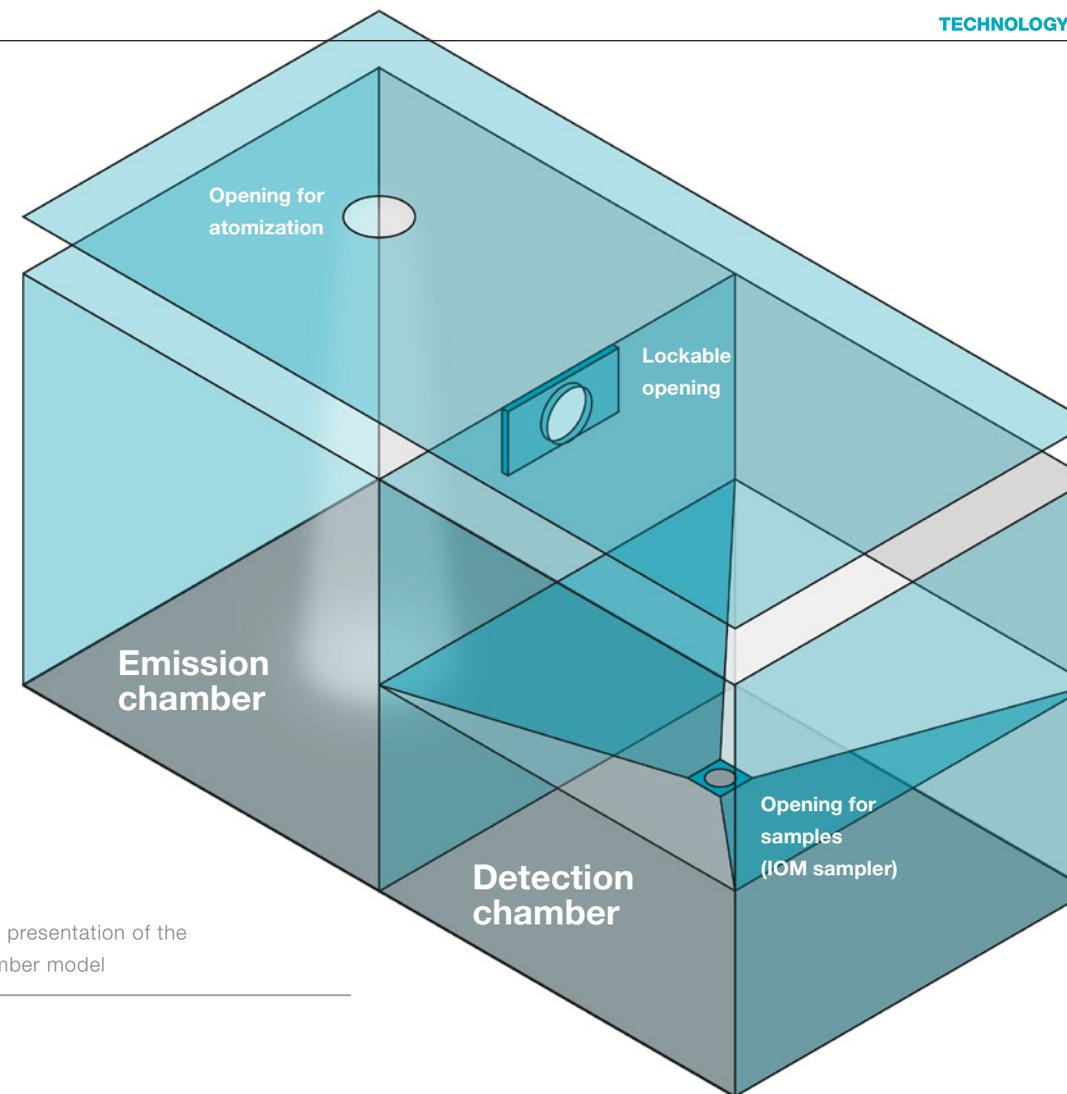
Flow simulation in the detection chamber of the dual-chamber model



Lack of transferability

The dust behavior of a pharmaceutical powder depends on many factors. The shape, size and distribution of the particles, the humidity of the powder and the ambient air, as well as electrostatic charges within the machine are only some of the relevant influencing variables. Another important role is played by the mass transport through which the dust is distributed in the surrounding space.

"Until now, the measurement results from different manufacturing plants could not be transferred to other plants in most cases, or only to a very limited extent," explains Wirth. The reason for this is simple: as a rule, for safety reasons, the tests are carried out with substitute substances whose physical properties are different from the actual pharmaceutical products. "In combination with all of the other factors, the deviating material behavior makes it almost impossible to apply the results," says Wirth.



Simplified presentation of the dual-chamber model

However, it is precisely this transferability that is of great interest to both machine manufacturers and pharmaceutical companies. Wirth: "Containment measurements are very time-consuming and therefore costly. Moreover, they have to be carried out anew every time a different active ingredient is to be processed on the machine. If we succeed in standardizing relevant measurement factors and thus making the results transferable, this holds enormous potential for cost savings."

The flap opens

This is where the dual-chamber model comes into play. "The new apparatus allows us to study the mass transport of dusts from real pharmaceutical powders, taking into account all the important factors," Wirth continues.

For this purpose, the apparatus is divided into two areas separated by a closed flap. In the emission chamber, a reproducible negative pressure first atomizes a firmly-defined

amount of powder. After atomization, the chambers are connected by opening the flap for one minute, whereby a certain amount of the powder dust passes into the adjacent detection chamber. There, the particle concentration of the ambient air is determined by a measuring device installed at the bottom of the chamber.

"Initial tests show that the dual-chamber model can be used to investigate the mass transport of dust very well," reports Wirth. "The tests can already be carried out with small quantities of 500 milligrams of a pharmaceutical powder and ensure high precision and good reproducibility. Of course, much more research is needed on this topic, but we are well on the way to better and more reliably preventing cross-contamination and operator risks."



Steffen Wirth, research associate in the Department of Pharmaceutical Technology at the University of Hamburg



Dr.-Ing. Martin Schöler, Head of Engineering & Design at Fette Compacting

GENTLE COMPRESSION

Metagenics Europe manufactures sophisticated magnesium tablets in Belgium. When looking for a high-performance tablet press from Fette Compacting, the nutrition specialist opted for an FE55, as this single rotary press has made it possible to combine high speed and gentle compression.

Health and well-being are high on the agenda worldwide. The corona pandemic has further strengthened the desire for a healthier lifestyle among many people. Consumers prefer high-quality and natural, but at the same time affordable products. Tablets are, and remain, the most popular product form. Their cost-effective, large-scale production makes them the most economical product on the market.

This high demand is felt by manufacturers like Metagenics Europe. The producer of micronutrients is characterized by an extensive portfolio of products and dosage forms. For its tablets alone, the company recorded a 45 percent increase in demand between 2020 and 2021. In order to meet this demand, Metagenics Europe expanded its production capacities. The motto here was: No compromises on quality!

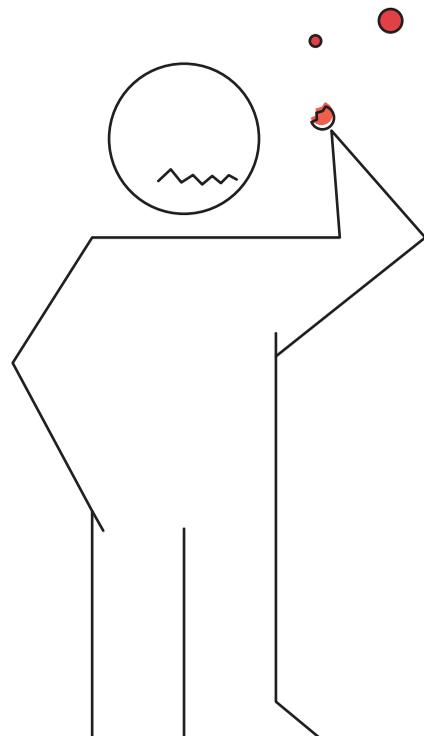
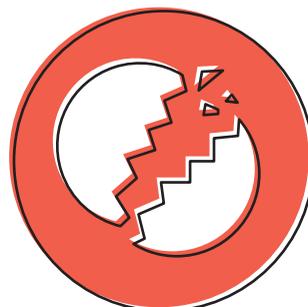
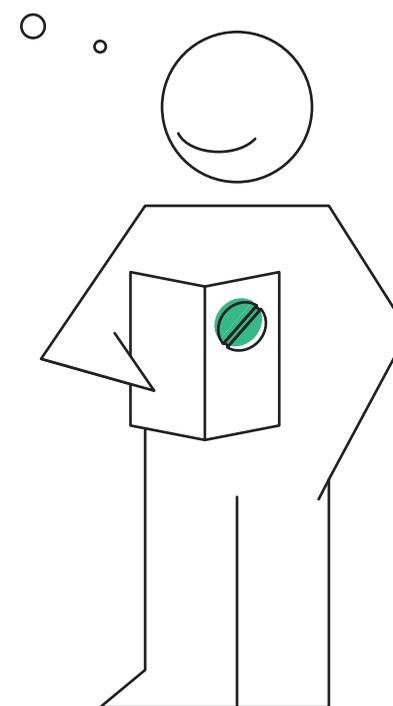
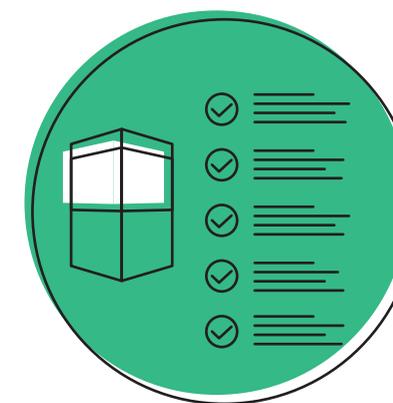
Forcefully efficient

Metagenics faced a key question with its very popular MetaRelax® tablet: How can the magnesium complex be manufactured in large batches in a reliable manner? Two challenges had to be overcome: Firstly, magnesium salt requires a lot of force during compression, which can lead to an increased error rate, especially at increased production speed. Secondly, the recipe contains many substances that can vary from one batch to the next.

In the search for a technical answer, the company sounded out the market for a tablet press that works powerfully and reliably even at high throughput speeds. Comparative tests showed that the single rotary FE55 tablet press from Fette Compacting runs up to twice as fast as other tablet presses.

Uniform and gentle compression

The machine has been in use at Metagenics since June 2020. The FE55 compresses the ingredients of the MetaRelax® tablets directly, i.e., without upstream granulation. In this process, the quality depends largely on the powdered magnesium salt being processed with sufficient and extended pressure. This longer dwell time ensures more uniform and gentle compression.



To achieve the perfect interplay of pressure and time, the FE55 is equipped with three compression stations. Pre compression and intermediate compression allow Metagenics to produce its tablets in large quantities and at high speed. In combination with the FS19® punches from Fette Compacting, the dwell time is extended by more than 80 percent. In addition to a longer tool life and pressure-holding time, these special punches also allow for smoother running overall, which has a positive effect on the tableting process. The use of segments also plays an important role in minimizing product loss, achieving higher output rates, and reducing changeover times by around 70 percent. In addition, segments with different materials and coatings can be customized for the respective application.

Quality assured

Another decisive factor for Metagenics was that the tablet press should be able to handle varying ingredients reliably. To this end, Fette Compacting developed a special production guide toward adjusting the FE55 to adapt to possible variations in texture and consistently produce tablets of the same quality.

By using these precisely coordinated technologies and services, companies like Metagenics can independently ensure the quality of their production – and thus react at any time to new trends, developments and demands in the dynamic growth market for food supplements

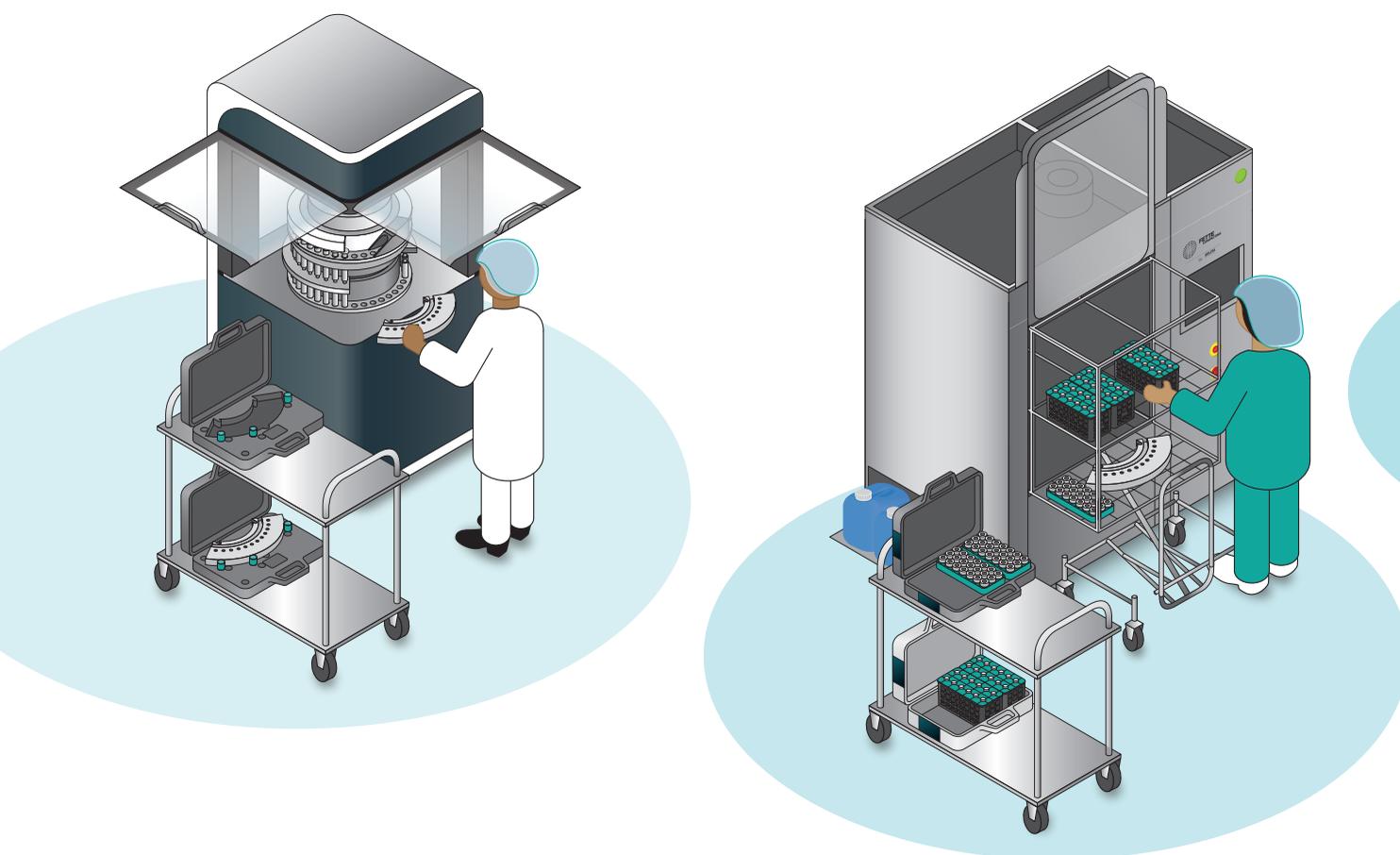


The FE55 in operation at Metagenics Europe.

SYSTEMATIC HANDLING

The transport, cleaning, preservation and storage of tableting tools play a decisive role in tablet quality. When the tools are not in use, EasyCare solutions offer the best options for handling.

In tablet production, the tools used need to cover quite a distance. Although many processes in production are fully automated, the handling of the tableting tools is usually still manual work. This is risky, as the delicate components can be damaged even by being knocked slightly against each other. But this is exactly what happens again and again during transport, removal from storage, or during cleaning. There is a user-friendly overall solution for making this handling as low-risk as possible.



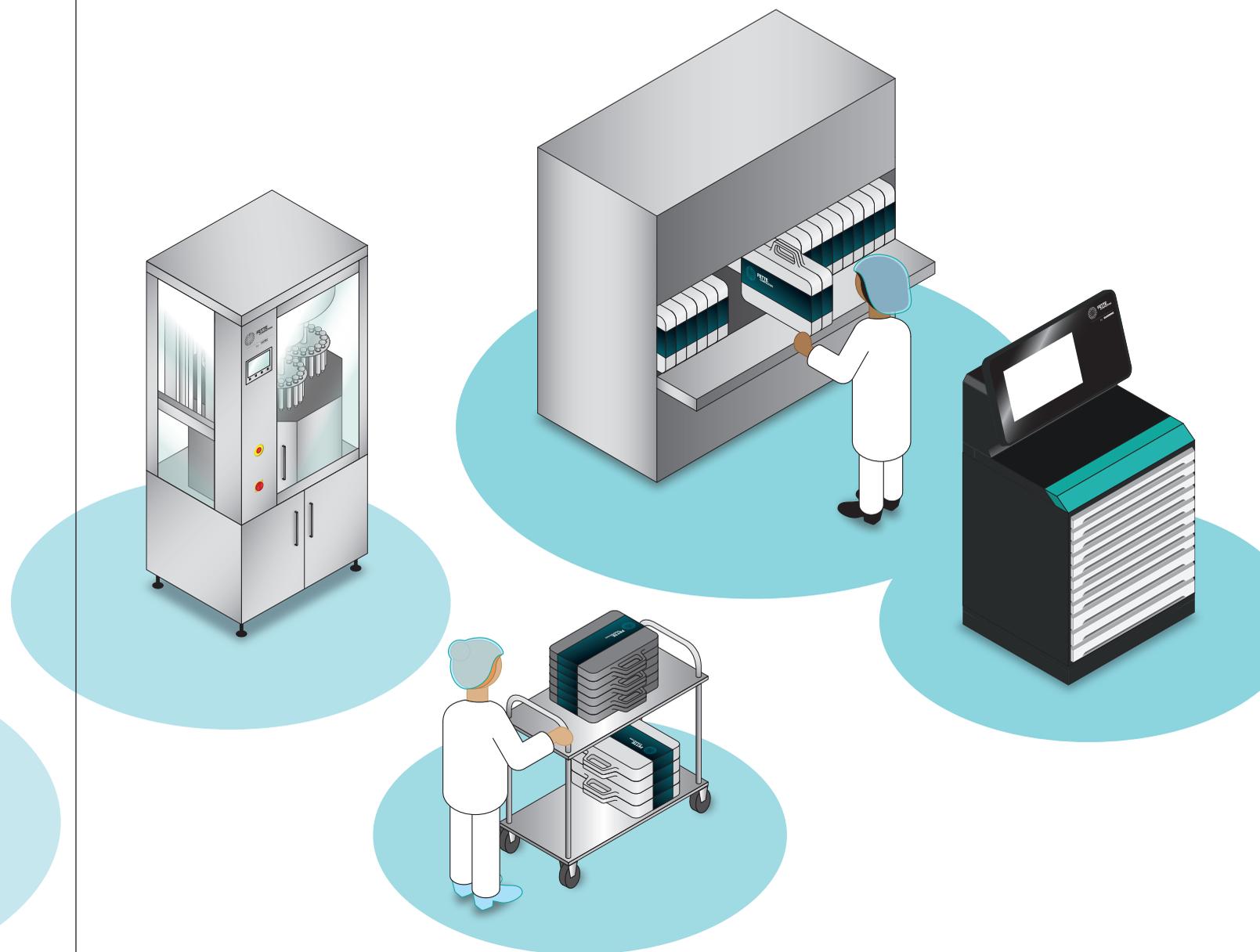
TRI.EASY Tool Box System

Fette Compacting offers an all-in-one solution that covers all tool handling steps in a single system. Thanks to an ergonomic design, the operator risk is significantly reduced. In addition, fewer handling steps are required, which optimizes production speed and quality.

The patented TRI.EASY Tool Box System comprises different box types for punches, segments and dies. The tools can be safely stored and transported in these boxes. The tools are stored in special trays in which users can place them directly from the box into the washing machine for cleaning. Among other things, this eliminates the need for time-consuming repositioning.

Cleaning

Good Manufacturing Practice (GMP) in tool cleaning is demanding: the complete system from Fette Compacting, ARUNA AG and Borer Chemie AG is suitable for GMP-compliant cleaning. The TRI.EASY trays with predefined positions for punches, segments, dies, bellows and dust caps, fit exactly into the Aruna cleaning system. With cleaning and corrosion protection agents from Borer Chemie, the tools are cleaned without leaving any residue.



Polishing

After cleaning, the tools should be polished by machine. A polishing machine from nortec is used. It ensures higher efficiency, maximum productivity and a lower risk of damage compared to manual polishing. It also prevents the tablets from sticking to the punches. Both the granulate used for this and the polishing paste are food-grade.

Tool storage

After polishing, storage in the Tool Box System is recommended. These are easy to stack and offer protection against external environmental influences such as moisture and heat. Thanks to the long-term preservative deconex® HT 1191, the tools can be stored for extended periods.

PartSite®

This tool management system provides simple and reliable system-based management of tools and machine parts. It provides information on the condition and availability of tools for dependable tablet production.

SAFETY IN MILLISECONDS

Airbags deploy in a fraction of a second. The fuel tablets from ZF Airbag Germany in Laage ensure that the gas expands extremely quickly - and saves lives in an emergency.

The production of micro tablets entails a whole range of special requirements. In addition to consistently high product quality, the main focus is on operator protection. Compression of the explosive powder mixtures, for example, requires strict segregation of individual zones: "For us, the powder must never escape from the compression chamber into other parts of the machine – such as the upper part of the housing or the drive chamber. There are often electronic components that are warm or do not have sufficient protection for direct contact with explosives. Tool breakage can also theoretically lead to ignition," says Michael Wendtland, Foreman of Fuel Production at ZF Airbag Germany, describing the working situation on the machines.

For this reason, the tablet presses are equipped with spark-extinguishing systems that use small water nozzles to prevent possible ignition of the fuel. Another requirement is the minimal use of plastics that could become electrostatically charged. "The machines from Fette Compacting meet our safety criteria. Their components are mostly made of stainless steel, offer space for safety attachments, and can be connected ex works with the additional control system we need. We were also always able to find a solution for all other special requests with our colleagues," says Wendtland.

Small tablets, big forces

The compression process produces tablets with dimensions within the range of a few millimeters. "Due to the requisite compression forces and the sensitivity of the product, high-precision operation of the machines is of enormous importance," explains Detlef Oetken, who is responsible for fuel production technology at ZF Airbag Germany. "In addition, we need as few extras as possible on the machine at the factory. For us, it is rather the programming options that are decisive, such as the start relief and punch-saving."

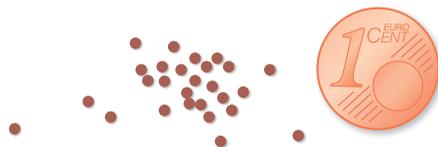
The programming options referred to above ensure optimum pressure conditions during compression: start relief reduces compression forces and friction, especially when the machine is started up several times. Punch-saving detects unusually high compression forces at the pre-compression station, such as those that can result from double compression. The tablet press then stops in time and allows the corresponding pair of punches to pass the main compression station before restarting.

Running like clockwork

The company uses a number of tablet presses of different types from Fette Compacting. These not only meet the safety requirements, but also enable a high throughput with high precision: "As everywhere, there is little room for delays in our production. At the same time, the tiny tablets allow only infinitesimal tolerances. Therefore, it is important that the tablet presses run like clockwork," is how Wendtland sums up the requirements. With the appropriate tools using EU19 punches, a very high output is possible despite the small dimensions involved. This ensures the necessary supply at the airbag production sites from Aschau via Xian in China to Mesa in the USA. The production capacity is more than 1,000 tons of fuel and 40 million gas generators, which are installed in vehicles all over the world.

Flexibility is the trump card

Wendtland cites the standardization of components at Fette Compacting as another criterion for the tablet presses. This reduces stock-keeping and increases flexibility, since, for example, an adjusting gear can be used on any machine. Added to this are the intuitive operation of the machines and the low effort required for maintenance and cleaning. Finally, this overall picture rounds off the high level of satisfaction with the support: "The service has always been reliable and fast, so that production could run smoothly," Oetken emphasizes.



As small as the head of a pin: the smallest tablets from ZF Airbag Germany



EVEN CLOSER TO THE CUSTOMER



GLOBAL CUSTOMER SUPPORT

our mission: your smile

Listening to customers, understanding their requirements, and developing new products and ways of working together with them: today, Fette Compacting's Global Customer Support is closer to the customer than ever before – and offers more and more digital solutions for this purpose.

Clients' demands for first-class customer service are increasing. We at Fette Compacting are also aware of this and therefore always try to stay one step ahead. To this end, we have grown continuously in recent years.

With our six product groups – spare parts, tableting tools, upgrades, used machines, training & consulting, and technical field service – we cover the entire spectrum: from advice on tablet design to control conversions for the Human Machine Interface to refurbishment of machines.

Digital upgrades

During the summer of 2022, we plan to launch eCAT 2.0, our electronic spare parts catalog. This will make ordering spare parts even easier and more convenient. The FMECA (Failure Mode, Effects and Criticality Analysis) software method is an elaborate but rewarding analysis for customers of their spare parts needs and management. It will play an important role in supporting our Lifetime Efficiency approach.

Lifetime Efficiency enables our customers to get the most out of their equipment. From machine purchase advice, to operation and staff training, to spare parts management: this holistic approach based on partnership improves performance as well as machine reliability, quality and safety.

Acting with foresight

Predictive maintenance means knowing in advance when which parts and assemblies of a machine need to be serviced. Customers are more willing to share production data today, even in real time, because they can rely on the security of our systems. With access to big data and the use of artificial intelligence and clouds, we can act before something fails, improving machine availability.

Our first digital products, such as LiveGuide, a mobile real-time connection between customers and our experts, are in great demand. We are also learning a lot for upcoming product launches, both technically, legally and operationally. Upcoming digital products from the OSDi Business Unit promise even further benefits.

We are facing exciting times and will keep a close eye on technological developments – always with the following question in mind: How do our customers benefit?



More than **1.000** LiveGuide users



>100 Service Technicians

“We listen closely to our customers and collaborate with them to develop new products and methods of cooperation.”

Lars Plüschau,
Director Global Customer Support
at Fette Compacting



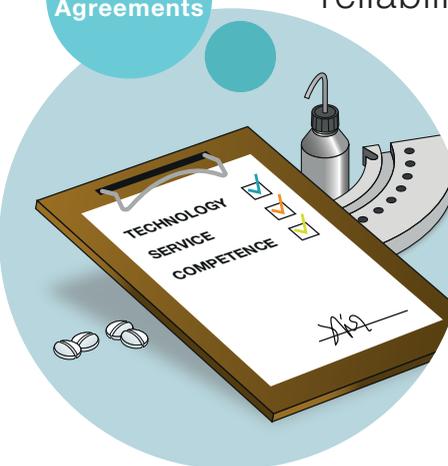
220.000 individual components

Available stock items

approx. **2.000** items available in stock

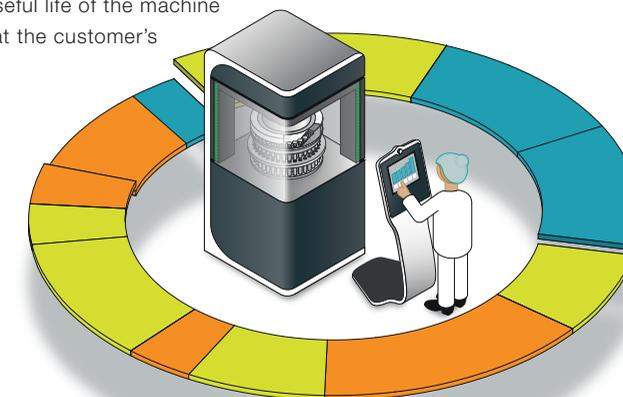
Service Level Agreements

270x reliability



Ø 25 years

Useful life of the machine at the customer's



Lars Plüschau,
Director Global Customer Support
at Fette Compacting

THE WORLD OF FETTE COMPACTING

At the two-day Continuous Manufacturing Circle in Schwarzenbek, renowned guests will discuss the state of Continuous Manufacturing with the experts from Fette Compacting. At this event we will be presenting the world's first FE CPS up close for the first time (more on this from page 4).



DR. MARKUS KRUMME
VP Continuous Manufacturing,
Novartis AG

KEYNOTE

- What does society expect of the process industry in a changing environment?
- How can companies tackle the urgent need for even more efficiency, less complexity, and faster responses to challenging market conditions?
- How will technology advances in Continuous Manufacturing transform pharmaceutical production?

Panel discussion

On the panel, industry representatives will be discussing the pros and cons on the way to continuous production.

CONTINUOUS MANUFACTURING BETWEEN THE STATUS QUO AND A REVOLUTION. OPPORTUNITIES, CHALLENGES AND WHAT'S COMING NEXT.

Workshops

Practical workshops will shed light on the direct pressing method. The focus will be on these questions:

HOW CAN CONTINUOUS DIRECT COMPRESSION ...

- be integrated in existing production facilities, with its compact and modular design?
- manufacture a wide range of formulations in one production line, through its process design and fast changeover?
- integrate process control as an easy to use option?
- revolutionize Continuous Manufacturing?

22. AND 23. JUNE 2022
IN SCHWARZENBEK, GERMANY

WHAT'S NEXT?

CONTINUOUS MANUFACTURING CIRCLE



SPEAKERS



DR. ANNA NOVIKOVA
Manager Application Center,
Pharmacist,
Fette Compacting GmbH



FRANK EISMANN
Venture Manager,
Bayer Consumer Health



LAWRENCE DE BELDER
Executive Consultant at
Pharmatech Associates



DR. MARTEN KLUKKERT
Manager Technology Center,
Pharmacist,
Fette Compacting GmbH



WAYNE SINCLAIR
Associate Director Process
Analytical Technology,
Teva Pharmaceuticals



Anniversary Segment technology is 20 years old!

In the early 2000s, Fette Compacting revolutionized the area of tableting once again as segments replaced the conventional turret die tables and the actual dies themselves. They make it possible to minimize product loss, increase output, and extremely reduce changeover times – by up to 80 percent! Today, the technology is one of the most successful in pharmaceutical and nutrition production.

40%

percentage of segments in machines sold worldwide since patent registration

40%

increase in output (maximum)

50%

reduction of product loss (maximum)

300%

extension of service life by using carbide inserts

88%

reduction in manual tasks for changeover

100%

dimensional accuracy compared to dies

80%

savings in time during changeovers



Salah Kaoula, Managing Director at Fette Compacting North-West Africa

Strengthened presence in North-West Africa

With the opening of a subsidiary in Algeria, Fette Compacting is strengthening its presence in North-West Africa. The new branch in the capital of Algiers specializes in more intensive support for existing customers in the Maghreb states, as well as the expansion of business relationships in the regional growth markets.

In Senegal, Côte d'Ivoire and Cameroon in particular, independent pharmaceutical production has become established in recent years. The main drivers of this development are investment incentives that the governments of the emerging countries are setting in a targeted manner. This aims to meet the growing demand for high-quality medicines that are produced locally. In the Maghreb countries, demand is also growing for flexible production solutions that meet global quality standards. Almost 90 percent of pharmaceutical companies here are contract manufacturers.

“By opening the facility in Algiers, we are investing in a growing future market and supporting high-quality and safe medication in the region,” is how Joachim Dittrich, CEO of Fette Compacting, explains the decision. “With our trained and experienced team, which is well connected in the region, we offer our local customers even better and closer support to further establish pharmaceutical production in the region.”

“We are very pleased with the trust that the management and owners of Fette Compacting have placed in us,” emphasizes Salah Kaoula, who will head the new Algiers branch as Managing Director. “There is a huge demand for modern production technology and especially for service and training offers. By connecting to Fette Compacting’s global network, we can offer our customers a unique proposition in all of these areas.” The new branch will focus on services, tool supply, training, and consulting in particular, but will also manage new machine sales.



ACHEMA is back!

After the break necessitated by the pandemic, the leading trade fair for the process industry will be opening its doors again for the first time in Frankfurt am Main. In line with the motto of “Inspiring. Sustainable. Connections.”, exhibitors will be presenting their new products and digital solutions from August 22–26, 2022. Fette Compacting will, of course, be there – in a joint stand with our Excellence United partners. We look forward to many stimulating discussions with visitors to the fair!

New trade fair dates

We are looking forward to being represented again at numerous other trade fairs around the globe in the second half of 2022, in addition to the leading trade fair Achema. An overview:

POWTECH
September 27–29 in Nuremberg, Germany

PPMA
September 27–29 in Birmingham, England

FarmaForum
October 5–6 in Madrid, Spain

AllPack
October 12–15 in Jakarta, Indonesia

CIPM Autumn
October 15–17 Tianjin, China

Pack Expo
October 23–26 in Chicago, USA

P-MEC
November 29 – December 1 in Delhi, India

be inventive

At Fette Compacting, we are:
The world market leader for tablet presses in the pharmaceutical industry.
Never satisfied with the status quo and always on the lookout for improvement. Innovative on a daily basis – and have been for decades.
Unbeatable as a team full of talent.

Fette Compacting Global Family – be inventive, be efficient.
Join the Family! www.fc-gf.com



**FETTE
COMPACTING**
be efficient

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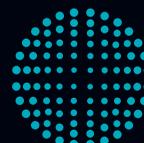
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